



HIT Policy Committee

Draft Transcript

June 30, 2015

Presentation

Operator

All lines are bridged with the public.

Michelle Consolazio, MPA – Federal Advisory Committee Program 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 call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Karen DeSalvo? Paul Tang?

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

Here.

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

Hi, Paul. Alicia Staley? Anjum Khurshid?

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

Yes, here.

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

Hi, Anjum. Aury Nagy?

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

Hello.

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

Brent Snyder?

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System
Here.

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

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System
Hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Chesley Richards? Chris Lehmann? David Kotz?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, David. David Lansky?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, David. Devin Mann?

W
Hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Donna Cryer? Gayle Harrell? Kathy Blake?

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kathy. Kim Schofield?

Kim J. Schofield – Advocacy Chair – Lupus Foundation of America
Here.

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

Hi, Kim. Terry Cullen? Neal Patterson? Patrick Conway? Paul Egerman? Scott Gottlieb? Thomas Greig?

Thomas W. Greig, MD, MPH – Chief Medical Information Officer – Department of Defense

Here.

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

Hi. And Troy Seagondollar.

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

Here.

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

Good morning, Troy.

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

Good morning.

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

And with that, I'll turn it back to your Paul.

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

Hey Michelle, this is Karen DeSalvo; I just wanted to let you know that I had joined.

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

Hi, Karen. Thank you.

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

Karen, do you want to provide some opening remarks?

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

Umm, I'd just like to say good morning to everybody and I'm really looking forward to the agenda today, there's some great stuff that we're going to get to talk about. And I won't keep anybody longer than that; thank you

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

Okay, thanks Karen. Okay, welcome everybody to our fairly brief virtual conference or virtual meeting. Like to open up, before I forget, to approve the minutes from May 22; you should have had the distributed to you. Entertain a motion to approve?

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W

So moved

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

Thank you. And second.

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

Second.

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

Thank you. And any further discussion or amendment to the meeting...minutes? All right, all in favor say aye please?

Multiple speakers

Aye.

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

And any opposed or abstain? Thank you. Okay, so I think you're already enjoy...we realize that we've worked this committee and its workgroups very intensely over the first couple months...couple quarters of the year and so we're giving everyone sort of a summer break in the sense of not traveling to Washington, DC as evidenced by this call and probably relaxing some of the goals for...the objectives for workgroups as they stand right now.

We have a couple of task forces, and that's sort of a new way we're doing business to try to keep on point and in a time limited way that are going to be working over the summer. One is...we're going to hear from today, which is the Quality Measure Task Force and the second one that will be started at the request of Congress to talk about various barriers to interoperability. And as everyone on the committee knows, we have been discussing this in various venues; we've had hearings, we've had workgroups, we've had Jason Reports; so there's been a number of times that we've deliberated on this and we will go back and summarize all of that.

In addition, we'll look a sort of a new area that we haven't talked about in depth which is the financial barriers to interoperability, and we all know that that plays a key role. We're going to put all that together to provide input to ONC as they report back to Congress. So that's something that will be occurring over the summer.

I want to close the opening remarks by providing special thanks and acknowledgment to Deven McGraw. You know that Deven's been with us since the very beginning. She's not on this call or at least

as a committee member because as of yesterday, she began her new job at HHS as Deputy Director for Health Information Privacy in the Office of Civil Rights. So we all know how much one, she's contributed to the work of this group. She has been a tireless and dedicated leader of privacy and security and we've had...we've worked with so many challenging issues and I think that workgroup has brought together a balanced set of recommendations that the committee's in general approved and sent onward to HHS. So we're going to miss her from this committee, but we know that she's going to be really working hard and be able to implement a lot of either recommendations that come partly from this committee as well as all of the input she and the department gets from the rest of the agencies. So thank you and best wishes to Deven.

Okay, so for today we're going to tackle three topics, two of which we need recommenda...or approvals from the committee. One is on the inpatient prospective payment measure system quality measures, and we're going to hear recommendations from the Quality Measure Task Force. Second, the Advanced Health Models had a...workgroup had a hearing and we're going to hear from them; Joe and I will lead that and we have some recommendations for approval there.

And then finally we're going to get it draft preview of work from the Privacy & Security Workgroup on big data, and this is a request from the White House. So they're going to present some preliminary findings and thoughts for comment by the group today and then come back either next month or the month after for final recommendations. And then we'll close with public comment, as we always do. Any comments about the agenda?

Okay let's begin with the Quality Measure Task Force talking about the Inpatient Prospective Payment System NPRM and that's lead by Kathleen Blake and Cheryl Damberg.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Thanks Paul; this is Cheryl Damberg and why don't we go to the next slide. I just want to acknowledge the work of the terrific set of folks who participated in this task force. They really represented a range of perspectives and I think that that was very helpful in carrying out our charge as well as looking at the recommendations that were made; they really do represent this range of perspectives.

If we move to slide 3; so our charge was to provide a set of recommendations related to clinical quality measurement provisions in the CMS payment rules, particularly related to the Inpatient Prospective Payment System. And the two areas that we were asked to focus on were the proposal for a 2015 Edition clinical quality measure reporting certification criteria and the associated standards. And then the second item was CMS was soliciting early comments on new types of measures that would utilize core clinical data elements in the hospital quality reporting program. Next slide.

So related to the first area that we were asked to comment on, the quality task force felt that many of the stakeholders are still working to support QRDA reporting and that ONC and CMS should support incremental changes. And I think throughout the recommendations that I'm going to share with you in the next few slides, I think what you're going to see is sort of a balance between the reality of implementation and what's going on in the ground as well as signaling on the part of the task force to promote innovation. So while there's recognition that the standards...some of the standards that were being proposed and the criteria were still immature, I think there was a desire to try to push CMS and ONC to continue to advance for the sake of innovation and greater harmonization.

So if we look at this first recommendation, the task force supported Release 3 of the QRDA Category 1 standard that's used for individual level quality reports and the November 2012 version of Category 3 standards with that September 2014 errata. And these are used for aggregate level quality reports. And the task force supported these versions because they represent incremental fixes; so they are better than sort of what's currently on the street so represent important enhancements. But I think that there was recognition that to go beyond this would present challenges for both developers and providers who are being asked to implement something that would go beyond this, to make sure that this was done within the time period laid out in the notice of proposed rulemaking. So I...the committee felt that there would be adequate time, that there would be an 18-month period, which seems to be about the right amount of time to get these standards in place. So that was sort of the underlying rationale for that.

If we move to the next slide, and this is now commenting on sort of this desire to move forward and promote innovation. So the task force strongly supports the direction of the Standards & Interoperability Framework Clinical Quality Framework Initiative to harmonize CDS and CQM standards. But I think there was an awareness that these new standards were not ready or mature for adoption. And the group felt that we should be signaling to ONC and CMS that they should continue to support the development and pilots of the harmonized CDS and CQM standards, namely the QICK and the FHIR-based standards. And that we would like the community to move promptly in this direction when these standards become more stable and mature.

So the recommendation was also that CMS has to signal their intent to work in parallel to support this implementation and set implementation milestones. Because it's not just enough for the EHR vendors and providers to commit to this, but CMS also has to commit to doing things on their end to ensure that these pieces work together. If we move to slide 6

So the second area that we were asked to comment on was the signaling around capturing and using clinically enriched data from EHRs to enable risk adjustment of outcome measures. And the committee members felt very strongly that this was a positive direction to be moving in. But I think there was concern about how best to collect this information and sort of how much information should be collected.

And I think that there was definitely support that data elements that are known to be required for risk adjustment should be included in the core data set and that CMS should identify Innovation and Measurement Centers that have the capabilities to quickly advance measurement of outcomes. And these would be centers that have access to large sample claims and clinical data, that they possess the framework to extract data, have the analytics to support this work and to advance this work around measurement of outcomes and identifying the necessary variables for risk adjustment. But again, going back to this issue of balance

If we move to slide 7; I think there was concern among some on the task force that given the language that was in the notice of the proposed rulemaking that the data element burden could become quite large and there was sort of a lack of specificity around which types of data elements would be required moving forward. And I think there was also recognition that CMS and ONC haven't necessarily been fully aligned in terms of the data elements across the different programs and that they should work to make sure that the data elements that they require be collected in the same way to get that alignment.

The committee recommended that rather than specifying a list of data elements that the QMTF suggest better integration of these reporting requirements within the existing EHR standards for reporting

clinical quality measure data such as the QRDA. And there were also comments about balancing the data collection necessary to measure outcomes without negatively affecting data validity and submission burden. So again, this balance between trying to encourage flexibility, innovation but also balances against feasibility, what's actually needed and burden.

If we move to the next slide; on slide 8. So related to the comments above about the data being pre-specified for a particular need, the task force felt that it was too early to determine if the QRDA Category I is the most appropriate standard without knowing what required data elements would be. And the task force recommended that CMS try to accelerate its work to identify the data elements and the definitions of the data elements that they intend to require so that an appropriate standard can be determined.

The task force also, moving to recommendation number 5 on that slide, also recommended that CMS use pilot projects to test an expanded set of data elements of potentially use in data quality measurement. And that CMS begin to undertake these pilots after they've first defined the core set of clinical data elements. So I'm going to pause there. Kathleen, I would appreciate if you had any additions to the comments that I've made that would be terrific?

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Sure, thanks Cheryl for presenting for the task force. I think that those on the call will recognize that the overarching theme here was to say, let's lay out a series of milestones and steps while...to be able to do what we might call the standard pathway, while at the same time striking a balance with allowing for some innovation. But getting the basic elements right was definitely a priority. And then I think also the recognition by the members of the task force that this really is a shared responsibility that timeframes that are defined for providers and for EHR vendors need to be the exact same timeframes for CMS, so that all parties are ready at the same time, at the same place. Thank you.

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

Thank you Cheryl and Kathy. Any comments, questions from members of the committee; and if you want to use the hand raising that'll help queue us up. So far I don't have any hands.

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

Paul, it's David; I haven't raised my hand yet, but I am.

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

Sure, go ahead.

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

Thanks. Thanks Cheryl for that report and for the work the groups been doing. I had a couple of questions, one fairly specific one; I guess its slide 7, number 3. The phrase requirements should balance data collection necessary to measure outcomes without negatively affecting validity and burden. I didn't really understand what the thought was about what needs to be balanced? Is that to say you are recommending minimum data collection necessary to avoid burden or maximize validity? So, in general obviously the question is, we only want to collect what data is necessary to measure outcomes and I

don't...I'm wondering if there's a guidance implied here that we should be thinking about beyond that. That's one.

The other one is a little broader; I think we all have the...that this availability of EHR to make access to data from quality measurement easier. But it feels like the group has been responding or reacting to a feeling that we need to highly specify the specific data items that CMS and ONC and others to agree on what that list is. And then build and deploy the data collection to a well specified set of items, rather than a more flexible interface that can be adapted to a variety of requirements that are going to be different by setting and specialty and time and everything else.

And the third question I have is about registries, which aren't mentioned here. There was a press story this morning about difficult of registries being viable without a more easy interface to the hospital data systems. And I just wondered if the group and talked about that issue? That's three and I can go back over them if I lost you.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Okay, I was trying take notes. Let me start with the last one. I don't have any recollection that the group talked about registries and the interface with hospitals. Kathleen, do you remember anything about that?

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

We did not.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Yeah. So, I'm not sure David whether you want us...since the committee is continuing to meet and the comments were already due for the IPPS Rule, but we sort of have a second leg of work ahead of us around PQRS. So it may be that you want us to kind of raise this topic for discussion with the workgroup when we meet over the course of the next month and a half. So just let us know on that.

In terms of what is on slide 7, number 3; I realize the language is a little funny here and here's what I think is meant by this. So when we looked at the set of data elements that were being proposed for collection and the language that was around that section of the notice of proposed rulemaking, it was unclear to some of us whether this list of elements would represent sort of a broader set of elements that would be applicable across many different types of measures. I know for myself personally, when I looked at that list I thought that was very specific to that particular application and CMS was signaling that they were going to continue to move down this path of collecting more data elements.

But it sort of was this open-ended possibility of collecting what I'm going to call endless data elements without some specific applications. And so I think the discussion of the workgroup back and forth was, well...it doesn't really make sense to collect data elements without sort of a specific application. And it's very hard for us to comment on sort of giving CMS sort of carte blanche to collect everything and anything. And wouldn't it be better to sort of build that into the actual quality measures such that you'd be collecting what you need for that specific application. So I think partly what you are sensing here is some uncertainty about the way the language was written and what CMS was intending to do. Kathleen, do you want to comment?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Yeah; I think that the key or perhaps maybe just one additional comment would be that there was sensitivity to the fact that entities such as CMS are processing over 1 million claims per day and that the magnitude of data elements that might come associated with those claims was daunting. And so rather than the broad sweeps and not really paying attention to the quality of the data I think our balance tipped really towards high-quality data that could be collected consistently across all platforms as opposed to what might be a great deal of variability.

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

Okay. Thank you

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

And so David, I don't know whether that sort of partially answers your second question in terms of sort of making access to data easier, and sort of these trade-offs between sort of a agreeing on a defined list versus creating a flexible environment. So again, I think you are sensing some uncertainty among the task force in terms of what CMS intent here is.

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

That's helpful. It's a very important question. I guess in speaking for other private purchasers as well as CMS as a public purchaser, I think there's a great concern that this investment in EHRs does need to produce a flexible reporting platform that can respond to purchaser's questions about value. And if we get to lowest common denominator, core set of measures, a very narrow predefined set of reportable items, we lose the purpose of the whole investment from a purchasing point of view. So I want to make sure that as we make these kinds of recommendations we don't over-specify or sub-optimize in order to satisfy one set of requirements instead of continue to build a flexible reporting platform.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Yeah and I think that that came up in our discussion to some extent and I think if you go up a slide back to recommendation 1, in terms of identifying innovation measurement centers and trying to help create activities that will identify what should be collected and put what I'm going to call better definition around this...excuse me. You know, to not...sorry, it's early in the morning for me, to not sort of lock people into a very narrow set of measures or data elements. So I think that this probably requires playing out more and I suspect maybe this next notice of proposed rulemaking for the physician quality reporting program will have some similar type of language. And I guess I would appreciate if we could work to refine this type of recommendation back to them because I think we're a bit murky on it

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

Okay, thanks.

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

Thank you. And Cheryl, this is a recommendation or a theme that we developed gosh, a number of years ago. And David had chaired a working group on quality measures and the notion was to try to play this balance between standardization so you could have aggregate reports that you can benchmark versus keeping up with the change in healthcare and move towards outcomes.

And some of the thought we had there was to one, leverage as you said, centers who already are working in more forward-looking and more outcomes oriented measures, and have them sort of feed into the pipeline. But the second was to have our toolsets, the EHRs and the HIT systems that collect data and create reports, have them be more of a platform where you can flexibly change the definition of measures to keep up with the focus of attention as it moves either as it pertains to a local situation or as the country figures out more what measures matter to patients and consumers more

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Yeah, that's very helpful and I do think that that was coming up in our discussion. But I think, and you may have already played this out in other conversations and other meetings, but I think the question that seemed to be in front of us was, do we have a sense of all the different types of outcomes? I mean, obviously we don't know all outcomes, but are there a broader set of outcomes that we can kind of look across these and see what would be this expanded set of data elements? Because what was in the notice of proposed rulemaking was one very narrow use and I think it was hard for the committee to get its head around, how could this be done in a broader way that would sort of promote that more flexible platform...

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

Right.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

...sort of in real implementation?

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

Right, so that might, as you suggest, I don't think we're changing any recommendations here. But as you move into other work, like the PQRS, if we can start mov...you might review some of the past recommendations where we talked about this innovation platform, I mean, yeah the measure platform that allowed for innovation to occur and maybe weave some of those thoughts into your future recommendations.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

That's terrific and I appreciate that guidance.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Office – Palo Alto Medical Foundation

Great, thank you. Any other...let's see, Anjum.

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

Yes, thank you and thank you for the presentation. You mentioned that the task force strongly supported the harmonization of clinical decision support and clinical quality measurement standards. Could you say a little more about, in your review where you see that process right now in terms of its finalization and the speed at which those standards will be developed?

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Kathleen, I'm not sure that the committee put a specific timeframe on when these new standards would be ready. I think there was recognition there was a vote that was going to occur in October and there would still be some settling after that. So vis-à-vis this 18 month period from the time something gets announced to it being able to be implemented and practiced on the ground with providers, I think there was a feeling that we're still probably, I don't know, 12 months maybe a bit longer out from having some of that stuff be a little more settled.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Cheryl, this is Kathy and I would agree with that. I think that we did have the advantage on the task force of some who are very involved in the development and in the iterative process of fixing bugs you might say in standards. And so what we were very sensitive to was the description that some standards that one might consider had not yet even been balloted and that other standards were much more advanced and had gone through a number of fixes with of course some fixes continuing to come through probably in the same way that you get them for your personal computers; but those fixes being much less disruptive to what you might call daily operations of an organization.

I'd like to just go back to the comment about are we sort of setting our bar perhaps a bit too low or is it a lowest common denominator? And I might say that we are looking for a common denominator in terms of the...since this is a rule and it's a rule that will apply to everyone, every system that we were sensitive to the fact that it needed to be broadly applicable, that it would be the exception not the rule that a system would not be able to perform. But our antidote you might say to what might seem like conservatism was to then say, we want to see pilot projects, we want innovative centers to be able to act in a forward thinking way and to lead the way. But in the meantime, that we needed something that is broadly achievable across the United States.

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

Very good, thank you. And, let's see and Kathy, you must have had...so you had your hand up and you got to say what you wanted?

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Yes, thank you.

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

Good. Thank you. Anyone else? All right, we need to approve this set of recommendations and I'll entertain a motion to approve them.

M

I'd move it.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Office – Palo Alto Medical Foundation

Okay, thank you. And a second?

W

Second.

M

This is...I second it.

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

Thank you. Any further discussions? Okay all in favor say aye.

Multiple speakers

Aye.

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

Any opposed or abstain? All right, well thanks again Cheryl and Kathy; excellent recommendations and those will move forward.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

Thanks Paul.

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

And you'll get your next assignment...

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Probably in an hour.

Cheryl Damberg, MPH, PhD – Senior Policy Researcher – Rand Corporation

It's going to be a long summer.

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

Thank you. Okay, our next topic is from the Advanced Health Models and Meaningful Use Workgroup and I'm going to take the lead because Joe unfortunately wasn't able to attend the hearing from a scheduling conflict, so I'll present the work of the workgroup. And if we could move to the next slide, please. All right; so the charge for this workgroup really is to facilitate the effective use of HIT to support outcomes focused, advanced models for healthcare delivery and value-based payment. Next slide, please. And these are that many participants on the work group and representing a diversity of background and perspectives, which is really helpful for our discussion. So really appreciate that and especially Joe, the Co-Chair. Next slide please.

So we're looking...the focus is what HIT policies are needed to support AHMs, Advanced Health Models capabilities to address really a holistic view of an individual and the communities. So key features are that we don't restrict ourselves to just clinical, don't restrict ourselves to just EHR, but really look at all the data about an individual, not just a patient. So clinical, social, psychological, behavioral and other data sources, which could include "nonclinical," it's hard to defined these terms, but "nonclinical

sources,” such as let’s say, a food pantry or a career placement center. So we’re also looking at the notion of, can we coordinate the health plan? We would really love to have a better definiti...better term than a care plan, but the plan for an individual’s health across the entire continuum of places and influencers on their health.

Next slide please. So we had a hearing on June 2 and really looked, the ONC staff Alex Baker and Sam Meklir really spent a lot of time trying to ferret out the exemplars of advanced health models so we could hear their story, hear what data they went after. How do they put it together? And how did they disseminate those data? And listened to their opportunities and barriers; next slide, please.

So we had three panels; one focused on integrating data across the various data sources, so sort of an integration, it’s like getting access to the stuff in the first place. The second panel concentrated on how do you use the data? How did the various stakeholders, the various influencers in an individual and communities health use that data to support whole health and wellness? And finally we looked more in the medical model of how do you support integrated care? Next slide, please. So I’m going to summarize the findings; there are number of bullets that were listed, but I’m going to try to combine some of those. Next slide, please.

So first we saw community organizations, the nonclinical, the nontraditional clinical organizations that are out there to serve individuals felt that they’re integral partners and they’re very motivated to share both data and to make use of the data so they could enhance their particular mission. Obviously as data gets moved around in the current state, it’s not very standardized and there’s really not much incentive for any one party, any one organization to create...to spend the money to create the data systems that would standardize and move the data around.

The second point is that although we’re making substantial progress of using existing data, so one approach is, hey, I’ve got some data and let me make it available to others; that even if you do receive data or access data, particularly smaller organizations don’t have the wherewithal to be able to apply data analytic methods so that you could understand the data and track it over time to see whether you’re making a difference.

The third point is that we’ve heard of...the goal really is to have each system be able to interoperate with others. But since that doesn’t really exist in a robust fashion today, we heard a couple of examples of different approaches. One is to provide other groups or organizations access to your data, let’s say your EHR data and the health system’s point of view. Or we also heard examples where a separate repository was started and data sources, organizations would submit...transmit data into the separate repository. Neither of those of course meets the ideal or the vision we have for each system specifically designed to serve their mission and being able to incorporate data from other sources, i.e. interoperability. Next slide, please.

So it’s clear that if we’re going to have new models of care and promoting health, i.e. these advanced health models, we’re going to need a data infrastructure that goes way beyond the “clinical data” in an EHR. So we’re really thinking of a data infrastructure, an HIT infrastructure. And that one of the first points that comes up, and it probably was mentioned by almost every panelist is, actually it would be really nice if we had a way to uniquely and reliably identify individuals as they cross the various organizational boundaries.

Currently, as you know, we haven't had much progress in that direction because of some restrictions in the federal participation. But we're encouraged by folks being so motivated to solve this problem that maybe you'll see one of our recommendations is maybe we need to have a private sector voluntary effort to create these, some people call it unique health identifiers; I think that's how it's referred to in HIPPA.

Now, it gets a little scary to start spreading data around to so many var...different organizations, in fact one panelist talked about having 9000 different community organizations. But the good news is that it's not as if you have to spread the entire "chart" around. Most organizations just need limited information about an individual so that they can better serve that individual from their point of view. And the other...on the other side, you wouldn't want to inundate all of these organizations with a lot of data, most experienced that, because you can get overwhelmed and actually be counterproductive to getting meaningful data out in the field. Next slide, please.

So speaking about privacy, this clearly is an area where no one person or organization really understands the full suite of either laws or regulations that apply to health data in any given location because that location fits in the federal space and the state space and even local policies. So it would be really nice even to know what we are dealing with, that is to have clarity, better guidance around the privacy and security issues for HIPPA and non- HIPPA entities.

So I'm not sure, I think we all appreciate that even HIPPA-covered entities don't fully understand what they are and aren't allowed to share and with what responsibility. And certainly the community-based organizations are not used to dealing with either covered entities or fall under HIPPA or how HIPPA would affect them. So just getting clarity around what exists and identifying the gaps, let's say, between the conflicts that may arise crossing a state boundary would be very useful and chances are, data could move around more freely and safely if everyone under...had a better handle on the various privacy laws and regulations. So that is sort of something that could be done today, we'd have a better understand...everybody would have a better understanding of what exists today and we'd have a better understanding of the gaps that we need to overcome.

The next topic is about shared longitudinal care plans, and as I say, we struggle with the notion of care plans because it's really more about health planning like you have financial planning, that it should be shared amongst the whole stakeholders, the team which of course includes the individual and caregiver. And that it be longitudinal, not a static record which used to exist in the paper world and with the electronic world we certainly don't need to be bound by that. So this is something that includes what are traditionally clinical and also nonclinical data and settings.

So across a whole continuum, wouldn't it be nice if the individual had an idea of their health plan just like you have a financial plan, and that everybody was "on the same page." That's the goal. Community service organizations may be very small, usually they're nonprofit, so they may not have the same kinds of support for managing data, or their data systems as a large health system might have.

Since social determinants and social services that apply or address some of those social determinants is a very important of taking holistic view of an individual. The lack of standards about those social services, everything from their hours of operation to what payers might be contributing, and who is eligible are things that would be very useful to have in standardized format so that the computer can help us do searches like you would with an Amazon for a particular product.

So that became a clear need and most of the panelists were working for these nonclinical data. So just as we heard from a quality measure group, we struggle with data standards in the quality...in the clinical space, it's even more so in the nonclinical space. But it's important for us to be able to have these standard data elements so that we can share and let the systems interpret it for us. Next slide, please.

So one of the ways one of the organizations that could help with collecting some of these nonclinical data are HIE organizations. And it's clear that, as we have talked about before even with clinical data, we need to pay attention to the governance and privacy challenges for these groups. And it gets multiplied a bit, as I mentioned, when we have non-HIPPA covered entities like community organizations.

Some of the innovative approaches to...so, it's clear that we need to understand what resources are out there and do somewhat of a match-making, so for relevant services to an individual. Some resource directories have used, let's say crowd-sourcing as a way to get that information because it just doesn't really exist. There are some efforts that are ongoing in certain communities to try to collect that data, but in a broad way, it doesn't exist; even though actually the federal government sponsors or at least gives grant money to a lot of these organizations.

So we want to point out in point 13 that it's really important that the individuals, I've mentioned this before, the individuals and their family caregivers in particular do have not only the access rights and the ability to use the information, but also to contribute to this information so that we can have a better view of all the things impacting that individual's health. Speaking of individual, and what's called patient engagement, the advanced health models are, at least that we talked to, are really at the early stage of having robust measures to engage people in sharing and contributing to their data.

And finally, next slide; we all recognize that the current fee-for-service system is not only not an incentive; it's truly a barrier to getting the right data to flow across. So as we go more towards global budgeting, pay for value...I'm sorry, value-based purchasing, we really would like to understand, one the data requirements across the continuum, but also what are the resource utilization, i.e. costs across the entire setting? Next slide, please; and then one more please.

So we wanted to...so that's...we really had wonderful people participating on the panels and we had a lot of common points we've tried to highlight in these past slides. But we wanted to come up with some critical few; you can't have a recommendation for each of the findings so we decided to focus on a relatively small number. But first, what levers does the federal government in particular have that can help us...enable...help us move the agenda forward on HIT support of advanced health model.

Well, the government has the ability to convene multiple, both public and private sector. The government can establish policies that make certain data or certain methods more transparent, that can help both with the understanding or awareness of the data, but also in protecting the privacy. Payment policy is extraordinarily important; payment policies or quality reporting transparency requirements are very important in trying to motivate folks for one, focusing on measurements that matter and interventions that matter as well as doing more...paying for more than just doing clinical things to folks.

One of the tools ONC has at its disposal and has used is voluntary certification. So HITECH has some mandatory certifications in the space of Meaningful Use, but it also...ONC also has the latitude to issue voluntary certification for HIT. And that helps both sort of standardize the features and functionality capabilities of the system, but it also helps the purchaser, the health system or community organization know which systems are more likely to deliver the functions and data in ways that they need it. Funding

for innovation is another, CMMI is, of course, a prime example of that and catalyzing through its convening or its dissemination strategies, shared learning that occurs across communities. Next slide, please.

So the first recommendation we have does have to do with standardization, it's sort of to be expected and you heard that plea from the panelists. And one of the areas to highlight, you know, we've talked a lot about clinical data; one of the areas to highlight is standardizations about information regarding human services. Now below there are things labeled considerations and the label is questions. I'd like you to think of this more as recommendations that follow, much like the Quality Measure Task Force had.

So there's an overarching recommendation and there are steps HHS or ONC can take such as establishing key use cases that would help us prioritize what standard should we work on first? Which should we align first? A second is there is something called National Information Exchange Model that does have some standards for nonclinical services. Maybe we need to up those standards so that human services organization can be a big participant they are. But maybe we need to standardize on some of the standards that are being promulgated by NIEM. Next slide, please.

The second recommendation has to do with standardization but of social determinants; just recognizing how more than the measly 10% that...of what we do to patients. So the outcomes are affected by many things about individual; healthcare is a very small minority, on the order of 10 -15%; social determinants is actually larger. So how can we standardize the data that relate to social determinants? And some of them are obviously reported by the individual.

So in the considerations and again, think of these as recommendations, that patient reported social determinants be prioritized as part of the new data collection standard, both the standard and what's required to be collected. Let's say NCHS has a number of surveys, could we collect more of the social determinate information so that it can feed into this combined data repository? What's the incremental path forward to integrate measures...integrate social determinate data into measuring measurements? And how can those also, the social determinate data, be used to improve our risk adjustment? Next slide, please.

We talked about this, the need for...we often talk about care coordination, we talk about care across the continuum; it's pretty hard to do, it's pretty hard to manage any project without having shared calls or a shared vision. So we really think this is something where that the workgroup felt very passionate about, as did the panelists, that is a key gap we have and it's not like any one party or one profession is already either owns or does this, but it's something that we all need in order to work off the same page. So we thought of it as one, being dynamic, two being shared, three being longitudinal and then, for lack of a better word right now, it's called a care plan, but we really think of it is a plan for health. So that includes information about the clinical situation, but also the nonclinical; let's say food, transportation, SES status; those all affect an individual's health and care.

So one of our suggestions is that ONC perhaps in collaboration with a private foundation, because we think this effort as primarily a private-sector effort, but it may need some kick start or start up with the federal government. And it would be nice to have a joint effort with a private foundation to convene; sort of we call it sort of a working summit. So it's a summit because it brings together many stakeholders who haven't been together for this purpose, but are necessary. So everything from the teaching

organizations through the food pantries at the end and the health systems in the middle need to buy into and help define what this dynamic shared care plan is.

So we're thinking that this would be sort of a working summit and then it's wo...the true implementation, the development would be done in the private, sort of as a public-private effort but sort of in the private sector because it's something that needs ongoing effort. But just starting the effort really...it so far has not been done. And so that our recommendation we have for ONC is to partner with a private foundation to carry on this working summit.

Another recommendation is really to identify the priority domains, because there's so much there, as Cheryl relayed her presentation. So what are the priority domains we should focus on? And fortunately there are just a few high priority things that were really need to know, many of the organizations that serve an individual needs to know. So how do we go from the standards developments we have for a static snapshot to a much more dynamic plan? And how do we incorporate the social determinants? Next slide, please.

Well, the individual magic strategy surfaces again. We understand the restrictions that the federal government and HHS has, and is in the latest appropriations bill as well, but we think, as I said, there was some energy around a private-sector effort to create a voluntary method of solving this problem for this identity problem...matching problem. And there could be efforts by the federal government to look at what strategies have been most effective and what data elements; this is been a previous recommendations that feed into matching strategies would be needed. Next slide, please.

The fifth one has to do with clarifying guidance around privacy. I mentioned in the findings how much a lack of clarity gets in the way, there is certainly information and materials already prepared by HHS. Making that available or probably finding ways to make that more accessible to folks and understand how this solves their problem may be one thing, but there probably is other clarification, especially in federal and state law overlap that could be further elucidated and would be useful to the folks trying to implement advanced health models.

So there are number of suggestions we have for that; guidance, FAQs, educational channels and sharing of best practices as ways to help people understand. Currently it is...people do not have a good understanding, so that's really in the way. And finally, next slide please is, and Cheryl mentioned some of this, the notion that we really need to work on outcomes-based population measures that really look across the continuum. And generally people thought of measures as across the health system or the clinical side, and the advanced health models really saw a need to know where everybo...is everybody working together as a team to affect the lives and health of individuals in the community.

So I understand that was fairly long, but it was really a very well prepared and rich hearing that we had, and we wanted to share as much of this information as possible with the group. So we welcome your comments. Joe any additions, if you're on the line?

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

I don't think we have Joe.

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

Okay, open to comments and questions and this will be something that we submit for approval.

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

Hi Paul, this is Troy. I'm not on the...

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

Sure, go ahead, Troy.

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

So anyways, first off, I really commend the group for digging in so deeply into all of the different determinants of health and it sounds like a very exciting group and you covered pretty much the whole gamut along the continuum. So that's fabulous stuff. A couple of questions I had, was there any discussions about, you know we always end up getting kind of derailed by the interoperability discussions, but was there any discussions about different applications or Apps, APIs that are being utilized in those community health centers to kind of aggregate all of the health information and the social determinant information that they're gathering on the clients?

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

That's a good question Troy. I'd have to say sort of the underlying assumption is that we have to and would like to get towards system interoperability so that the data gathering and reporting can be much more integrated and seamless. And having said that, these were folks that were picked as exemplars for, well they got some part of the job done anyway.

As I mentioned, there were sort of almost two extremes on the spectrum; one is...one organization, as an example, gave a lot of organizations access to their EHR, as an example, including read/write access. Another organization as I mentioned, actually created a separate repository so everybody could dump into this separate...this common repository in a sense and then have access to it.

So I think people were reaching out and saying; one, we really want to have standards so we can...all our systems can operate on this data uniformly. And two, it's got to flow more seamlessly. And so your suggestion and what appeared in the NPRM as APIs is one of those examples of how that could be done. But we concentrate on, what would you do with this...what data do need and what would you do with that and how would it benefit the individuals?

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

Wonderful, that was...you just answered my next question, so, I appreciate that. Thank you very much

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Offer – Palo Alto Medical Foundation

Thanks Troy. Kathy?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Yes, Paul, this is a very wide ranging and far-reaching process that you've led and I have to congratulate the group for thinking so broadly; a couple of thoughts of really some areas of synergy or potential harmonization. I think as many on the phone know, the Institute of Medicine recently issued its report called Vital Signs for Health in America, the core measures of our health and well-being and really is looking at a lot of population level priorities and just, where I see some of this interacting very much with social and community organizations. For example, overweight and obesity which would have to do with access of course to places to exercise and places to purchase healthy food; addictive behavior, which can significantly influence the health of the community; unintended pregnancy and its impact on educational attainment by young women, as well as the health of their babies. And a whole variety of other topics that we have not traditionally thought of perhaps as being just clinical problems but really are shared problems, so I'd urge the follow-on work to look very carefully at that Vital Signs for Health in America report.

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

Thanks Kathy, it's very important; I had the privilege of serving on that committee and you reported exactly right, it focused a lot more on all the aspects and influ...measuring all the aspects and influencers on an individual's health. And of course a lot of that is nonmedical or nonclinical. But thanks again. And this is the focus of this workgroup's attention, actually, so this is just a beginning. Thanks.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Great.

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

Karen? You might be on mute? Karen, we can't hear you yet. We'll come back. David Lansky?

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

Thank you, Paul. I was at the first day of the hearing and I thought it was really fascinating and hopeful and optimistic and great to hear how many people around the country are working hard on this and making progress and identifying some of the challenges that maybe we can help with. So I thought...I again applaud you guys for doing this work. I was also thinking that it is a really big scope that we're beginning talk about and it might be worthwhile in the recommendation to sequence or prioritize them in terms of where we think ONC or others should be giving their attention.

And as you can guess, I would say number 6 is the most valuable place to put some effort, the identification of outcomes that wraparound the different services and data sets into something purposeful, particularly because of some of the new payment models are going to reward those population health outcomes. And it also to me suggests, at the least hearing the testimony made me think about needing a learning collaborative of some kind where we can harvest what people are learning by the different experiments we started to hear about.

And on the flipside of that is I felt a little cautious about being too prescriptive is on things like the shared care plan given the uncertainty or dynamics or learning mode that we are in. And I don't know

what the middle ground would be in terms of staging, perhaps it's several experiments and shared care plans where we learn what is worth capturing, what can be standardized, etcetera.

Another thought I had was around the standards issue which was mentioned early on and I felt a little wary about it because of our challenges getting standards adopted and conformed to in mainstream medical care. And that led me to a larger thought might also be something to include in recommendations which is, whether we have tried to capture things we've learned over the last five or six years in the extension of the healthcare and medical care data systems. And what have we learned that should guide our thinking about reaching into these other domains of social determinants and social services. So some of the things have been very hard to succeed with, some things that have been pushed back from providers on, places where we wished there had been more flexibility. It would be nice if we had an inventory of our learnings that would guide our thoughts about extending those to new domains.

And then the last thing I wanted to mention really struck me listening to the testimony was I...maybe the outcome is sort of the need for the humility or caution that we don't let the healthcare system become the drivers of all of the other systems, which have their own intrinsic value and importance and relationships and funding and so on. And I think there's a little tendency in the healthcare world to think as we become population minded and we receive global cap...global budgets or capitation that we then sort of have the responsibility or right to reach into all these other domains and capture data and start creating standards and care plans and all the rest of it. And I think we need a multi-stakeholder process to balance the way the healthcare people think about that responsibility with what the other stakeholders who have a lot of experience in other domains bring to that table.

And the last part of that is, there was a sense that I heard, maybe others would correct me that many of the speakers thought that the move to global payment was driving a lot of this. And conversely, as payment changes, might be...we might want to focus some of our early attention in markets or geographies or products where that has already happened. And then be very sensitive to areas where it hasn't happened and the different levels of difficulty in achieving interest and adoption of some of these approaches in markets where the payment changes are happening more slowly. But thanks for bringing...moving this along; it's very valuable.

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

Thanks, David and...

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

Oh hey Paul, this is Karen. I was speaking into mute, so if I can get back in the queue? I wanted to...thank you. I wanted to add my thanks to you and the group for thinking big. It's so important for us to try to align our future strategic policy approach, technology approach to one that's going to be much more person-centered and this one that's going to allow us longitudinal picture of someone's health and not just their healthcare.

And you all are touching on, I think, what is already being asked of the system, not only by consumers, but as we really endeavor to do work like precision medicine, we're going to need a digital picture of a person that is comprehensive in the way that you're describing to really be able to meet that...meet everyone where they are and have their own little micro learning system and big learning health system.

So this is really exciting. I agree...I was going to make the same comment about the prioritization, I think the biggest challenge is how to decide which of the standards or privacy, or other key elements we need to item order first.

I think as you know, in our interoperability roadmap we stayed pretty focused initially on the inputs and outputs related to healthcare as one of the many aspects of someone's overall health. But sooner than we can all realize, we're going to need to make sure that we can have good standards and good policy around the data issues and data sharing issues for information that goes well beyond the healthcare settings; the patient-generated data and information that tells something about the social determinants. So some guidance on what's the right set of priorities? When and...would be extremely helpful. Thank you

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

Thank you, Karen. And going back to the many points that David raised; I think in, I mean, if I were to try to combine what David said and what Karen just said. We really have so many stakeholders who didn't even know they were part of "health team;" that's, I think, a real basis for why think this working summit kind of idea of just even bringing together folks and even understanding what other people do.

And to your and David's point, this learning about what other people and making sure we don't either mess up community organizations or learn from what community organizations are doing to coordinate some of their efforts. It just seems like there's so much to do, it's not well defined but there would be so much benefit to everybody that that's why our idea of having...starting this with a federally convened working summit and then moving on. So anyway, that's the Genesis. Anjum?

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

Thank you Paul and thank you for the presentation; I really like the fact that the recommendations range from focusing on individual's access to data to the broader population health measures. I had two questions; one regarding your last recommendation where you talk about population health outcome measures. And the term accountable community is used, so community being I think a good geographical unit at least in terms of looking at population health. But did you have any, on the committee in making those recommendations any specific scope in terms of what an accountable community, what you meant by accountable community?

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

Okay...

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

And my...

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

Go ahead.

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

Sorry, my second question was regarding this reference to the National Information Exchange Model.

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

Um hmm.

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

I had frankly not heard about this before and as I was looking at this, it seems like it is an organization that has been in existence for 10 years. So if you had explored kind of is this like health is an important part of this? Or is this something that has been looking at other data and not necessarily health. Where is it located right now in terms of, I think, looking at the broader health data?

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

Okay, thank you. So let me answer your first question, leads into your second so the term accountable care community, what we're trying to do is two things; one, avoid being pigeonholed into a CMS ACO, but really the major point is that it isn't just the health system or provider groups that...influences or is touched by an individual, related to their health. So we tried to expand the concept which was really the theme of the hearing, of who are the various pe...who's the community that impacts an individual's health. And so we meant that in that sense and also geogra...typically those are going to be geographic as well.

And that feeds into the standards; so this was pointed out in the context of multiple people were essentially building their own list of community services so that they could even just function. And so this, I think it's called 2-1-1, but I think this group works on standardizing various services and services as they impact health is just one of...or just one set of them. So we wanted to piggyback on things that are already being done and see if we can't expand on them; as you pointed out, it's been around for a while, not a long, long time but a while and maybe we just need to build on that as a way of extending the standards efforts in various...for various services that are relevant to health.

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

Thank you.

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

Thank you and my screensaver went on so I have to...okay, any other questions or comments? Okay. So I'll entertain a motion to approve these recommendations? Now, so these are just a starting set, as I said, our work group is really fixated...focused and fixated on this broader expa...this expanded view of organizations that impact and things that impact in individual and community's health and we intend to continue to pursue this as far as how can information systems HIT support these effort...these activities? Entertain a motion to approve?

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

Motion to approve...

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

Okay. And a second...

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

...this is Troy Seagondollar.

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

Thanks, Troy.

M

Second

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

Thank you any further discussions? All those in favor please say aye.

Multiple speakers

Aye.

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

And any opposed or abstain? Well thank you for your support and I want to thank again the ONC staff that really helped put this together and the marvelous testimony we had from the hearing participants and the workgroup.

Okay, any finally we're going to hear our first round of thoughts from the Privacy & Security Workgroup on big data privacy, and this was something that was called...asked by the White House. Big data is a big deal, but we also have to make sure that we're protecting individuals' data which becomes part of big data and make sure that we don't have inadvertent harm. As you know Deven was Co-Chair with Stan, Stanley Crossley and Deven is no longer in the committee as of yesterday because she joined HHS. So Stan is going to lead us through their provisional recommendations for your feedback. Stan?

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

Great; thanks very much, I really appreciate it. And yeah, and I am in no way going to try and fill Deven's shoes, at best I'll just give a shot at trying to do a representation of the committee's perspective on the workgroup's perspective here. So again, add my thanks to Deven's incredible leadership over the last few years and especially the last years I worked closely with her.

So the recommendation you're getting today is kind of a penultimate recommendation, kind of where we think we're near final, but we'd really like your feedback on where we've landed. You gave us some

pretty specific requests the last time we talked on trying to narrow in on the key issues and go for a few issues that could have a big impact rather than a dozen or more issues that may not have as significant an impact overall. Because this is a topic, as has been said today already, that permeates a lot of this area and big data and privacy and security, there could be dozens of recommendations.

So what we're trying to do is we tried to find those four areas that we thought were critical. And so, if you could go to the next slide for me; the...one of the values that Deven helped establish the core value of the Privacy & Security Workgroup was that patient's needs and expectations should be considered and that patients should not be surprised about or harmed by collections, uses or disclosures of their information. And really nowhere is this more difficult than with big data.

So, if you go to the next slide, what we tried to do is consider both the im...those types of impacts as well as consider the White House's charge to consider appropriate use, consider innovative use while still trying to protect privacy. And we held public hearings December 5 and 8, as well as February 9 within this last year and heard from 21 separate presenters across a full spectrum of stakeholders from patient advocacy groups to privacy advocates to researchers and others and really trying to then focus in on the scope of privacy and security issues, potential harmful as well as beneficial uses. And out of scope, we tried to take those things that weren't in that core; data quality, data standards, non-representativeness of data, all important issues, but afield too far for us at this moment.

So really coming out of those hearings and after conversations with you all, we focused in on a couple of what we think are very significant areas; concerns about especially de-identification and security and then preventing harm...redressing harm then, the complexity of the legal landscape. And we've kind of broken these down into harm, uneven regulation, de-identification and security. So those are the areas we've chosen to focus on and what you'll hear from me over the next few slides is a problem statement followed by a recommendation for a potential solution and we'll do that across each of these four areas.

So, next slide; so the potential for harmful or discriminatory practices. We had a fa...we found this a very significant challenge, ensuring both the responsible use of big data analytics and understanding the increasing risk of harm as it might result, of which discrimination is one of the harms that could arise. Some US laws prohibit discriminatory uses of health data; you have GINA, you have ACA you know that prohibit the use of health insurance or health data for instance for health insurance purposes, genetic information for health insurance. However, other discriminatory uses of health data are not expressly prohibited by law or are, in fact, expressly permitted for the use for data for life and disability insurance, for instance. It's difficult to make policy because there's no consensus on which uses are harmful, and we heard that just a little bit ago; unable to predict which future uses could be harmful, even predicting the future uses in order to understand that harm.

And then, the final harmful aspect we looked at was this poor transparency, the ability to reinforce biased and unfair practice, where you don't even realize the bias exists until you understand the process that was used to arrive at a decision. And we heard from many folks who testified on the concern that there's a community bias can exist to entire segments of population that isn't even known because of the inability to understand the algorithms that are used to reach these decisions.

So in light of these harms that we looked at...if you go to the next slide please; we came up a set of recommendations. There are two slides on these potential solutions and recommendations. Overall, we really felt it was going to be very difficult to make meaningful progress here until we tried to get to some type of a national consensus on what constitutes harm. We heard testimony that the ends of the

spectrum are fairly easy to address, those things that are clearly bad that everybody can agree on and there are things that are clearly good that everybody can agree on. But we have really no consensus about the 80% that is in the middle that makes up most of the use cases and it's going to be important for us to try and understand that.

And so the workgroup wants to issue a recommendation to encourage ONC and other federal stakeholders to more promote more public inquiry to fully understand the scope of the problem both harm to individuals and to communities. For example, to address health insurance discrimination Congress limited health insurance ability to use health data for insurance decisions as part of the ACA. And so we know there's precedent, but this is a fairly significant effort, but really we think it can only be done if the federal stakeholders decide to create some type of a consensus on what harm we are really worried about.

The next slide furthers this and says, not only do we want to try and do this consensus; it can't be a point in time. We have to determine a way to continue to monitor the use of health big data to understand how it's evolving and then what data is used for health...not only the health data, but also the data used for health purposes. And we heard a little bit ago as well, the ability to infer health status from non-health data is growing rapidly and is an area where we need to understand if there are gaps in law or regulation or there are other areas that we need to kind of bring to light.

And that brings us to transparency. The...we see transparency as generally a good disinfectant in a lot of ways, as has been said before. We look at the Fair Credit Reporting Act as a law, a statute in regulation that kind of set a best practice to we could perhaps use for governing algorithms. There's difficulty in transparency with algorithms because of the proprietary nature that the companies assert or entities assert in doing their algorithms but at the same time, we need enough transparency to understand when bias is being introduced.

And so the FCRA, which was really the first big data law if you will, it set up a transparency where consumers have access, they understand when decisions are made that could harm them and when they've been rejected and the basis for that. And so looking at that as a model, there may be a way to create some transparency in a similar way for health insurance or health information and privacy. So as our first set of recommendations on these issues, we can pause now and talk about that or if you want me to continue with the problem statements?

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

I think let's go ahead.

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

Okay.

Paul Tang, MD, MS – Vice President, Chi Innovation and Technology Officer – Palo Alto Medical Foundation

Because there are a number so we might as well go ahead and then come back. Thanks.

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

Perfect. The next problem statement is again, the different domains of regulation HIPPA and other, if you will. The idea that there are covered entities covered by HIPPA that are highly regulated and then the exact same information held by a non-covered entity, you know, industries, a manufacturer or you know a website, a hoster or others is completely unregulated with respect to health information protection specifically.

And so that legal complexity confuses consumers and imperils trust; again, we heard very similar and hauntingly familiar recommendations from the prior workgroup and you're going to hear it again from us to try and address this issue, but this unevenness is...doesn't make a whole lot of sense, and with health data actually getting created more rapidly outside of healthcare than inside at this point, with all of the different potential health App...mobile applications, an examination of this and at least an understanding of this is important. No comprehensive, FIPPS-based protections for health data analytics in any domain really outside of HIPPA and certainly in many domains, it's hard for us to find one outside of HIPAA that does it.

And access; individuals often lack the ability to access, use and share their own data including research for learning health system activities and this is true outside of HIPPA for sure where there's no legal obligation for entities to provide access. But it's also inside, as we've documented before, that the inability or the difficulty in individuals getting access to their data.

Transparency; the lack of clarity on how data is used and exchanged in a big data ecosystem, the layers are pretty extensive, especially once you go mobile. You've got a data use layer, you know, where did the data originate from? What type of data is it? Who are the participants? What are their obligations? All of those layers are very difficult as you move through to understand, certainly by consumers and patients.

And then research; the rules do not necessarily regulate based on privacy risk. For instance, there's a higher hurdle for using data for research and generalizable knowledge than there is for using it for healthcare operations, if you're a covered entity. And so, you know, when you look at that and that doesn't seem to make a lot of sense and so there are other areas like that we see as a problem where the regulation that does exist, doesn't exist on a risk basis. Please go to the next slide.

So in light of these problems, we have three slides here on how to address or recommendations on addressing these issues. So the uneven policy environment; we've made recommendations and we would ask that you leverage those recommendations made by the Privacy & Security working group on better educating consumers as well as covered entities and healthcare providers about the privacy and security laws and the uses of data both inside and outside of HIPPA. And we made that recommendation just in May.

Promote FIPPS-based protections for data outside of HIPPA. So, and this is a lot of conversation by the workgroup on this point and the idea that the industry outside of HIPPA could adopt voluntary self-governance codes of conduct. We believe these should be strongly encouraged by the FTC and by all of the other agencies HHS, ONC, to try and encourage this activity and HHS, FTC and other agencies should help guide the efforts. If done in a vacuum, then I think there's going to be some fairly untenable codes of conduct, but if done with guidance and involvement, we can very quickly establish rules of the road

that would enable trust. And it should be emphasized in the process that these codes should include a transparency of use and data collection.

The individuals should have access to the information that are being processed about them, that there's accountability on how the data is secured and handled and then that there are open use limitations on the data that has been collected. And we see that since we really aren't in an environment where we're going to make recommendations about holistic legislation here, a voluntary adopted self-governance code that can be enforced by the FTC when it's publicly declared; we see that as the fastest and most effective path in this area.

The second slide here kind of reinforces previous recommendations that policymakers should reevaluate existing rules governing data use that contribute to learning health system to be sure they provide incentives for responsible reuse of data for learning purposes. For example, treating as healthcare operations, learning uses of health data that other entities control; this comes about where a covered entity that is in essence doing research type of activity, but is not publicizing it for public good, can be treated as healthcare operations. But as soon as they use that for a learning health system purpose, it becomes research and then a separate set of authorizations is required.

Policymakers should also consider modifying rules around research uses of data, we believe, to provide incentives for the use of privacy protecting architectures such as data enclaves. And so the idea that if the data is going to move into a secure data enclave with controls around it that that should be given a consideration and allow a broader research use.

And then the final slide of recommendations on this problem; again undressing uneven policy regulation...policy environment regulation; individuals should have strong rights to access their health information. We see the access to information as a really critical piece to this and so when encouraging the self-governance codes outside, we want individuals to have access to their health information as easily as they can with their financial information. And that applies both inside of HIPPA, but clearly outside of HIPPA where no such rights of access currently exist and then over time, as we've also discussed, strengthening the access provisions perhaps with HIPPA to bring it into the digital age.

And then finally, educating consumers and healthcare providers, technology vendors and other stakeholders really across the big data ecosystem or the Internet of things ecosystem if you will, about the limits of legal protection that exist and then reinforce other recommendations about how you do that education and then the self-governance codes come into play. Okay, the next slide, please.

The next problem that we took on, and this was a fairly lengthy and in-depth day of testimony dedicated solely to this topic on de-identification and re-identification; in general the workgroup believes there's an overreliance on de-identification while no accountability for re-identification. There's no overarching standards for de-identification of data outside of HIPPA, you know, where they do exist, they're voluntary; concerns over safe harbor and expert determination; since no objective criteria governing the expert method exist.

The increased risk of re-identification when combining data sets, the mosaic effect; and then de-identified data is largely unregulated and this specifically an issue because there are no penalties for re-identification or negligently leaving data vulnerable for re-identification. De-identification reduces the value...then on the other hand it is not the panacea for innovation. De-identification clearly reduces the value of data and doesn't...and extra methodologies and is time intensive and costly and also is difficult

to replicate across multiple areas, so the reuse is difficult. So with those problem statements in mind are our recommendations for solutions. Next slide, please.

Okay, so again the call on OCR to a better steward of HIPAA de-identification standards and conduct. We'd like to see them conduct ongoing review of the methodologies and policies and to seek assistance from third-party experts, such as NIST. Urge the development of initiatives or programs to objectively evaluate statistical methodology to vet their capacity for reducing re-identification risk to very low in certain contexts. OCR should consider granting safe harbor status to those methodologies proven to be effective in particular context in order to encourage use of proven methodologies, and there are 3 slides on this topic. The next slide.

OCR should also consider establishing a risk-based de-identification requirements in circumstances where re-identification risk has been lowered, other than through treatment of the data. And so there's no ability to kind of titrate the de-identification requirements based on risk of the environment. So access to data is restricted in secure enclaves or those holding or accessing data have little to no motivation to re-identify the data and are prohibited from doing so in an accountable environment, should there be a consideration of data sharing here that should be part of the reevaluation of re-identification risk, so, considering this other criteria. Slide 3.

And then finally, the workgroup desires accountability for re-identification and certainly negligent de-identification but recommends against specifically asking Congress to address at this time. This is a difficult conversation and we discussed this with some depth, realizing that asking Congress to pass legislation that for instance others have called for to criminalize re-identification, unauthorized re-identification could create some liability and actually act as a disincentive to utilize de-identification when it was appropriate or to rely on that or perhaps create a disincentive for data exchange. And so exploring this and understanding this a little bit more and then...creates some level of accountability certainly within the self-governance codes that would be encouraged, but then exploring other ideas as well.

And then if we go to the next slide, our final set of problem statements is around data security. And this was probably the easiest of the conversations to identify the problems and to unify really around possible solutions, but also we understand the complications that are here on the policy side. But from a problem statement, there are silos of protection, no end-to-end secure environment for health data, certainly as you move across these environments from a HIPAA-protected space to non-HIPAA, or even across state lines.

No entity responsible for assuring end-to-end protections once it leaves one entity and goes to the next, you know, the accountability for the data ends with the disclosing entity and is now in the acquiring entities requirements. There's no legal incentive for privacy-enhancing technical architectures right now. Acknowledge Congress is the only policymaking body equipped to provide a baseline level of security for health data, but we're really not calling on congressional action at this time. We still think that that may be premature until there's a better understanding of the entire big data ecosystem and the complications that could arise from a call for end-to-end security legislation.

And then the solutions that we did come to recommend, back to voluntary codes; we see these as critically important, especially as enforceable by the FTC that they should include robust security safeguards that the entities themselves are saying that they should comply with. And we think that that self-governance can be very powerful. Call on public and private sectors to educate stakeholders about

cybersecurity risks and to recommend precautions. Call on policymakers to provide incentives for entities to use privacy enhancing technologies and architectures; for instance, secure data enclaves, secure distributed data systems. The idea that you could have distributed architecture with interface without having data move, but still have accessible and usable.

The next slide and the final slide; and then re- endorse our prior recommendations from the Tiger Team that Deven led, security policy for entities collecting, storing and sharing electronic health information needs to be responsive to innovation and changes in the marketplace. Security policy needs to be flexible and scalable. Providers need education guides on how to comply with security policy requirements, the HIPPA security policy requirements. HHS have a consistent dynamic process for updating security policies and rapid dissemination of new rules and guidance. And then a call on NIST to update the NIST 800-66 Revision 1 to include a description of technology to help meet the requirements.

And so that's the conclusion of our formal recommendations we'd like you to consider and give us some feedback on the ideas, that we would then come back the next time in July or in August as determined, and provide with a final set of recommendations. So with that, I think we're open for discussion

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

Thank you, Stan. Really a yeoman's job; this is very challenging, it always is, area and the summary of the issues is really comprehensive and cogent and your group's recommendations, I thought were spot on. I have a few comments, maybe some wording.

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

Good.

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

Some of the things apply to, alluded to some of the statements that were phrased as questions in our recommendations that we just presented and I wonder if in your next round, you could present some of your things instead of "call on" and "consider," we've gotten some feedback from HHS that sometimes it's hard to deal with all of these "considers." So, what do you do, you consider for 10 seconds and move on...

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

Right.

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

...or make a statement where the workgroup can say, OCR should be a steward and do the following things.

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

Okay.

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

A question I have against when you said recommend to get, this is on slide 14, having to do with re-identification and you talked about recommend against specifically asking Congress to address it, even though they're the only ones that can do this. One of the thoughts I've always contemplated is, as you pointed out, there's a lot of expense in preparing these things and de-identifying and doing a lot of things in order to prevent somebody from accessing when really what I think we...an alternative approach is go punish the bad guys.

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

Right.

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

In other words, when people misuse data for discrimination or something, then have the law be able to enf...you know, penalize folks who do bad things with it. As you pointed out in your first discussion, it's really hard, big data has made it sort of impossible...it's expanded the ways you can discriminate...

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

Right.

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

...you share certain things, but now you can sha...because of big data methods, you can derive ways to discriminate and that's the thing that we want to chase after. So what caused the group to recommend not having penalties for doing bad things versus having all of these barriers in not sharing? And I have a couple more, maybe I'll tee up. Umm...

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

Okay, go ahead, I'll wait then.

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

Ah, let's see; yeah, a lot of these "call ons" and that kind of thing I think...but maybe that's my biggest question there.

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

Okay, it's a great, that's a great question; it's exactly what we debated in our conversations. There was, you know initially, honestly we came to a recommendation that said yes, we should call on Congress to recommend legislation to prevent re-identification, unauthorized re-identification. And then the concerns were brought up that I think are valid, that what type of disincentive might that apply? If done incorrectly, where liability for re-identification lies with the entity that did the de-identification and in order to do the data sharing how far does the liability extend? And can we define what the limits of that

liability are such that it would, one, address the risk re-identification appropriately, but still incent companies to use de-identification and exchange the data.

And ultimately we just kind of came, I think, to the conclusion that we may not know enough yet to make that recommendation, because we fear bad legislation almost as much as no legislation, or perhaps in this instance, more than no legislation. And so the idea that if we could somehow build it into the self-governance codes, could that become an enforceable mechanism to prevent re-identification. But we're certainly open to further conversation if you'd like us to discuss this more deeply.

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

I think, I mean, you may have taken this particular aspect to its conclusion as far as holding people accountable for re-identifi...that act of re-identification is...are there other ways to have laws that target bad behavior rather than processes that...essentially right now we're limi...we have processes that limit access and that causes a lot of barriers to access for the appropriate reasons and it creates a lot of cost. Is...should we...and then you get into unintended consequences as you prescribe more and more processes.

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

Right.

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

Is there more thought on how to target the bad outcomes, bad behavioral outcomes so that you can loosen up prescriptive process regulations? It's just sort of a philosophy and I wonder if you could talk more about that, not just in the context of re-identification.

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

We did not talk about that specifically about how to differentiate between potentially targeting bad behavior versus a negligent control on de-identified data, for instance. And so we did not get into specific conversation about targeting bad behavior.

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

Okay, just food for thought.

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

Hey Paul, this is Lucia; if...I had my hand up. Just to weigh in on that, I think the other thing to recognize, and Stan did a great job of describing both the fulsomeness and complexity or the workgroup of identifying a consensus set of harms. But you have to know what the harms are that you want to prohibit or punish and those two things kind of go together.

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

Ah, correct.

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

Yeah, I agree Lucia and thank you so much for pointing that out. There is, I mean, I think there is potentially a separate, you know even to some extent just as de-identification doesn't necessarily consider harm in the...for the environment where the it's...where the de-identified data's going to be located, which is one of the recommendations we've come back with. Similarly, re-identification in and of itself is that bad, even if we can't identify a harm that it's associated with. And so we did talk a little bit about that and I think it was worth the...I'm glad you mentioned it.

But just the act of re-identification itself, in a lot of the data use agreements, for instance, there's a prohibition on the re-identification of data and with limited data sets for research. And so companies that sign that are now contractually obligated not to attempt to re-identify. But beyond that contractual enforcement, there's nothing else that exists that would say that they can't do it. And so that was kind of what we were trying to focus on was should we make the simple act of re-identification impermissible versus re-identification that leads to harm? And I think those are both relevant considerations.

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

I think you're right. I'll make one more statement on this topic and then go to the next hand. And I didn't want to focus just on re-identification, I think it's more with your first points you raised in terms of use of this tech...use of the access to big data sets and the methods have made the ability to do harm, and let's say, let me give you an example. Discrimination; so you can imagine that, I'm just giving an example, not with a specific and right, whether it's housing discrimination or employment discrimination you can easily imagine that there are ways to discriminate using nontraditional data, i.e. the data that's proscribed as far as you can't discriminate on race, color, creed.

But there are lots of other ways to discriminate in housing or employment, for example, or education, selection processes that could take advantage of the large data sets. Those are harms that'll be hard to...so that's the kind of behavior that I was thinking when I said bad out...behavioral outcomes is to use data unfairly in discriminating when we have equal protection for let's say housing and employment.

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

Yeah, well...

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

So that's the kind of thing, but I think you did a really great job in elucidating the kinds of things that are now possible and maybe thinking broadly on the recommendations of how could we deal with this?

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

Okay. Good.

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

So, anyway, thank you; really appreciate it. And I think Anjum was next. No actually Kathy.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Thanks Paul. And I have to say, this is a daunting task that the workgroup has taken on. A couple of thoughts about it, and one area that I'd like to see there be further work on has to do with the movement of data back and forth as the electronic health record becomes really a mix of information. And I'm thinking particular about patient entered data.

There...at a meeting yesterday at NQF, there was a strong plea on the part of patients and consumers to be able to have data that they basically have their own data entered into their medical records, and yet at the same time I think we all have to acknowledge that without proper vetting of those entry vehicles, we may be opening up systems to a higher level of security risk than we even understand.

With regards to the comment that was made with respect to calling upon Congress, I'd certainly understand the reluctance to do that in an area that is so fluid, but at the same time, there's clearly a priority that's been placed on promotion of interoperability. And so I think that as Congress addresses the issues of interoperability, this committee addresses it, the department does; I do think that some of areas will need to be incorporated into what you might call a blended approach.

And lastly, I do think that the notion of, is it the data itself or is it the use of the data that should be the basis for what we might call liability? And I lean strongly in saying it's the usage of the data and it's something where certainly in the PCAST report, I was persuaded that really having these bastions of data security, they will always be subject to breaches. We've seen breach after breach after breach, even when best efforts are made and so I think it's the usage that might be the better lever in terms of penalties.

And then just lastly on the same theme, I would like to insert the words about proportionate liability. And certainly with medical professional liability there is the concept of different levels of responsibility for the bad outcome that happens at the end of a chain of events. And certainly the party that has exerted best efforts to try and maintain security and yet the data is breached or the data repository is breached, and then it's used for bad reasons; it should be the user, the bad user that should be penalized, perhaps more or perhaps even exclusively. So I'll stop there, but thank you again for a terrific report.

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

These are if I could comment; these are really insightful comments because it does go to a lot of the conversations we also had within the workgroup. In particular we had a lot of conversations about consumer generated data and the idea that health data is growing exponentially outside of the traditional healthcare system and patients, as we've heard in several settings, really do want to have their data considered and see it as a viable data. So it's an interesting comment that maybe you also have that observation.

I'm not sure where or if that forms a part of any of the recommendations that we've made. It certainly is the beneficial use concept that we need to keep in mind and we'll look at the report to see whether we need to improve that a little bit. And then that kind of goes with the calling on Congress; we'll try to come back and make our recommendations more specific on what we're asking for.

And the last comment I would have on your comments there Kathy is, I think we did have a consensus that the use of data is in fact the issue. This kind of goes back to Lucia's point she just made that we really feel like we need to understand harm much better before we get to a place where we can talk about appropriate use of data. And if we understand that harm and were able to then identify it in a way that's actionable if you will, then that could lead us to come with a better framework around appropriate use of data and not rely, and this did come up quite a bit, not rely only on consent.

We saw consent as also being problematic, especially in the circumstance where the individual who's being asked to consent often can't understand or doesn't understand the scope of what that consent would mean. And so it's sometimes an easy way for inappropriate uses to take place is to get a very broad consent that someone can't understand. And so all these issues are tied together and if we understand harm, that could create the...use and then we have some defaults that we can fall back on to say, this is appropriate and this isn't and then action can be taken on the bad actors.

And to some extent, we've laid a lot at the feet of self-governance and admittedly. But we also see the likelihood of Congress acting in this space quickly enough, we think quickly enough, we don't see likely and so we would rather see some self-governance from industry and others stepping up to do what we know they can and defining what they would hold themselves accountable to and then declaring it publicly to allow the FTC to be an enforcement body and see the agencies here being involved in kind of constructing those frameworks that could include appropriate use of data, clear harm and accountability. So that's kind of our thinking and we certainly agree with all of your comments.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Thank you.

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

Any other comments or questions? I want to thank you again Stan and the workgroup, excellent presentation and excellent deliberation on a lot of these issues and it's clear that the group spent time trying to tease out the issues and weighing potential options. So thank you so much for that.

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

Thank you, appreciate it.

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

And Lucia, you have another comment?

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

Yeah I just have a logistical comment that I want the Policy Committee to be aware of. So our plan is to present a final draft for your approval for your July 14 meeting. And obviously provide you with as much time as possible as we can for your review this...a document that will be narrative but based on the content you've seen today in the slides. And Stan, I don't know if you or Michelle wants to weigh in any further about the process, but I just wanted to alert the committee members that in fact the next time

you hear about this it will be literally a narrative document in the form of a proposed transmittal letter. So people should pay attention to that content when it comes across their e-mail transoms.

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

Thank you, that's a good heads up. Kathy?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Yes, given that this might be our last or next-to-last bite of the apple, I think it might be worthwhile for the committee to reference some of the ongoing...the fact that there are some ongoing private initiatives through Healthways and other groups to be able to set up what you might call trust authorities. And so there may be a need or a benefit to mentioning some of those efforts at self-governance.

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

Kathy, this is Lucia; that's a really good catch. If I could propose that Stan or I follow-up with you offline to get a little bit more detail about what you're thinking and we'll come up with something appropriate for the next draft.

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

That would be fantastic.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

That would be great, thank you.

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

Did you already have a call with a workgroup to review some of this feedback?

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

Michelle, I do believe we have one more workgroup call, correct?

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

We do.

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

Yes.

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

I was just thinking of the timeline because if you're going to be delivering quite a bit of prose, which I think you will, we need to give the committee enough time to get through that, so we need time for your workgroup to work on some of these comments.

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

Yeah, we have a few logistical things that we'll have to work through because the meeting is the day before the committee meeting.

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

Okay.

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

So, we'll touch base offline. Thank you, Paul.

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

Okay. Yes, thanks. All right, any other final comments on this or any other thing else you heard about today before we open up to public comment? Well you can see that there's a lot of good work going on and tackling a lot of healthy, challenging and sometimes controversial topics, all of which are needed. I mean, if we don't address some of the policy issues, it can come back either to impede or bite us in the future. So, it's really important work and really appreciate the workgroup chairs and workgroup members in spending part of the summer on this. Okay, why don't we open to public comment, please?

Lonnie Moore – Meetings Coordinator – Altarum Institute

If you're listening via your computer speakers, you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

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 July 14 and it also is a virtual meeting. We're probably going to make it a much shorter meeting, probably about two and a half hours, so just look for that update to come soon. And we do have a public comment from Shelly Spiro. Shelly, as a reminder public comment is limited to 3 minutes.

Shelly Spiro – Executive Director - Pharmacy Health Information Technology Collaborative

Thank you, Michelle. My name is Shelly Spiro; I'm the Executive Director of the Pharmacy HIT Collaborative representing over 250,000 members of the majority national pharmacy associations including pharmacy education and accreditation. Our members include key pharmacy organizations involved in health IT including ANSI accredited SDO, NCPDP and 8 associate members representing e-Prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacy services.

The Pharmacy HIT Collaboratives vision and mission are to ensure national healthcare systems is supported by the meaningful use of health IT, integration of pharmacists for provision of quality patient care and to advocate and educate key stakeholders, such as yourselves, regarding the meaningful use of health IT and the inclusion of pharmacists within technology-enabled integrated healthcare systems. The Collaboratives goals are to ensure health IT supports pharmacists in healthcare services delivery, achieve pharmacist integration with health information exchanges and to support national quality initiatives enabled by health IT.

A major focus of the Pharmacy HIT Collaborative is to assure pharmacists in all practice settings, community, health system, hospital, managed-care even long-term and post-acute care are integrated in the national HIT infrastructure. In reference to the Advanced Health Models and Meaningful Use workgroup presentation, pharmacists play a critical role in facilitating effective use of health IT to support outcomes-focused advanced models for healthcare delivery and value -based payment.

Pharmacies are growing as primary care locations, especially related to wellness; and pharmacists provide essential medication related care management to our nation’s patients. The Pharmacy HIT Collaborative is requesting pharmacists and pharmacy perspectives be included in the health IT Policy Committee’s recommendation to ONC as part of the continuum of care and any future discussion related to this topic. Thank you.

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

Thanks, Shelly. And we have no more public comment.

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

Good, thank you. And thank you everyone for participating in this meeting and we will see you in just a couple of weeks and take care.

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

Thanks, Paul. Thank you everyone.

Meeting Attendance								
Name	06/30/15	05/22/15	05/12/15	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15
Alicia Staley					X			
Anjum Khurshid	X	X	X	X	X	X	X	X
Aury Nagy								
Brent Snyder	X	X	X					
Chesley Richards				X	X			X
Christoph U. Lehmann			X	X	X			X
David Kotz	X			X	X	X	X	X
David Lansky	X	X	X	X	X	X	X	X
Devin Mann					X	X	X	X

Donna Cryer	X	X	X					
Gayle B. Harrell		X	X	X	X	X	X	X
Karen DeSalvo	X	X	X		X	X	X	X
Kathleen Blake	X	X	X					
Kim Schofield	X	X		X		X	X	X
Madhulika Agarwal	X			X				
Neal Patterson			X	X		X	X	
Patrick Conway								
Paul Egerman		X	X	X	X	X	X	X
Paul Tang	X	X	X	X	X	X	X	X
Scott Gottlieb		X		X		X	X	
Thomas W. Greig	X			X	X			X
Troy Seagondollar	X	X	X	X	X	X	X	X
Total Attendees	12	13	14	16	17	17	17	17