HIT Policy Committee
Final Transcript
August 11, 2015

Presentation

Operator
All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Lead – Office of the National Coordinator for Health Information Technology
Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. This is a public call and there will be time for public comment at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Also as a reminder after roll call if you are not the person speaking if you could please mute your line that would be appreciated. I'll now take roll. Karen DeSalvo?

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

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

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

Paul Tang, MD, MS – Vice President, Chief Innovation & 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
Here.

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

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
Aury Nagy? Brent Snyder?

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

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

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

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Chris Lehmann? I believe he was going to be running a little late. 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? Donna Cryer?

Donna R. Cryer, JD – Principal – CryerHealth, LLC
Present.

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

Donna R. Cryer, JD – Principal – CryerHealth, LLC
Hello.

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

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Gayle's here.

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

Kathleen Blake, MD, MPH – Vice President – AMA-Convened 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? Terry Cullen? Neal Patterson? Patrick Conway? Paul Egerman? Scott Gottlieb? Thomas Greig? 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
Hi, Troy. Okay, with that I'll turn it over to you Karen or Paul.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services
Thank you Michelle. Good morning everybody and happy August. I hope everyone has been having a nice summer. We've been incredibly busy at HHS and ONC. We have a busy fall ahead and so we've been spending this summer making sure that we're getting ready for all of that.

We are, as you will all remember, still working on finalizing the Federal Health IT Strategic Plan that you all gave us great input about which sets a broader framework for work for the next several years about how we make sure we get to the kind of return on investment for electronic health information that everybody is expecting consumers, doctors, providers and all the other key stakeholders.

We've also been working on finalizing one of the key priority areas to go deeper in that strategic plan around data access and interoperability and so we'll be learning a little bit about that work today and what we're thinking in terms of evaluation but I just want to remind everybody that we have those two big plans coming out in the fall one is the bigger strategic frame and then the roadmap about how we're going to within that strategic frame address that top priority of seeing that electronic health information is available for everybody for all the many use cases that are so important to the stakeholders in the ecosystem.

So, just want thank again this committee for your service, input and guidance and I'm really looking forward to some of these conversations today because they are going to help us frame particularly some of the short-term challenges that we're trying to address to make sure we have the right regulatory balance, the right opportunities for market innovation and the kind of secure but available data that everybody needs to do the important work that they want to get done and be the kinds of engaged consumers they want to be. So, with that I will turn it over to you Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thanks Karen and welcome everybody especially during the summer months. We appreciate you being on the call. We do have a very informative day or morning plan for you or I guess it is afternoon no it is still morning on your side. It begins with the data updates from ONC and there are some actually very interesting and encouraging data about interoperability that Vaishali is going to present.

Then we're going to go onto hear the final presentation from the Privacy and Security Workgroup on big data recommendations, it's really superb report that they've put together, very informative and well thought out and some great recommendations for us to approve.

Following that we're going to have an update on the Safety Program, Andrew Gettinger from ONC, and a look at the roadmap for working towards an HIT Safety Center.

And then conclude the morning with review from the Quality Measure Task Force and there are some CMS proposed…and looking at those kinds of measures, the new kind that CMS is proposing. So, that will be interesting as well. So, very informative morning, early afternoon and some great work to review and approve and with that I'll entertain a motion to approve the minutes that were distributed earlier, please.

M
Move it.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you and second?

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you and any other additions or discussions to bring up about the minutes? Okay, all in favor please say "aye."

Multiple
Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And any opposed or abstained? All right.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
David Kotz abstains I wasn't there last month.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
All right thanks David. Okay we're going to begin with Vaishali Patel from ONC giving us a data update about interoperability.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Great, thank you. If we could move to the…I guess the second slide of this presentation, great, thanks. So, first I'll be describing the current landscape of interoperable exchange across nonfederal acute care hospitals. These represent findings from a nationally representative survey of hospitals that were conducted with the American Hospital Association in the later part of a 2014. And today's presentation is drawn from three different ONC data briefs from the survey and the latest of which we're hoping will be posted later this week. So keep your eyes out for that.

And then following the traditional serve data update I'll be briefly introducing the draft interoperability measurement framework which we plan to use to assess progress related to interoperability on a national level across a variety of settings and populations. Next slide, please.

So, just to start off nearly all hospitals have the infrastructure to enable exchange, adoption of EHRs by nonfederal acute care hospitals is nearly universal. Close to 97% of hospitals have a certified EHR as you can see and this is drawn from the American Hospital Association survey that I mentioned. Next slide, please.

Additionally, exchange with outside ambulatory care providers and hospitals has been increasing significantly over time with about three quarters of hospitals reporting they electronically exchange laboratory results, radiology reports, clinical care summaries or medication lists with ambulatory care providers or hospitals outside of their organization. And this growth has been significantly growing as you can see since 2011. Next slide, please.

But when we begin to examine electronic exchange of health information in a more refined manner by examining the specific types of exchange activity hospitals are engaged in we find a bit more variability exists. The majority of hospitals, about three quarters of hospitals, are sending summary of care records electronically and about half receive summary of care records electronically. However, the ability of hospitals to use or integrate summary of care records into their EHRs without manual entry lags behind with about 4 in 10 hospitals able to do that.

Nearly half of hospitals, about 48%, report that their providers engage in electronically finding or querying their patient's health information from sources outside their organization or hospital system and overall approximately 1/4 of hospitals reported they conducted all of these four types of activities so finding, sending, receiving and using electronic information to and from sources outside of their hospital system. Next slide, please.

And overall in 2014, 41% of nonfederal acute care hospitals nationwide reported having necessary clinical information available electronically from outside providers or sources when treating a patient that was seen by another provider or setting.

So when we take a look at, you know, what the near-term impact of the movement of information is, you know, about 4 in 10 hospitals have data from outside sources at the point of care. However, hospitals that engaged in greater interoperable exchange activity, so hospitals that were engaged in finding, sending, receiving, using, were significantly more likely to have information electronically available from outside sources at the point of care.

So, for example if you look at the bar on the most right-hand side 1/4 of hospitals that did all four of those activities sending, finding, receiving and using were nine times more likely to report they had information available at the point of care from outside sources compared to those who did none of those activities.

And one can also see that as hospitals are engaged with more and more of those activities, you know, whether that's 1, 2, 3 and then ultimately all 4, the information that's available to them from outside sources at the point of care significantly increases with each additional activity. Next slide please.

We examined a number of technical, operational and financial barriers to interoperability as part of this survey and we found that lack of exchange partners with the capability to electronically exchange, to receive information rather, whether that was because they lacked a system or because their system lacked the capability to receive the information was a top barrier to interoperability reported by about 6 in 10 hospitals respectively.

Other common technical barriers related to provider directories and patient matching which are areas that are the focus of the roadmap. Most common operational barriers really related to usability, about 3 in 10 hospitals reported cumbersome workflows to send information from their EHR system and similar numbers, a little bit over 1/4, reported that the recipients of their summary of care records didn't consider the information as useful. And about 1/4 of hospitals reported that the additional cost associated with exchange was a barrier to interoperability. Next slide please.

So in summary, exchange activity among hospitals has been increasing over time. However, further progress is needed, you know, although most hospitals possess certified EHR technology almost universally and are exchanging key clinical information with outside providers including ambulatory care providers and hospital systems as we examine exchange activity in further detail in a more refined manner we can see that hospital rates of conducting different types of interoperable exchange do vary.

While a majority of hospitals send and receive summary of care records electronically the rates of integrating these data within their EHRs lags a bit behind. One quarter of hospitals conduct all four types of interoperable exchange activity and about half, close to 45%, conduct three out of the four types that we mentioned and can be sending, receiving, finding and using.

And hospitals that are conducting more interoperable exchange activity have significantly higher rates of information electronically available at the point of care from outside sources and settings. So on average about 4 in 10 hospitals report that they have information from outside sources or providers electronically available at the point of care.

And hospitals that are engaging in all four of those activities have…only close to 90% of those hospitals have information electronically available from outside sources at the point of care. So there's great benefit that we can see from the survey from engaging in those activities.

However, there are a number of barriers to interoperability that were reported by hospitals that relate to technical issues and to a lesser extent operational and financial issues and the top barrier reported by hospitals relates to the limited capability of their exchange partners to receive information that they might be able to send electronically. Next slide, please.

So, I'm going to move onto talking about the draft interoperability measurement framework. So, I'd like to take a step back for a moment and share with you how we selected some of the measures that we reported on just now across hospital settings and also more broadly share some key aspects of interoperability that we think are important to measure across populations and settings.

This particular slide shows and infographic that describes the interoperability roadmap as a journey to achieve better health and care with the ultimate objective of supporting a learning health system. And, you know, as we go along this journey measuring progress it's critical to understanding where we are today and the extent to which we're achieving our goals.

And as you can see along this journey, along the road, you know, we've identified some key milestones along the way. So at the three-year horizon being able to send, receive, find and use critical information along the care continuum and by individuals is critical so that's one key milestone that we want to achieve and that's how we are focusing our measurement around these key goals.

And then, you know, within the six-year horizon the goals focus on assessing the impact of that, you know, in terms of improving healthcare quality and cost and also expanding our focus beyond the health care continuum to non-healthcare settings and then the 10-year horizon, as I mentioned, is focused on supporting the learning health system.

And also along the way there are roadblocks that we're sure to encounter and so measuring and trying to understand what those roadblocks are is also important in trying to refine the roadmap and understand why if we're not meeting our goas why we're not meeting our goals and trying to address those barriers and gaps along the way. Next slide, please.

So in thinking through that journey and translating that to specific concepts that we need to measure, we developed a preliminary framework to identify some key concepts that we want to measure our progress over time, over the 10 year horizon, and we've split this into a near-term framework which focuses on the 2015 to 2017 timeframe associated with the roadmap and then the long-term which looks at beyond 2017. And I'll be describing the near-term and the long-term in a little bit more detail. Next slide, please.

So the near-term measurement framework, the 2015 to 2017 horizon, focuses on evaluating our progress toward achieving the three year goal of the roadmap so enabling providers along the care continuum and individuals to send, receive, find and use information across systems, organizations and geographic boundaries.

You know we also think that it's important to measure, as I mentioned earlier, barriers to interoperability so we can identify and address those so that is another key area of measurement that we want to be able to do. And during the three-year horizon measuring the near-term impact of interoperability that we think are important really relate to increasing the availability of information at the point of care. Again, so those measures…the measure that I had pointed out during the hospital update that is one of our key measures. And also, measuring the usage of that information so not just assessing whether that information is available at the point of care, but ultimately whether it is used to inform decision-making will be critical as well.

And then, you know, from the consumer perspective ensuring that all of this increased availability of information and the usage of that information to inform decision-making reduces gaps in information exchange experienced by individuals is another key near-term impact that we want to be able to measure.

And on the left-hand most side the strategies to enable interoperability we'll want to be able to assess how the drivers, market forces, policies, the infrastructure all are enabling the capability of providers and individuals to send, receive, find, use information across the care continuum. Next slide, please.

So the longer-term framework again is in sync with our longer-term goals of the roadmap which call for expanding measurement across the care continuum so expanding that to include public health, to include non-healthcare settings such as schools, social services and ultimately, you know, thinking about entities that are going to be enabling a learning health system such as research consortiums. So we need to expand our measurements to reflect our longer-term goals.

And then we also want to reflect our measurement to meet, you know, our longer-term objectives in terms of measuring beyond those near-term impacts to assessing the impacts on processes that are enabled by interoperability as well as outcomes that are sensitive to interoperability.

And a key aspect of the long-term measurement framework will really be to flesh out and identify key processes that are enabled by interoperability across that are specific to the populations and settings of interest and also to identify outcomes that are sensitive to interoperability that we can track over time and that's something that we are going to be working on over the course of the next couple of years is really to flesh this measurement framework out to be able to report on this for the long-term. Next slide, please.

So in summary, the near-term interoperability measurement framework, which is the 2015 to 2017 timeframe, focuses on measuring the movement of health information across the care continuum and individuals, assessing barriers impeding interoperability so we can identify and address them and also assessing the near-term impacts on increasing the availability of information and subsequent usage of that information.
And then the scope of the long-term measurement framework so beyond 2017 really expands and builds on the near-term to reflect the goals of the roadmap to include settings beyond healthcare and also to assess the impacts on key processes and outcomes that are sensitive to interoperability that we can track over time. Next slide, please.

So in terms of next steps, we plan to report on baseline levels of interoperability and exchange for the near-term. Similar to what we did today in the hospital settings for physicians and consumers. So we are hoping to be able to share those with you in the upcoming months.

And then we also plan to share updates to this draft measurement framework as the roadmap is published later this year and as we further refine the measurement framework and the key concepts that we wish to report on to assess progress related to interoperability.

So, I'll stop there and if there are any questions I'd be happy to take them. And there are also some additional data slides in the appendix that are for your information as well. And as I mentioned earlier, if you want further information on the methodology or the graphics and data that I presented today these are all available in data briefs that are posted on the ONC's dashboard. And we're hoping that the interoperability data that I presented today will be available later this week. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you Vaishali very interesting update and I have a couple of questions. One is you talked about 97% having the infrastructure for interoperability but 59% have a problem with an exchange partner, lacking EHRs or other systems to receive data maybe that's the definition of receiving data.

And the second question I had is your draft interoperability measurement you reported some from the, AHA data. Is that the kind of data you're thinking about, i.e. it's a survey data to assess interoperability?

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Sure both are really good questions. So the first question with regards to the gap between those reporting that they are exchanging with, you know, the 59% who report that, you know, or close to 6 to 10 who report, you know, either their exchange partners lack systems or lack the ability to receive data. If we think about…yes for hospitals the infrastructure is nearly universal but that's not the case for all providers along the care continuum.

In the appendix slides you can see that there is a graphic, you know, from the AHA survey where we talk…where we report on exchange with providers, behavioral healthcare providers and long-term care providers as an example and rates of sending and receiving data between those providers is considerably less than ambulatory care providers and other hospitals which points to the fact that not all exchange partners at hospitals have EHRs or have the capability to electronically exchange information and so that may be, you know, one source of where that gap comes from, you know, when they are trying to exchange data with behavioral health care providers, long-term care providers and other providers that, you know, don't have electronic health records or other means of electronically exchanging information. So I think that that addresses the first part of what you are asking about.

And then for the second part, with regards to the near-term, so at this current juncture we are primarily limited to national survey data as well as data from the EHR Incentive Program data so participants of the EHR Incentive Program but we are in the process and, you know, trying to identify additional data sources that would allow us to not rely on survey data and self-reported data and also be based more on transactional type of data. But that's part of the process of fleshing out this measurement framework is not only refining the measures and identifying the specific measures but also identifying national level data sources that would allow us to report on interoperability.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
All right thank you. Let's see anybody else, I don't have my…okay, Troy?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Yes, Sir, thank you, Paul. Thank you for this I'm really excited to hear that there is a deep exploration on the interoperability aspect of it because it is going to be vitally important in the long run.

One of the things I wanted to ask you about on slide seven you talked about the difference between, you know, the exchange of data internally and what I was curious about, we explored this some time ago in a number of different venues, but we looked at the question really comes down to are they able to exchange data within the same network, that is to say they're on the same EHR platform, you know, it's an EPIC to EPIC exchange or it's Cerner to Cerner exchange or are they outside of that particular network? So, they're doing a Cerner to EPIC or an EPIC to Cerner. Was there exploration into the different aspects from different vendors back and forth and was that part of the study?

And then the other question I have is the summary of care. There's a lot of different formats that you can send a summary of care and still meet the Meaningful Use criteria. So, was there any exploration into what exact format that was? Was it an electronic PDF embedded into a secure e-mail or was it put onto some other form of electronic media like a disc or even a flash drive? Did you get that deep into the weeds or thing still out there in the future to come?

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Okay, great, I'll take the second question first and then I'm going to need to clarify, because I didn't hear the first part of the first question, but for the second question, we didn't dig into say the variation on, you know, say the different formats of the summary of care record but we do have additional information, we did ask some follow-up questions as to how they were exchanging a summary of care record so whether that was via secure messaging or, you know, some other mechanism and we do plan

to report out on that information and so there is a little bit more information on the how but not to the level, the granular level that I think you are you are referring to.

And we did specifically ask about, you know, excluding eFAX as part of it. So, you know, this is something to keep in mind that we were focused on with regards to the methods of exchange. We were…electronic methods of exchange we defined eFAX as not electronic, but hopefully that will be coming out soon as well, data related to that.

So, with regards to your first question where you referring to slide number seven which was the barriers slide or I think I missed the slide number you were referring to.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
It was slide seven as noted in the right lower hand corner.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Okay.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Now, whether it's slide seven on your deck I'm not sure. But, really the question is this, I mean, you know, if you're on the same…if you're using the same vendor what was the difference between being able to exchange from hospital to hospital if they're using the same vendor, right, versus a hospital to hospital exchange if they're on different vendors? So, I'd be really curious to see which vendors are actually pushing the envelope in interoperability and creating that, you know, bridging that gap.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Right, so for this analysis we didn't focus on cross vendor exchange and that's something that we could look into although probably not in as a refined manner like as what we reported out on here. We have information that could report out on the capability of hospitals to be able to send data to an EHR that's different, has a different vendor from their own but we wouldn't have a way for us to compare that with rates of exchange, you know, within the same system. We didn't have a question around that.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Okay, that's fair…okay.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Yes.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
So, really the question wasn't asked? Okay, thank you.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
No.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you. Next is Gayle please.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thanks so much Paul and I have several questions along the same line and I'm hoping that perhaps in the next survey that's done you can approach it at a more granular level and really ask those very specific technical questions as to what are the barriers. This is pretty general. I think it's we are looking down the road where many years into this and spent a whole lot of money when I only see 23% of hospitals able to really do all the essential elements that are necessary for true interoperability I get a little nervous about all the money we spent and we're not getting the bang for the buck that we really anticipated. So I'm hoping we can define this even further so that we really know what those technical barriers are and that we can address those as we move forward either through Meaningful Use or certification.

But I have a question on a different subject that I'd like her to please address and that is really in looking at the behavioral health and if we're going to go down the whole long-term, the whole continuum of care and addressing long-term care and behavioral health we really…were there providers in the survey in those arenas you've talked about them, and what percentage of those providers did you find really had electronic health records that were interoperable with hospital records.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
So, this survey focuses on, you know, from the hospital perspective their rates of sending or receiving data with different types of providers including long-term care providers and behavioral healthcare providers.

There are…as far as, you know, we've explored, you know, the…trying to report out on exchange capabilities of long-term care and behavioral healthcare providers and there are some national level data sources on a portion of the long-term care providers however it doesn't represent, you know, all types of long-term care providers.

So there's not…as of right now there are not really great data sources that are nationally representative for reporting out on the exchange capabilities and, you know, the extent to which they've adopted EHRs that are interoperable as far as, you know, we're aware, you know, for long-term care providers and behavioral healthcare providers.

However we are, you know, trying to collaborate with our federal partners and CMS. We are actively, you know, having conversations with SAMHSA who is in the process of doing an assessment of their grantees regarding Health IT readiness and exchange capabilities.

So these are gaps that we have identified and what we're actively trying to identify data sources to address those gaps in partnership with our federal partners.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
And may I ask one more question Paul if I could be so bold?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Yeah, try to make it quick because we're over time already. So, we have…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Okay, on the outside ambulatory providers did I hear that you're going to do a further survey of them and I would really ask that we when you do that that you get very specific on the barriers so that we can have some very detailed information on that.

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
So, we do an annual survey of office-based physicians and we have included questions related to barriers. Something to keep in mind though with regard to respondents of these surveys with the hospital survey we have hospital CIOs who answer the survey so one can ask some more technical questions.

But with regard to the physician survey, you know, we have asked and will continue to ask about barriers but you can't get too technical because not all physicians are able to respond to some of the more technical types of barriers. So, that's just anyway something to keep in mind and to your point, yes, we have asked about barriers and will continue to do so with regard to our physicians and hospitals.

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay thank you. We're over time so we have three people in the queue if you could limit your question to one please. Anjum is next.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute
Thank you and thank you for the presentation, very interesting data. My question is related to…so looking at slide six as you compared these different hospitals in terms of their interoperability capabilities and exchange is there a plan to dig further into this and compare them also in terms of not just process measures but some either quality metrics or patient outcomes because that would be a very important, I think, argument for interoperability and exchange?

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Yes, as I mentioned as part of our long-term measurement we are planning to assess the impacts on outcomes that are sensitive to interoperability, however, that doesn't preclude us from beginning to examine that now. And we do have analyses underway that are looking at outcomes of hospitals that are engaging in exchange but these are, you know, research type studies that we are conducting as well.

So to your point I think in the long term on a national level we are planning to measure and assess impacts on outcomes sensitive to interoperability. So, our…for example our hospitals that are sending, receiving, finding, using achieving better outcomes compared to those who are not and we also have analyses that are underway right now that will allow us to begin reporting out on that, but in terms of a regular measurement and broader strategy that would be more for the longer-term horizon.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute
Okay, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you. David Lansky? David Lansky, please?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
Thanks, Paul. Just one thought with an extra comment. I think the overall approach…it's very interesting, we've made a lot of progress and we should be appreciative of that.

I'm a little concerned that the framing of this is very EHR centric and I think our responsibility at a Policy Committee level is broader and when I think about interoperability and the flow of Rx data, lab data, claims data as populating a broader view of personal health we should be reflecting that in the way we developed the interoperability metrics that we're using.

And to the last point, I want to concur with that. I'm a little concerned that the slides that depict the measurement strategy going forward don't really accommodate the use of interoperable data to construct a longitudinal health record that can be used to measure outcomes, measure performance, look at total cost of care, look at value.

In the era of new bundled payment arrangements from CMS obviously constructing a longitudinal record and evaluating performance is very important. So, I hope the measurement framework will be faster, more accelerated in the ability to construct that record using multiple data sources. Thanks.

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

Vaishali Patel, MPH, PhD – Senior Advisor, Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Thanks.

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

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, this is Kathy Blake just a couple of comments. The first has to do with the survey's asking practicing physicians about their experiences and about the capabilities of their systems and I think this is a good opportunity to actually enlist the practice managers some of whom may have IT directors within their organizations because I think that the boots on the ground practice physician will not be able to give you the kind of information you're looking for.

And then secondly, I'm looking at the appendix slides and slide 19, and just would make a request that when we focus for future survey's where we're going to direct our attention, I think it's best directed at the…in one instance for sending it's 77% that are still relying upon what we might call mixed methods of transmittal and when we look at the receiving 67% are relying on mixed methods to receive and what that says to me is that they do have the electronic capability that in some instances they are successfully sending and in some instances successfully receiving.

So this is a group from which we might be able to tease out some of the other factors that they could tell us about of why in particular instances they are not able to use electronic means of communication whereas in others they are able to do so. Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Good point, thank you. And thanks again Vaishali, very interesting data and certainly stimulated a lot of comments and questions and a lot directed at future measures really as you assess our success of interoperability and trying to get beyond the survey and into a use of all of the potential recipients, potential recipients of that data. Thanks again and look forward to hearing future reports.

Okay, next up is Stan Crosley talking about the Workgroup's final recommendations on big data and privacy. Stan?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
Yes, thanks very much I really appreciate it and thanks so much to the committee and our workgroup has been diligently working through the summer coming up with these recommendations and they've done some great work as has ONC staff to support us and we really appreciate that. And also I would be remiss if I didn't say that Deven McGraw as the Chair of the Committee really was the architect of much of our discussions and the framework that we utilized so again my appreciation to Deven.

So, that brings us to today and we have a very simple slide deck and you can just see it, it says review the recommendations on health big data. And so what we wanted to do is really kind of take you through the paper itself with the recommendations.

As we go to the next slide though, part of that we wanted just to remind you where we've been and what the process has been through the last nine months beginning with public hearings on health big data topics and including multi-stakeholder meetings and all of this was an attempt to answer the charge that we had received from the White House and other federal initiatives to investigate privacy and security issues related to big data in the healthcare space.

And we looked at this both to recommend actions to address critical challenges, challenges that would come to privacy and security because of big data as well as challenges to the use of big data that could be brought on by privacy. So the opposite side of the same coin we see these very closely related.

We really focused in on, you know, five areas for the public hearings trying to get input from very broad multi-stakeholder groups from industry, nonprofits, nonprofit patient organizations, nonprofit privacy organizations, academia and law, and we got some really good input on the opportunities in big data, the concerns that we had from a privacy and security perspective with big data, how the learning health system should be enabled and then the protections that would need to be particularly keen to understand for consumers. And then kind of the issues with current law.

And so with all that as background and the idea that as the volume, velocity and variety of information continues to grow, you know, the workgroup really did believe that there are potential risks that are arising from potentially unknown and inappropriate uses of health information as well as constraints on the use of health information that may not be appropriate.

So we want to focus today then on the recommendations themselves, and I will go through them. We have four buckets of recommendations as you've seen before. And we want to focus in on the key recommendations here. And I'll go through each recommendation and if you like I can pause briefly on that recommendation to see if there are specific questions and then again at the end if there are questions over the entire recommendation package I think that would work.

So, let me dive into the first set of recommendations. We have the first recommendation is found in 6.1 of the paper that we've delivered its roughly on page 15. We really…the workgroup wants to encourage and state that they encourage ONC and other federal stakeholders for more public inquiry to understand the full scope of the problem both harm to individuals and communities.

In other words, to some extent, even though there has been a lot of conversation around privacy and security with big data, much of the harm that we're trying to prevent or trying to address still remains a little bit elusive. And it would certainly benefit the policy makers and regulators to know more about what the consuming public believes are the harms that they're concerned about and make sure that we're really trying to take steps to address those harms.

In particular, we also had, you know, the idea that if we increased transparency about the actual use of health information and to do that we would need to convene multi-stakeholder groups, you know, both in industry and in public domains and in those who are utilizing the big data and understand what those uses are and then try and understand the harms that could come from some of those uses.

As we received testimony and debated within the workgroup it's clear that there just isn't a great understanding, certainly not by the public, as to the uses of health information in the broader scheme of things and the broader big data ecosystem or the Internet of things ecosystem if you will.

And so we thought those two concepts that we generally need to understand what the scope of harm that could come to individuals and communities but also in particular with respect to the use of health information may not be well understood.

In addition to that, we do believe that policymakers should continue focusing on identifying gaps and legal protections. Again, sort of likely to be an evolving set of harms from big data analytics so this is not a stake in the ground point in time as the analytics evolve, you know, the harms could also evolve. And so it's going to be challenging but we really believe that federal stakeholders need to continue to evolve with that understanding to identify those potential harms.

And then finally in this section we're really interested in trying to explore how we can add more transparency around the use of algorithms. The concerns that the workgroup expressed with algorithms is that it is kind of a potential hidden harm that you only understand if harm in fact exists in that setting and if you understand the process that was used to come to the decisions that were made. The decisions themselves on their face may not appear discriminatory or harmful but unless you know the process undertaken or have transparency around those algorithms the decisions themselves could be reached in a way that was disadvantageous to certain groups.

And so, this is a struggle for the workgroup to come to a concept and that's where what we really wanted to see was if policymakers could in fact take on this exploration of how to increase transparency.

We understand that, you know, on one hand, you know, these algorithms are in some cases proprietary. And they are clearly, you know, machine generated and the data that is utilized is ephemeral and moves through and so it's very hard to increase transparency around them but on the other hand the risk of not having a transparent process is that we lose trust in the system and trust in the process and what could be a tremendous use of data analytics and big data could fall by the wayside because of a lack of trust in the process.

So, let me pause there just momentarily to see if there are any specific questions on the first set of recommendations on addressing harm? Okay and you'll have plenty of chances at the end too.

The second set of recommendations in 6.2 of the paper talks about addressing the uneven policy environment and this is a policy environment that is created on one hand by HIPAA and covered entities within kind of a traditional healthcare setting and on the other hand by pretty much by the rest of the country where if you are not a covered entity then HIPAA doesn't apply and the use of the exact same health data outside of that HIPAA setting has a much different regulatory and legal overlay.

It's not that there isn't regulation or laws that apply to these areas and there are layers of laws both at the state level and at the federal level but they're not uniform it's an uneven policy approach. And it's difficult for consumers to even understand that.

So our recommendations were really targeted to try and see how could…what is the most effective, potentially the most efficient and the most direct approach to even out a policy environment like this and the workgroup's recommendations pretty solidly were while we understand that congress could address it through legislation we really believe that voluntary codes of conduct are the way that we would like to see both the FTC and HHS work together to pursue and encourage these codes of conduct.

Importantly, the codes of conduct have to be credible. I mean they have to meet and we have a strong recommendation that if codes of conduct are going to be utilized they have to include transparency in their process, individual access to the information or information about how that data is processed about individuals, the accountability to make sure that they are in compliance with the very codes they're suggesting and then data use limitations, you know, when the use of certain types of data should be considered off-limits or impermissible.

The second set…along with that we believe that this is only going to work if you have a good dialogue between HHS, the FTC and other federal agencies directly with the entities, industry and academia, researchers and others who are developing these codes of conduct to more quickly establish, as we put it, the rules of the road.

Importantly, one of the final things we added to this recommendation was the consideration of the sue of community risk assessment review boards, you know, risk review mechanisms have been referenced in a number of papers, including the idea that there be an independent review mechanism as part of the accountability process and a community risk assessment review board and looking at, for instance, the health precision medicine workshop on patient engagement discussed this activity. So, we see that as a potential way to improve a code of conduct that may not in itself be strenuous enough.

The next recommendation is around really enabling a use that policymakers should evaluate the existing laws and regulations, you know, governing use of data that can contribute to a learning health system. We really want to promote responsible reuse of data to contribute to the generalizable knowledge and we think that is critical.

And the workgroup also wanted to, you know, reiterate that, you know, the Policy Committee had previously recommended treating certain research uses of data conducted under the management and control of the HIPAA covered entity as operations which would not require consent or IRB review and that's the idea that, you know, in one setting if they are going to publicize or share information it would be considered research and would need the consent and IRB review but the exact same entity with the same provisions, if they were just using that for…not for generalizable knowledge that would be considered operations, it would not require review and so the recommendations that were made previously we just wanted to reiterate those.

Policymakers should also modify the rules around research uses of data to incentivize entities to use more privacy protecting architectures, for example by providing safe harbors for certain behaviors and levels of security. So, the idea there is that if private entities or entities who are doing research set up a safe harbor that had the appropriate levels of security they would not have to de-identify data to the extent currently required under HIPAA but they could utilize more identifiable data which could further their research efforts knowing that the risk of re-identification given the safe harbor security is much lower and also there was direct accountability.

The next recommendation on policy environment is to support an individual's right to access their health information regardless of where it sits. I mentioned this earlier and we actually reference it at least a couple of times in the report because we do believe that this right of access, even if it's never used, is incredibly important to individuals just like, you know, the ability to believe that there is, you know, control or an understanding of an accountable use of their data very important rights that individuals should have and while this is provided by HIPAA anything that moves outside of HIPAA is not currently covered so we included that very specifically in the recommendations on self-governance codes.

And then finally in this section, it's just very difficult to understand this environment, to understand the complexity of it moving from a HIPAA environment to a non-HIPAA environment and the interoperability that's necessary to achieve all of the advantages of big data.

And we're I think on a continuing quest to educate individuals, healthcare providers, technology vendors and other stakeholders, you know, one about the actual limits of legal protections and then next about the best protections to protect the privacy and security of health information.

And so, you know, the policy committee again recently endorsed recommendations from our workgroup on this guidance and we reinforced those recommendations that were provided in August of 2011. So, we really encourage the continuing effort for education.

I'll pause again, for specifics? Okay, it sounds like questions at the end maybe the most efficient then. I'll move through the last two and then we'll pause.

In 6.3 we came with recommendations to protect health information by improving trust in de-identification methodologies and reducing the risk of re-identification. This was a very significant undertaking by the workgroup while, you know, trying to understand what has occurred before looking to other activities and incorporating those as much as possible. We had quite a bit of public testimony on de-identification and re-identification and really the recommendations from this workgroup come down very strongly on, you know, OCR, really we do believe the Office for Civil Rights needs to be a more active steward of the HIPAA de-identification standards not only on conducting ongoing review of methodologies but also to, you know, seek assistance from third-party experts such as the National Institutes of Standards and Technology and really updating methodologies and policies based on those interactions.

As we said earlier, you know, this is going to be a very vibrant and very fluid environment and in order for regulations to be meaningful, both in its robustness as well as in its ability to utilize the data, OCR is going to have to be an active steward.

We also and perhaps more specifically would like to urge the development of initiatives or programs that would objectively evaluate statistical methodologies and determine, you know, whether there is a…what their capacity is for reducing risks and if those are met then potentially OCR could, you know, grant a safe harbor status of sorts to those types of methodologies if they are utilized and there are a number of methodologies such as HITRUST Alliance recently released theirs where it suggests it could be used for health information use.

So, allowing the methodologies, you know, the experts in de-identification and statistical methodology to create an economics of, you know, where is it most efficient, where is it most protected and how could this utilized and utilizing that marketplace to create that with a review by OCR we think would be very effective.

And then finally, OCR should establish risk de-identification requirements in circumstances where re-identification risk has been lowered, as we talked before and we mentioned other places in the reports, the use of data havens or secure data enclaves where those accessing use the data have, you know, no motivation or little motivation for re-identifying, you know, the data. And so we think that would be a significant advance on the de-identification methodologies.

And this brings us to the final recommendation from our report. We believe that we have to support the secure use of data for the learning health environment. So, we really urge development of voluntary codes of conduct that address robust security provisions. It really is, you know, baseline security, you know, as was discussed in the working group is really the table stakes to being able to utilize health information whether, you know, companies are inside of the HIPAA environment or outside.

And while congress could certainly address the issue we do believe that instead of that legislative fix at this time that voluntary codes of conduct should really include robust security provisions and, you know, coupled with the idea of educating stakeholders about cyber security risks.

So providing incentives for entities to use privacy enhancing technologies for instance, we made a recommendation in the report for that. Public and private sector organizations should educate the stakeholders about these risks, it is not just an OCR outreach it is private sector organizations need to be incented to create this learning system, this education process as well.

And the Tiger Team, Privacy and Security Tiger Team, which provided recommendations which were endorsed by the Policy Committee in 2011 with respect to the HIPAA security rule and we reiterate those as well.

So, in addition to the security recommendations on what we think should be a baseline security requirement brought on by robust voluntary codes of conduct with accountability mechanisms potentially independent review boards that could then have a very level setting effect on security. We also want to reiterate the HIPAA security rule recommendations that were made previously.

So, with that, I know I went pretty rapidly through these things, the committee has heard much of this before and I wanted to just make sure we covered the entire base, the entire playing field again, but I'd be happy to take any questions or any discussions as we wrap this up.

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

Thanks, Stan. For those who haven't had a chance to read through the document it really is outstanding. It is comprehensive you'll learn about the current issues, concerns and sort of how the workgroup thought about it in terms of, well how do you balance the needs for big data to do good versus the potential harms as Stan talked about and with the improved methods there are lots of things you can both deduce or you can use to re-identify.

So, it's a challenging area but this group has really done an excellent job both in gathering all this information which is well cited and giving the recommendations. Other questions or comments for Stan? This is something we're going to take a vote on.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
This is David Kotz, I'm actually on the Privacy and Security Working Group and I'm very pleased with the way the report shaped up and many thanks to Stan and others who did most of the work.

I just wanted to say that I was a couple of week ago out in Santa Clara at a workshop held by NIH for the Precision Medicine Initiative and one of their big question marks is of course when you have a million people in a cohort and you're collecting data about them over say 30 years you end up with a lot of data and privacy was mentioned over and over again as a big question and challenge for that project.

And so they are very keen to receive a copy of this report when it's ready because I think it may be helping them as they think about that kind of data and setting up their cohort.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Brent? Brent you might be on mute.

Brent G. Snyder, MBA, Esq. – Chief Information Officer - Adventist Health System
Thank you. I appreciate the report. It is extremely well drafted. I'd just like to maybe have a better appreciation of why the workgroup believes that this could be effectively adopted through a voluntary process and without any type of regulatory basis to ensure a common framework is in place.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
I'm sorry Brent; I didn't hear the first part of that? What was the first part of that question?

Brent G. Snyder, MBA, Esq. – Chief Information Officer - Adventist Health System
I said, the workgroup stressed an approach that it be a voluntary approach…

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

Brent G. Snyder, MBA, Esq. – Chief Information Officer - Adventist Health System
For the framework rather than one that's, you know, statutory or regulatory and I'm trying to appreciate what the basis is for that approach. It seems like it will be somewhat challenging to get a consistent adoption through a voluntary process but maybe I'm not totally appreciating that.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
No, I think you are appreciating it, you know, it's a tradeoff on one hand between, you know, a law or a regulation that is very difficult to set in a world that doesn't have a uniform practice, right, I mean, so, you know, we're not talking about, as I know you know, you know, hospitals and doctor's offices we're talking about a very broad and varied stakeholder group and so if we can set the expectations essentially for data use.

So, for instance the, you know, the codes of conduct kind of go hand and hand a little bit to the call for, you know, let's make sure we understand the privacy harms we're really trying to address and we really care about and then make sure that those, you know, governance codes have those elements in it and so the interaction with HHS and FTC again they can be very persuasive with private industry and with the stakeholders, with academia and research.

So, I do think that the idea that the baseline fair information practice principles, right, the fair information principles that govern, you know, the general use of information that are basically agreed to globally those are a standard that can really underpin most of the codes of conduct that we would expect to see and the conversations currently occurring but those are then flexible that apply in all of the various stakeholders settings.

So, we just felt like, you know, that type of approach where the expectation is consistent but the application is nuanced for the stakeholder, you know, made the most sense and then with a potential regulatory oversight with the FTC once you publicly declare your code now you have an enforcement agent who is very expert, very skilled and has quite a bit of expertise and history in enforcing those types of activities.

Brent G. Snyder, MBA, Esq. – Chief Information Officer - Adventist Health System
Okay, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Well I don't…and finally Troy.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Thank you, Paul. This is Troy. Thank you very much this was I'm sure extremely difficult to tease out. The one thing that I am not understanding clearly is the re-identification process, unfortunately I'm having difficulty seeing the slides this morning, but you mentioned that the data, if requested, there should be some capability to re-identify the data and be able to disclose where the data is being used, who is looking at it to the consumer, is that my understanding?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
No, I'm sorry; I probably completely confused the issue. So, on one hand we are calling for the right of access to individuals to their data or at least to understand how their data is being utilized similar to what exists in HIPAA taking that expectation and applying it in the non-HIPAA world.

And then second that we have a robust means of preventing re-identification and, you know, there is a call for transparency and algorithms, and a transparency in processing but it wouldn't mean the ability to re-identify individuals, you know, so if for instance what you're asking is if a data set is de-identified and exists in an enclave and an individual asks for information about how that data is used the response would be it's been de-identified, you know, we don't know if your data is even included in this dataset or not. So, there wouldn't be an expectation to re-identify that data to let an individual know if their data in fact had been de-identified and used.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Okay, good, thank you.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Hey Stan and Michelle, this is Lucia, just to give a little bit more complete example, when you read the report this is a little bit clearer than we could do orally this morning, but the re-identification problem is when you combine multiple datasets each of which might be de-identified in its own right but have certain fields removed that other de-identified datasets did not have removed because that's a statistical calculation. When you start putting them together and it sort of becomes inferences can be drawn that might not have been able to be drawn from a single stand-alone de-identified dataset. So that's really the de-identification/re-identification problem in a nutshell.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
Yeah, I would agree and in response to the specific question, you know, there isn't an expectation of a proactive requirement to re-identify in order to answer a request for access. Other questions?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
We don't have any more hands so really want to thank you again Stan to you and Deven, and the workgroup, excellent work it will really…it's such an important topic and this is going to be a good body of work to inform the efforts on multiple fronts and trying to protect the individual's data, the confidentiality of their data as well as making progress and refinement.

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
So, thank you so much. Okay, next on the agenda is Andrew Gettinger from ONC to talk about the Safety Program.

Andrew Gettinger, MD, FCCP, FCCM, CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
Good morning everybody. If you could get my slides on the screen. The first thing that I want to say is you're going to hear me every once in a while in the course of this slip back into what we're now calling old language to talk about a Safety Center and we are no longer calling it a Safety Center we're calling it a Safety Collaboratory and we're going to be talking a little bit about the program and the effort that led us to this.

For those of you who are scholars collaboratory was a term that was coined by William Wulf in '89 and enhanced by Cogburn and the key attribute and why we're using at is that it explicitly doesn't talk about bricks and mortar and that's going to be a theme that's very important. Can I have the next slide?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And Andrew, this is Paul, I'm sorry I'm going to have to interrupt for a second because I forgot to take a vote on approving the recommendations from the Privacy and Security Workgroup.

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
No problem.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Could I go back…sorry about that…entertain a motion to approve the recommendations that the group put forth?

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you and a second?

M
Second.

W
Second.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thanks, any further discussion? All in favor say "aye" please?

Multiple
Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Any opposed or abstain? Okay, thanks again Stan and sorry Andrew.

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

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

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
No problem Paul it's always hard to follow a conversation on privacy anyway so not an issue at all. So, I want to put the current roadmap in the context of really a series of initiatives that have come forward starting with ONC's commissioned IOM to investigate and propose sort of how we could improve our stance relative to Health IT safety and a lot of good information came out of that but one of the key themes is this notion that Health IT safety is really a shared responsibility.

We responded with our own safety action surveillance plan and we outlined a number of steps that would be necessary to move forward but again the emphasis was on collaboration and private and public sector efforts around this.

Congress, as part of the reauthorization of the FDA, asked both the FDA and ONC to comment on Health IT as part of their reauthorization and the FDASIA Report that was issued in the spring of 2014 talked about support for creating a Health IT Safety Center and the really important point there is that it was non-regulatory, they called for a non-regulatory solution to this and again a public/private entity and the last picture that you see is the front piece for the report that I'm going to be talking about today. So, could I have the next slide, please?

So, here were the considerations that we asked RTI to think about. We asked…and RTI was the prime contractor on this so in fact I'm talking about a work product that RTI submitted to us. So we asked RTI to define core activities and you can see them, I'm not going to read them, also think a little bit about operations in government and then to say how could we move forward with funding. Next slide.

And this was done within the context of sort of limitations around our current statutory authority so things that we suggested were not going to be in scope was that this Safety Collaboratory was not going to do a direct investigation or surveillance. It wasn't going to try and replace or supplant the operations of a PSO and it wouldn't do direct data collection, and especially pertinent for this group, it wouldn't perform the functions of FACA committees. And by definition the federal government can't give to another entity the authority that only the federal government can maintain. Next slide.

So how did this happen? What did RTI do? And I think the really important element of this and the strength of what we're going to be talking about is the nature of the Task Force that was convened to think about this. And you can see from this list this was a very substantial number of stakeholders and the individuals who came from these organizations and entities are really the leaders in the field of Health IT safety and, you know, they were and are, in many cases, diametrically opposed, in terms of prior statements in this space, and the really superb work that was done by RTI and some of the internal members of the Task Force was to develop a consensus. Can I have the next slide, please?

So here are the examples of the proposed, and again, in this slide it says Safety Center because that's what the project was working towards at the time where you can see convening research and then dissemination and that is trying to identify what are the most significant safety issues, trying to study what they are and then something which I think has really been lacking since…as a consequence of how do we then get that knowledge that we know out into the community and adopted by the community. Next slide.

So here's what it looks like in terms of an org chart. This isn't perfect and you can sort of see a funding agency, I'm going to talk about funding in the last slide. But we're imaging that the safety collaboratory will be housed within a host organization that's already involved in the field of Health IT safety, that they'll be an executive director, an advisory board, an advisory board that's drawn from the kinds of stakeholders that participated in the Task Force and that the Safety Collaboratory would identify workgroups that would then take on specific projects, there would be research staff, convening staff and dissemination staff. Next slide, please.

A little bit of a busy slide I'm not sure you can read it unless you have a particularly big screen but you should be able to see this. In the top, in the colored bars it tells you who is doing what, the advisory board, executive director or workgroups, research staff, convening staff and then dissemination staff and you can sort of see that for this to work effectively all of these different components of the Safety Collaboratory are going to have some really fluid movement back and forth in order to make progress. Next slide.

So, how are we going to get this funded? So, the proposal on the table is that we're going to start this with a cooperative agreement awarded through an open competition and that will enable us, because it is in a pre-existing organization, to rapidly launch this.

It's going to ultimately be a mix of federal funding and host organization flexibility to extend some resources, but to over time in this 3-5 year time period, for this collaboratory to become self-sustaining and autonomous.

So, there are some cost estimates. The total project ranges between 17.8 and 20.6 million, why the variation, it has to do with the…that's the cost of the cooperative agreement, it has to do with the success of the collaboratory being able to start identifying funds. Last slide, please.

So if you don't have a copy of this RTI has stood up a website that not only has the roadmap but also has the webinar series, a highly successful series that thousands of people actually participated in over the course of the last 10 months. Our last webinar is actually a conversation about the Safety Center and we'll have some of the Task Force leads talk about how we came to the conclusions that we did.

I think I made it within the 10 minutes that was allocated, Paul, so I'm happy to take some questions.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you very much and we do have some time for questions. I might start out. I'm sure the Task Force looked at this, but you talked about the recommendations from the IOM, etcetera, about…and the IOM actually looked a little bit on the NTSB model…

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
Right.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Which is non-regulatory either and one of the questions is, if…we currently have PSOs for example and we still have…we don't have a consolidated way of gathering data or reporting data for that matter and then a way of looking at that aggregate data and coming out with new insights and recommendations.

What would change if you formed this collaboratory and it doesn't have some kind of way of gathering data, new ways of gathering data let me put it that way?

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
Yeah, no, Paul that's a great question. So, first of all a couple of things, in all of our conversations throughout the course of the Task Force we imagined that the PSOs either individually or through a consolidated PSO, and as you know there are some those that are interested in Health IT safety, would be a vehicle to share information with the collaboratory so that exactly what you just said doesn't happen today would happen in the context of this.

There was extensive conversation about the National Transportation Safety Board model or what I think is a more pertinent model is the ASIAS model, the FAA model, and that is a voluntary collaboration on the part of all the airlines where signals from near misses, takeoffs and landings go directly to an, entity, the ASIAS entity that then reviews, looks at information and then makes suggestions either to the National Transportation Safety Board, to FAA, to other entities. So, it's the airline industry version of this.

There were some real concerns that surfaced about the federal government actually having detailed protected health information, specific examples, and so some really good conversation about, well, what model would be similar to that but would have a little bit of a firewall between the actual detailed content to address the concerns that were raised.

And the other piece of this is we, you know, we "ONC" in partnership with FDA, AHRQ, CMS, FCC really have to configure our collective response and how we're going to take this recommendation and move it forward and of course none of this will go forward absent congressional funding and perhaps additional authority if congress sees fit for that.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, thank you. Gayle?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thanks, so much. I do have a question about this, nobody talked a little about governance of this type of organization and if you're pulling together reports from PSOs that many states have them, many states do not and how they are governed and what happens with the information that they have. There are public record laws that allow for information to be made public.

Is there going to be some organization…whoever takes this over and does it, how are they going to be governed and what kind of safeguards are there going to be for patient safety?

And also you have a lot of adverse incidents that wind up in court and med/mal situations. So, was there any conversation along the lines of protecting information?

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
Oh, very much so and, you know, I didn't go into that in detail both because of the short presentation timeline but also because we anticipate that the director that takes this over jointly with a hosting organization will need to attend to that as one of the very first things that they take on and we explicitly didn't want to constrain things.

As you may know, ONC has funded a number of initiatives looking at some of the data that is available so the CRICO Report which is currently submitted for publication and not yet made public is an investigation of the impact of Health IT in closed claims and we partnered with the Joint Commission to look at their sentinel event data and to identify Health IT information.

So all of the information in those two initiatives, those holders of the data were able to retain the legal constructs around which they received the data and the privacy concerns and yet make the themes from that data, which are generalizable and really the key focus of what the collaboratory will do available for us to interact with. So, I believe that it is a model that the collaboratory will use.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you. Also on the funding, I do have a question about that. Are you looking for direct congressional funding or is this to be a grant from ONC or FDA, or is this to be a limited amount of startup funding? Give us a little bit better idea on what the goal is?

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
Okay, so I'm smiling a little bit, I wish that ONC had 20 million, approximately 20 million dollars to invest in this over the next five years or FDA, or AHRQ for that matter, but we're really looking for congress to fund this. Now they may fund it through either a specific legislation that has authority around it or they may fund it through the appropriation's methodology, either one would certainly be welcome.

We, in our 2015, in the President's 2015 and 2016 Budget ONC asked for 5 million dollars in each year to get underway and our…well our 2017 budget isn't out yet, but as we anticipate the future we're really talking about sharing among the different federal agencies that currently have authority to move forward with this.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you.
Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
Was that helpful?

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

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
By the way before I…at the end of this we anticipate this will be a self-sustaining entity and will not require long-term federal funding and again, as I started this I said there are no bricks and mortar associated with this.

There is no regulatory component of this. This is voluntary and the model that you should think of, if you're a healthcare provider, is the model of sort of how we investigate problems that occur in clinical care now in a nonjudgmental, open, root cause analysis kind of construct, no blame.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thanks, Andrew, well, let me follow-up a little bit on Gayle's question about the sustainability part. Did the group think about how, what kinds of models might be available to this inside an organization function?

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
We discussed fairly extensively what the likelihood was for an entity such as this to be able to develop, outside of the federal government, funding over the timeframe that we talked about and a number of participants in the Task Force articulated positions that they thought some of the companies and developers in this space would voluntarily help to participate in that.

We discussed some of the not-for-profit grant making organizations that potentially would have interest in this and, you know, if this is wildly successful and the rate limiting staff becomes the financial side of this then it is not inconceivable that we could continue to seek additional funds from the federal government as well.

You know if you really step back and say, where could benefit derive from this, individual institutions that in their own risk management programs will have fewer and fewer safety events which are costly in time and resources potentially could be convinced to contributed as well at least one of the members of the Task Force representing hospitals suggested that might be the case.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
All right, thank you, very much. Oh, Kathy?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Yes, thanks, Paul. So, just briefly, and I think I did hear Jodi Daniel join the call, but I wanted to be sure that the group that you're working with to develop this type of program also references or is able to review the report from the Brookings Institution in collaboration on behalf of the FDA looking at establishment of a post-market medical device national safety surveillance program and many of the same questions that have been raised today with regard to sustainability and who the key stakeholders are were examined by that panel and the long and short of it is that the, shall we say, return on investment differs amongst the stakeholders and in hearing mention of the potential interest of manufacturers I think that there will need to be a very robust analysis for them to be able to bring back to their boards of directors to justify new expenditures.

And so along the lines of these are the things that we will no longer have to do by ourselves, but these are things where we can share the cost amongst many were messages that we heard loud and clear.

Andrew Gettinger, MD, FCCP, FCCM CMIO – Chief Medical Information Officer; Acting Director, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology
I agree completely. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
All right, thanks very much. Thanks, again, Andrew. And with Kathy on the line we will continue onto our final topic which is from the Quality Measurement Task Force looking at CMS PFS NMPR measure.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Right, Notice of Proposed Rulemaking.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Proposed…thank you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Thank you, Paul and I do also want to thank Cheryl Damberg, Cheryl is the Co-Chair of the Task Force and took the lead on providing an initial report on other topics to this committee and certainly also to thank the many members of the ONC staff who helped us accomplish our work in a very short period of time of about 3.5 weeks. So, if we could go to the next slide.

This is to remind people of the members who participated on the Task Force and who again responded to our very short timeframe by providing comments on the questions that were put before us and then next slide.

And a thank you also is really merited to Dr. Charles Truwit and Dr. Michael Mirro, we brought them in, invited them to serve as subject matter experts on the first of our topics which had to do with implementation of appropriate use criteria in electronic Health IT systems. Next slide.

So if we look at the charges that the Task Force addressed, we were asked to provide a set of recommendations regarding clinical quality measurement provisions that can be found in the CMS Notice of Proposed Rulemaking for the 2016 physician fee schedule and there were three focus areas.

The first of those had to do with appropriate use criteria for advanced diagnostic imaging and for clinical decision support tools associated with that.

The second had to do with revision of certified EHR technology.

And the third had to do with our opinion and recommendations with regard to a Meaningful Use measure for Accountable Care Organizations. Next slide.

So, we did spend and you'll this from the materials you received in advance but also from our slides we did spend considerable time looking at appropriate use critical and we were asked to describe what we thought would be the key attributes and the principles for how certified Health IT, as a clinical decision support mechanism, should support the processes described in the Protecting Access to Medicare Act of 2014, Section 218 going into the future. And this statute has language which requires the Secretary to develop a plan and then implement appropriate use criteria going forward with a set of milestones between now and 2018.

So as part of the vision of how Health IT supports this ecosystem the principles that we proposed include the following. And the first of those should be the ordering professional, so we are making a distinction between ordering and providing professionals.

Ordering professionals should be able to use a certified Health IT demonstrating applied usability principles and they should be able to use this to access approved AUC for advanced diagnostic imaging seamlessly and at the point of care so to minimize, in other words, the burden that might otherwise be associated with this important task.

The second of these is that certified Health IT should support APIs as a means of gaining access to approved AUCs that are updated regularly recognizing that there will be clinical guidelines, updates and that those guidelines, updates will then drive updates to AUC. And that these should be delivered through certified Health IT tools.

The Task Force also felt that it would be important that certified Health IT should enable users to easily switch between approved AUC content providers and this came out of the recognition that on some clinical topics there are AUC documents and algorithms that have been produced by a number of providers.

Certified Health IT should allow capture of additional information within established workflows about not just AUCs when they were followed but we thought importantly, as part of a learning healthcare system about why AUCs were not followed and the importance of capturing that is that the Task Force believes that it would then support continuous quality improvement, it would provide meaningful performance feedback that promotes learning, it would improve clinical decision-making and importantly it would then enable further refinement of the decision-support tools overtime.

The recognition being that what might have previously been called inappropriate is now called more likely than not to be inappropriate or not warranted but that may change as new information becomes available.

And then the next set of our recommendations is that certified Health IT should display, so be visible to the practitioner it could be by a variety of different methods, seamless, actionable recommendations to the clinicians that are based on third-party data derived from AUCs. So, in other words, this should be something where it's not just enough to know if something is appropriate or deemed appropriate or maybe appropriate or not but actually for that to be coupled to some actionable recommendations of what might be a more appropriate strategy to adopt or pursue and that AUCs should be available in standardized formats that can be consumed by any certified Health IT application. Next slide.

We were then asked, and one might say this is the other side of the coin, to say then our thoughts, provide our thoughts about the major strategic considerations that would be key decision points around standards development and prioritization that ONC and CMS would need to focus on.

Of these the first is that we recognize that currently available CDS standards may not be as ready as we would like currently to serve these needs today. And so the Task Force recommends that ONC continue to support pilot testing to ensure that standards will be more mature at the time when they need to be implemented and adopted.

The second is to say that an API should be required at a minimum, that this would allow exchange of information and the application of AUC and the accompanying clinical decision support tools, but we also recognize that a link to a hosted service that is embed in an EHR could serve as a robust compliment to a decision support standard, but the strong preference of the group was towards APIs at this point in time.

And then thirdly, the Task Force recommends, as I alluded to before, that ONC and of course CMS anticipate what some of the challenges might be of addressing potential differences between AUC guidelines developed by multiple organizations. Next slide.

So, Paul I'll go ahead and address the next of the issues that we were asked to consider and I think maybe taking the approach others have I'll answer all questions at the end.

So, the second question that we had, had to do with revision of CEHRT to require eCQM reporting using CMS's QRDA Implementation Guide for providers who choose to submit eCQMs, this was a question that CMS asked in the Notice of Proposed Rulemaking and the Task Force agrees with the proposed rule to revise it, a definition to require providers to possess technology that can report eCQMs using industry standards so QRDA Categories I and III and in the form and manner of CMS submission according to the CMS implementation guide. Next slide.

The third topic that the Task Force was asked to address had to do with a Meaningful Use measure for Accountable Care Organizations and maybe just as a bit of background to that, the measure that is in place was adopted and was promulgated in the November 2011 final rule. And the measure has to do with the percentage of primary care physicians within an Accountable Care Organization who successfully qualify for an EHR Incentive Program incentive. And then there have been some updates to that measure over time.

And in the 2015 final rule after the comment period the name and specification of the measure was changed to the percent of PCPs who successful meet Meaningful Use requirements and so at this time it's important also to realize that what we are being asked is to provide comment but that CMS is not proposing any changes to the current measure, what we might call the 2011 measure, but instead is seeking comments about how the measure might evolve in the future to make sure that the agency is incentivizing and rewarding providers for continuing to adopt and use progressively more advanced Health IT functionality, and secondly how it might broaden a set of providers that have adopted these tools.

So, with that as background the first recommendation or statements is that the Task Force supports this direction of future expansion of the members to include more eligible providers beyond just primary care physicians but to do so when the platforms are usable and have achieved the necessary level of interoperability and to use this as a strategy for ensuring that more providers are being incentivized and rewarded to use more advanced functionality.

The second is really an assessment by the Task Force that the current measure, we agree with CMS, does not provide incentives to innovate and that we would support updating the current measure to motivate and reward providers who have achieved higher levels of Meaningful Use recognizing that there will be a gradient with respect to the level of achievement that is reached by individual providers and by those participating in an ACO.

The Task Force was also asked to recommend or to consider whether there were additional measures that could focus on the use of Health IT that would align with improving patient outcomes and the recommendations included measures that would address preventable harms, that would result in reductions in re-admission rates, of course unplanned re-admissions, thirdly they're being timely and reliable closing of the referral loop as one category of care transition amongst providers and medication reconciliation during transitions of care.

Fourthly, the Task Force also recognized that this is an area that has a great need for innovation and recommends supporting APIs during the early stages of development thinking that this would get us where we want to go faster.

And then fifthly, the Task Force recommends including a technical requirement to demonstrate accurate and automatic collection of data during the processes of care. Next slide. So, I'll now open it to questions from the committee.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you, Kathy. I'll look for hands, while we're waiting I will ask a question on your first recommendation and it looked like…so is the recommendation to be specific to let's say AUCs, because it seemed to get pretty detailed especially in the sub-bullets about standardized formats and being able to plug in these things so that as the recommendations, the guidelines, change would automatically change in the clinical decision support?

So, that's pretty advanced in terms of both the standardization and the way of incorporating these externally maintained rules and its effect in a specific EHR. Is that what you mean? And is this limited to AUC versus talking about CDS more broadly?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Right, so what we might do if staff could bring us back to that slide and I believe it's slide five from this set, but to start to answer your question Paul, really you're focusing on an area we spent a lot of time on which is are we envisioning that there would be a certification of the AUCs themselves, the actual content, or a certification of the developers of AUCs and the opinion of the group was that it should be the developers of AUCs and that there are established best practices for the creation of appropriate use criteria and also for the clinical practice guidelines that frequently underlie some of the AUCs.

And yet, at the same time saying that this is not an area that the federal government in particular is doing itself and so there's a recognition that there would need to be within that certification process of the developers some agreement about the frequency of what we might call the look back so that the criteria could keep up with changes in the medical evidence. So I think I've answered part of your question but I'm not sure I've answered all of it.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, so one is certifying developers and that seems like it's a little bit different from what we've been doing since we've been certifying, actually not even the vendors, certifying products, EHR products in particular so far. So one is you're expanding that to certifying actually developers of content essentially, and the other is the heavy bullets on the certified HIT so that's going back to the products and the last, the bullet of the HIT being able to incorporate these standard AUC guidance and we haven't gone that far for any other CDS so I just want to ask whether the committee is asking to go that far meaning an API to consume specific clinical decision support rules, i.e., AUCs, into any EHR and then being able to act on it. Is that…some of the bullets seems to say that and I just wanted to check my understanding of that.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Right, so, there was considerable discussion about the challenges that would be associated with having every single electronic health record vendor space a requirement to integrate these into their systems and so we instead looked more and were much more supportive of a cloud-based strategy where data from the EHR could go to the cloud, the AUC could be applied as well as clinical decision support tools and then the recommendation or the next steps, the results of the analysis would return to the user of the EHR that we thought that it would be unwieldy for every EHR to have to develop their own adoption strategy or integration strategy and so instead felt that being able to access it was a better approach.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, thank you. Other comments or questions? I'm not finding any hands but maybe others could react to this recommendation as far as being able to automate this process of taking in data and then generating recommendations in a more standardized cloud-based way? David Lansky?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
Thanks, Paul. I don't know a lot about this area it just strikes me that I know we've had four or five years ago presentations to the Policy Committee about the CDS standardization process that various institutions were developing and I know there's a comment in maybe the next slide that there was a concern by the committee that there wasn't enough standardization on that top bullet of the CDS standards and that strikes me as a concern.

And I know that in the statute CMS has required, by next April, to identify at least the first library of CDS standards or AUC standards that would be the basis for implementation by the providers. So it seems like there are enough pieces in motion here that we should take a…it seems like both a smaller and more aggressive stance that to anticipate next April's identification by CMS of the specific AUC standards and the 2017 implementation requirement of those standards that the…I like the API approach and the cloud approach that we just heard about, but it seems like if we could focus on an aggressive set of recommendations that the CMS identified AUC are available, that the certified EHRs can access and use the April 2016 identified standards and that this be the sort of accelerated path. So, we're not boiling the ocean but really focusing on the immediate implementation of a set of standards that we know are coming.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, Paul, I have a response to that and thank you David. I think that there are a couple of protections we might say in this domain from the risk of trying to boil the ocean and one of those is that although there have been appropriate use criteria developed for many, many conditions that the statutory requirement is specific to advanced diagnostic imaging. And so we think that this an area in which there has been a great deal of activity both within the radiology community also within the cardiovascular community in particular for development of AUC.

I think the cautionary note is based on hearing from our two subject matter experts that there is variability in terms of the readiness of the various AUC content to be accessible in the ways that we're talking about here.

Some of these are AUCs that go back a number of years, there's not currently an agreed-upon standard we might say for the frequency of updates of these and so what we might call the specialty society developers of AUC are presently juggling how they'll expend their resources, but I think there is agreement that there is already a good content library and that the focus should be on getting those into accessible formats for clinicians.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Hi, Paul, this is Troy. I can't raise my hand I'm not on the…

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

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
I'm not on the…

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
That's all right.

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

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

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Thank you, very much. One question I have and while I do support the use of APIs I'm a little concerned about using APIs to do clinical decision support, I mean, typically clinical decision support is done in real-time and I think, you know, when you look at the infrastructure that we have, the network requirements that it would take for, you know, a provider to make that successful that may be a little cumbersome and if the network does go down and that particular aspect is not available. What are the provisions for meeting the requirements?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, thank you, I think this maybe serves as a good opportunity to go back to what's required and is not required in the statute itself because what you're addressing is the issue of timeliness and in the statute there are specific exclusions of a requirement for use for example by emergency medicine providers. So, there is recognition that there may not be time to wait for that kind of information. The second…or that kind of feedback.

The second is that there is a requirement that the ordering provider apply the criteria but that the performing provider, so oftentimes someone different who maybe in a different health system even that they report the results and show there is a two, shall we say, two opportunities for that information to be obtained and that this would overcome some of the concerns that you've mentioned with respect to a system going down.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Any other questions? I think I want to follow-up on, again, it's the first recommendation, if I look at, David Lansky alluded to us, discussing cloud-based clinical decision support and standardized clinical decision support we were really looking for plug-in so that you can plug-in rules for whatever domain you're interested in into your EHR sort of across the board.

We've found that the standards were pretty early on that in a number of cases, one is the content standard it's the format, it's the API for the various EHR vendors and had to back away from, you know, incorporating that into Meaningful Use at this point. We set that as the vision and wanted to get there and continue to make progress on it, particularly the standardization of the content.

Would that be an appropriate place to put this same ask instead of…I'm a little nervous that there's a number of things that are maybe premature for, one, as you said the content standards aren't there, we had the same situation of theirs many of them.

Two, we don't have the format, we don't really have a cloud-based CDS server right now, that sort of concept, and this call for a very specific API for a specific, in fact it's not just AUC it's AUC for high cost imaging, and there's so many things that are in motion right now it seems like it would be pretty hard to speck out calling for a specific certification rule in a sense in this recommendation. Would you feel comfortable in moving it more…describing it more as the vision and the same concepts and consistent with the other CDS recommendations we've made in the past?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, I think the short answer to that is "yes" because that's acknowledgment of the multiple challenges. I think the pressure that the Task Force found itself under was that we know that CMS is required to take the first of four steps, as David alluded to, by the spring of next year. So, the Task Force repeatedly did come back to saying which route is likely to be the fastest to meet that timeframe and felt that it was APIs.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, so maybe the modification though would be…it's sort of…well, one is congress asked for standards for the…in the sense it's the rules, and I may not be right in this and so somebody correct me, but I wonder if what our contribution could be is from the HIT world or the ONC world to make sure that those rules are executable, in other words, if the…so there are standards and then there are format standards and definition of data elements, define it to that level, i.e., down to the data element level so that in the future you can execute on that vision of an EHR sending up information that's requested by this CDS server that says, hey, if you're thinking about, in this case, high cost imaging, advanced imaging order send me the following information, I'll process it and then I'll make the…send the recommendation back to you.

But if we could…maybe this is what David is thinking about, if this could be our first foray into this cloud-based CDS server in this specific instance but we've developed the content in a way that it can be used in this automated fashion that might be a major progress and one, as you point out, it's important from its medical appropriateness, it's important for a cost basis but it still needs to have the standards well defined and in particular the data that you request from the EHRs. So that could be a major…

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Advance in a very narrow focus.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
I would agree completely with that.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
How do others feel on the call? I mean, would this be a useful modification to the recommendations proposed that's consistent with where they want to go?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
This is Troy, I agree with you totally Paul. So, it's a great vision, great concept I just think we need a little bit more time.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
All right. Others?

Brent G. Snyder, MBA, Esq. – Chief Information Officer - Adventist Health System
Paul, this is Brent, I'm supportive of what you outlined it makes sense.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you. Okay, so maybe Kathy if this is sort of…if we could reframe the proposal on the slide to something more along the vision and maybe include your cloud-based server concept and then talk about how this could piggyback on the April 2016 requirement and just sort of specify it a bit more so that it can be automated in the future.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Sure, will be glad to do that.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Great, thank you. Any other comments about this set of recommendations because we do have to vote on these? All right, could I entertain a motion to approve?

Brent G. Snyder, MBA, Esq. – Chief Information Officer - Adventist Health System
Move it.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thank you and a second?

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thanks, any further discussion or Kathy do you have any other questions for the group or…

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
No, I think that we'll modify the language, I'll work with staff to do that and then if we have any issues we'll bring those to you Paul to make sure that we've fully captured the intent.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, thank you very much, okay, so let's a vote then, all in favor as modified?

Multiple
Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And any opposed or abstained? Okay, well, thank you very much, thanks Kathy and thanks to the workgroup that did such a big job in a short period of time in trying to meet CMS's timeline, so really appreciate that. And I think we are ready for public comment.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Caitlin or Lonnie can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute
Yes, if you are 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. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
I'll just remind people that we have the September meeting is face-to-face, it's got another heavy agenda, we are going to get into our fall season.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And also we just moved the October Policy Committee meeting so it will be a joint meeting with the Standards Committee and that is on October 6th also in person. And it looks like we have no public comment. We did have a comment in the public chat that I will follow-up and share with the committee members.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, thanks everybody for sharing some time in your August summer month and we will see you in September as it says. Thank you, bye-bye.

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

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

Public Comment Received During the Meeting

1. Regarding the AUCs, the HIMSS Standards and Interoperability Committee worked to agree/disagree and or recommend standards to be followed. In order to measure this, it is important to use established metrics which are recognized by specific national entities (Radiology, CV, Trauma, etc). I think the "cloud" is too fluid, and cannot be vetted in real-time to be reliable for a national effort to utilize effective diagnostics.

Meeting Attendance								
Name	**08/11/15**	**06/30/15**	**05/22/15**	**05/12/15**	**04/07/15**	**03/10/15**	**02/10/15**	**02/10/15**
Alicia Staley						X		
Anjum Khurshid	X	X	X	X	X	X	X	X
Aury Nagy								
Brent Snyder	X	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
Donna Cryer	X	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	X				
Kim Schofield	X	X	X		X		X	X
Madhulika Agarwal		X			X			
Neal Patterson				X	X		X	X
Paul Egerman			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		
Troy Seagondollar	X	X	X	X	X	X	X	X
Total Attendees	**13**	**12**	**13**	**13**	**16**	**17**	**17**	**17**