HIT Policy Committee
Draft Transcript
September 4, 2013

Attendance

Members present:

- David Bates
- Christine Bechtel
- Neil Calman
- Arthur Davidson
- Paul Egerman
- Judith Faulkner
- Scott Gottlieb
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Farzad Mostashari
- Marc Probst
- Alicia Staley
- Robert Tagalicod
- Paul Tang
- Connie White Delaney
- Aury Nagy

Members absent:

- Madhulika Agarwal
- Thomas Greig
- Patrick Conway
- Connie White Delaney
- Aury Nagy
- Joshua Sharfstein

Presentation

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Good morning everyone this is the HIT Policy Committee meeting. This is the 52nd meeting of the Policy Committee. This is a public call and there will be actually be two times for public comment once before lunch and once after lunch. As a reminder to those making a public comment, public comment is limited to 3 minutes. Also, to those on the phone and in the room please make sure that you state your name before speaking as the meeting is being transcribed and recorded. For those on Twitter today's meeting is "hashtag hitpolicy," and with that I will take roll. Farzad Mostashari?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Paul Tang?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
David Bates?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Christine Bechtel?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
I'm on the phone.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Hi Christine. Neil Calman?

Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Art Davidson?

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Connie Delaney? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur
Here, on the phone.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Judy Faulkner? Scott Gottleib?

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Gayle Harrell?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Charles Kennedy?

Charles Kennedy, MD, MBA – Chief Executive Officer, Accountable Care Solutions – Aetna
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
David Lansky?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Charles Kennedy are you here?

Charles Kennedy, MD, MBA – Chief Executive Officer, Accountable Care Solutions – Aetna
Yes I am, can you hear me?

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Deven McGraw? Yes, we can hear you, thank you.

Deven McGraw, JD, MPH – Director – Center for Democracy & Technology
Deven is here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Aury Nagy? Marc Probst?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Josh Sharfstein? Alicia Staley?

Alicia C. Staley, MBA, MSIS – Patient Advocate, Co-Chair – Tufts Medical Center Patient & Family Advisory Council
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Patrick Conway? Thomas Greig? Rob Tagalicod?

Robert Tagalicod – Director, eHealth Standards & Services – Centers for Medicare & Medicaid Services
Here on the phone.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Hi, Rob.

Robert Tagalicod – Director, eHealth Standards & Services – Centers for Medicare & Medicaid Services
Hi.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
And Madhulika Agarwal? Okay, with that I will pass it over to you Farzad.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thank you. Good morning, good morning. I want to just make some brief remarks mostly to talk about some of the conversations that I've been having in light of also the discussion last time about the Meaningful Use Stage 3 and the shift towards outcomes and the question of the support of Meaningful Use and certified electronic health records for new delivery and helping people meet the challenges of new payment systems whether it's value-based purchasing for hospitals and providers, whether it's accountable care organizations meeting the readmission adjustments and so forth.

There are a whole series of new ways of paying for care, paying for value over volume. And our belief from the beginning has been that it is in conjunction with those new shifting incentives for care that the true power of health information technology to improve quality and safety and patient centeredness can become manifest and yet in turn those new payment models require a capability of Health IT that are widespread to be able to support them.

I've been having conversations with groups around the country this past few weeks talking to them about – and these are the brave souls who are embracing the new delivery models, they're not hesitating with a foot in the canoe and a foot in the kayak. They're all on board to try to deliver care differently, to try to fundamentally change how they deliver care.

And one of the things that I want to reflect back to you is that many of the capabilities that we have been laying the track for are exactly the capabilities that you need in these new systems. They are not what you necessarily need if you want to just do volume, if you just want to just get heads in and heads out, get people in beds and get them out, but it is what you need and in particular what I heard was that the first thing they really all talked about was being able to understand the full history of the patient. To know the patient, to have the knowledge of that longitudinal experience of the patient, to have that information be retrievable and able to be analyzed as opposed to, you know, in text and in paper and scattered among many, many different sites.

So, that's encouraging. We also talked about the need to do population health management and I know that there's a lot of uncertainty still about what exactly that term means but it was helpful talking to them because they made it very practical. We need to understand which of our patients have care gaps. We need to prevent those care gaps from happening in the first place by having standardized protocols in place. We need to be able to reach out to patients when they do have a care gap and we need to be prepared for the visit to close those care gaps and have the right thing to do be the easy thing to do when they do come in.

There are also a lot of discussion about notifications that all too often today we don't even know when our patient has hit the emergency room in another hospital or in the case of the physician ACOs in the hospital even across the street, we don't know about it so we can't do anything about it, we can't prevent the unnecessary hospitalizations, the unnecessary and potentially harmful procedures or imaging or other tests.

And, as I think to what we have put in place in Stage 1 and now moving forward in Stage 2 it is absolutely directionally in the right direction. We still have a long way to go in terms of having that felt experience for these Accountable Care Organizations be of the quality that we hope it is. It's still too hard for them to use the certified electronic health records in the way that they want to. It's still too hard to get the information out of the systems into for example third-party applications should they choose to use them.

It's too hard for them to use the electronic health records, many of them have the capabilities but they are not optimized or they don't fully support their need to identify for example the care gaps to have flexible tools for querying the population, to have the ability to monitor what happens when you institute a decision-support or an order set to be able to effectively reach patients regardless of the mode of communication that the patient chooses to be able to track adherence.

So, it makes me look anew at the progress we've made but also at how we can't rest. We have to keep pushing to meet the true spirit and intent of these terms when we talk about patient registries or decision-support or quality measurement or interoperability and transitions of care. We have to dig deeper. It's not necessarily that much broader but we do need to go deeper.

We need to optimize and we need to get to the true intent. Some of that is taking the tools that are already there and configuring them appropriately and optimizing them. But a lot of it is getting to a common base, a common floor of capabilities across the country so that these providers who many of them still feel that they have very little negotiating power with regard to the vendors that they choose to use and they really, I think, do need to have some common assumptions about what the capabilities of the systems will be around interoperability, around population health management and patient engagement.

So, I think we are on the right track and I think the focus of the Meaningful Use Stage 3 Workgroup's deliberations of the Workgroup in terms of setting a context, a framework for shifting towards outcomes is the right one. But, I also heard from these groups about how many different things they're trying to work on simultaneously.

And again, I embrace the Meaningful Use Workgroup and the Policy Committee's advice that we should be able to focus down on things that really matter and perhaps wean ourselves off of some of the measures for which the burden of just reporting it maybe exceeds the benefit from the measure itself.

So, this is my final meeting with you and the Policy Committee and it's with, I think, great appreciation for the work you've done and the direction that you've set, the roadmap that has proved remarkably robust even as there have been so many changes over the past four years.

The fundamental framework, conceptual framework for what you've done and it goes beyond Meaningful Use, has been, I think, quite impressive. So thank you and thanks for working together. We are – this Policy Committee is by statute diverse.

There are many, many different perspectives, including some perspectives that we don't typically hear from associations and those who are among the regulated bodies who care obviously very deeply about the regulations that may have implications from this. We always hear from those groups and we welcome their insights and their perspectives and most of all the data they can provide, but this body was deliberately created with a broader perspective than that with consumer representatives and purchaser and payer representatives, state legislatures representatives and public health represented, research and privacy advocates. And there is a reason for that and that is that this really is about the public benefit that we can achieve for America.

And the key to this working is you all being able to not just bring the perspectives of your entire community to the table, but help find the solutions, help find the compromises, help find the consensus that represents the best for all. So, I thank you for your service and I will be listening from now on with rapt attention. Thank you.

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

Well, thank you very much Farzad and I definitely would agree that we've had a wonderful relationship. I think your leadership and your passion and your collaboration with this group has been exemplary and I think the accomplishments are in large part due to that kind of collaboration.

I also echo Farzad's sentiment about the wonderful diversity that makes up this group and the way that we not only make sure we get all the grounds covered but that we also drive towards some consensus agreement that really I think has pushed the recommendations forward. I know each and every one of you thinks about the public's interest as we deliberate. So I think it has just been wonderful.

I also think Farzad's talk about his tour around the country and listening particularly of those involved in this ground setting work in terms of the new payment models is a good preamble to what we're going to talk about in the Meaningful Use Workgroup. We took your advice to heart and I think we have a good framework to go forward on. So thank you for that.

Let me review the agenda we have for today and thank you all for coming. It's a really good showing. We're going to hear the final report from the FDASIA Workgroup, David Bates is going to lead us through that discussion that's also been a work from the heart and with a lot of diversity but coming towards consensus to help provide input to HHS as they prepare their report to Congress.

The Meaningful Use Workgroup is going to present an update from our last committee meeting to talk to you about an outcomes oriented framework that we've developed and hope that you will endorse going forward as we continue our work on Stage 3.

We'll end with public comment before lunch and then afterwards hear a data update. In addition to the usual statistics Steve Posnack is going to clarify some of the numbers I think in a very, very helpful way particularly regarding certified electronic health record systems and technology.

ONC will provide us updates on policy and standards and we will close with some announcement about the multiple hearings we have coming up to further contribute to our work and then conclude with public comments. So, any additions to the agenda? You also had distributed to the minutes from last month and I'll entertain a motion to approve those?

Deven McGraw, JD, MPH – Director – Center for Democracy & Technology
So moved.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Any second? And any further discussion on those? All right. All in favor.

W
Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And opposed or abstained? Thank you very much. Okay so we'll begin right away with Dr. David Bates who is the Chair of the FDASIA Workgroup and he is presenting the final report from that group for your consideration and approval. Thanks, David?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Thank you Paul and it's a pleasure to present to you the final version of the FDASIA report although we reserve the right to make some minor corrections to it this is essentially the final version and I want to thank the members of this very lively and diverse group it was definitely a diverse group. And we've had a long series of very highly productive interactions, a great deal of public input, although we did not agree about everything we were able to reach consensus in many areas and I think that's one of the strengths of this sort of activity.

I apologize in that this version will be fairly similar to what I presented several weeks ago but I'll try and address the things that are different and we've attempted to address the comments of this group previously and we'll also address some of the comments that have come in from the public since the last iteration.

This slide shows the committee membership but we had strong participation from many organizations and as the policy committee is diverse this group was really very, very diverse as well. We also had quite strong representation from the three involved agencies and the leadership from the agencies are all here today.

I want to thank in particular, the leaders of the three Subgroups. To address this formidable task we divided it into three subgroups. The Taxonomy Subgroup was led by Patty Brennan and Meghan Dierks. The Risk and Innovation Group was led by Keith Larsen and Paul Tang. And the Regulation Subgroup was led by Julian Goldman and Brad Thompson. And all of them devoted many hours to doing the work that we'll describe.

Again, as I went through last time this describes our charge which calls for the HHS Secretary to post a report by January 2014 that contains a proposed strategy and recommendations on a risk-based regulatory framework pertaining to Healthcare IT and we focused on some of the key things that were identified here. We had to include mobile applications. We had to think about things that promote innovation that protect patient safety and that avoid regulatory duplication.

Again, the next step will be that FDA, ONC and FCC will take these recommendations and then develop the actual framework over the next several months. Our process involved several months of deliberation and one in person meeting, the three Subgroups and then dozens of conference calls in both the Subgroups and larger groups and a lot of online processing.

We, again considered the prior work in this area, got lots of input and had public commentary on the FDASIA process and I want to note that the products that we've developed include this presentation, which not only includes the slides, but their attached notes which explains some of the things in the slides which are by necessity a little bit telegraphic, but also, three two-page summaries which have been distributed to everyone, which basically provide additional detail and explanation of the recommendations in the areas addressed by the three Subgroups.

With respect to the public comment, FDA, ONC and FCC requested public comment on the development of a risk-based regulatory framework through a notice that was published in the Federal Register on May 30th. The comments that we got by June 30th were forwarded to the FDASIA Workgroup. We received 14 submissions by that time although additional ones came in subsequently. Those submissions were discussed at the July 26th meeting and consistent with FACA guidelines and at the close of each FDASIA Workgroup and Subgroup meetings the members solicited and considered any public comments that could inform these recommendations. So, onto the actual report.

The backdrop again is that the literature suggests that HIT in the aggregate clearly improves patient safety and there are lots of studies that support the benefits. However, the literature also includes many anecdotes that show that HIT can create new safety risks.

And while we are uncertain about the absolute magnitude of harm and the impact of Health IT on patient safety overall is not completely clear, some of the reasons for this are that Health IT by its very nature is heterogeneous, it's implemented in different ways in different places, there are many different clinical environments that are variations in workflow from place to place and the FDA has had the authority to regulate HIT but by and large it has not done so except in limited ways which I will describe and the authority has been limited to HIT that meets the definition of a medical device.

Now here are a few specific problems that have been associated with HIT. At the University of Pittsburgh the mortality rate went up in a special care unit after the introduction of a widely used commercial CPOE application.

In another study a group developed a flight simulator approach in which people could put standardized data about patients into an application and then figure out did they have the right sort of decision support in place? And the key finding from that was that electronic health records detected only 53 percent of medication orders that would have been fatal. I'll note that subsequently the hospitals that got that feedback did improve the next year and they were able to put in, you know, more of the key decision support.

There is also a clear problem of providers writing electronic orders on the wrong patient because they can't tell which record they're in that happens in every record at a finite rate and there are approaches for dealing with that approach which are not necessarily widely implemented.

Another example is a situation in which with sensors attached to an asthma rescue inhaler and it records the location where the medication is used but not the time and when the information is uploaded to a computer the time of upload and not the time of the medication use is recorded. And finally, when even very serious safety-related issues with software occur there is not a central place to report them to and they typically at this time do not get aggregated at the national level.

It's also clear and it appears likely that regulation can have an adverse effect and here is one example. In closed loop systems one application can drive another process and an example would be that oxygen monitoring might tell an IV device to stop delivering narcotics if hypoxemia is detected. There are many cases in which deaths have occurred in which patients were getting intravenous narcotics and the infusions were not turned off. And part of the reason may be that it's very challenging to get through the current regulatory limitations around putting in what is referred to as a closed loop sort of approach and there is more explanation of this at that website.

Another example of this relates to patient controlled analgesia. So, patients can call the nurse to ask for more analgesia but when they're overmedicated they can't call for help. And comprehensive monitoring is not routinely used in organizations today typically because of high alarm rates from things like pulse oximeters and capnographs.

Solutions would be smarter alarms that could combine signals from patient monitors and clinical information systems connected by an HIT infrastructure to suppress false alarms, detect respiratory depression early and put in place real-time decision support to communicate with the pump to stop medication infusions prior to injury.

But these solutions have not been widely implemented and there many reasons that but one of them is that from the regulatory perspective it's very complicated to describe exactly what you would do and in ways that help you get through the current regulatory process. So that is the backdrop.

The next thing that our group did was to develop a taxonomy for healthcare IT and HIT was assigned to one of two categories either being subject potentially to a risk-based regulatory framework or not subject to that risk-based regulatory framework.

The guiding principles that we elected to follow were that all entities addressed by the risk-based framework can be described by a set of defining characteristics, that framework has to be robust enough to meet future undefined needs because we can't tell exactly what HIT will look like down the road.

We have to avoid creating inclusive inventory for determining what is regulated and the group recommended using a decision tree approach that emphasizes functionality as a primary scoping criterion but with the notion that functionality will help distinguish between two similar innovations one which requires risk-based regulation and one which might not.

These were the planning characteristics which the group suggested be included as dimensions of HIT and I won't read these again as I did last time. But here's an example of characteristic seven. And characteristic seven is product categories so things that would possibly be subject to a risk-based regulatory framework would be things like electronic health records, hospital information systems, decision support systems, visualization tools for anatomic tissue and imaging, health information exchange software, electronic and robotic patient care assistance, templating software tools for digital imaging, and surgical planning.

Things that would likely not be subject to the framework would be things like claims processing software, health benefit eligibility software and you can read the rest of these. Now just because something is possibly subject to the framework does not mean that it would necessarily be regulated in our estimation.

And, this slide shows the decision note approach and we suggest asking the question, here the question is use intended to inform or change decision-making about initiating, discontinuing, modifying, avoiding care interventions or personal health management? If the answer is "yes" than it would be in scope. If "no" then it would be out of scope.

The group also developed a risk framework and the patient risk framework enumerates a number of important factors which influence the risk of software systems and devices. It does not wait or calculate any specific risk score for a given product but rather serves as a framework to assess the factors to consider when evaluating the potential risk of potential harm arising out of the use of a system.

And there is a matrix, which we'll go through in a minute, which characterizes the relative risk of certain conditions of each risk factor. These are intended to serve as directional guidance only and exceptions for each relative risk exists.

We also went through and have provided a lot of definitions which are listed here. You can see the basic definitions and then this is the core. This matrix is the core framework and there are a number of dimensions of it which are on the left side and then in the columns are low risk, medium risk, and higher risk.

And, amongst the examples of things and the dimensions on the left side are the purpose of the software product, the intended use, how severe the injury is and I'll go through some – and so on. And I will go through some specific examples to help illustrate this which I think are useful.

So, here is a use case. The specific use case is an mHealth nutrition App. And you can see this application would score as relatively low risk across the board. It's the sort of thing that therefore would appear to be quite low risk from a regulatory sort of perspective.

Here is another example which relates to a closed loop insulin pump with continuous glucose monitoring. This is a substantially higher risk. So, for example the purpose includes automated decision-making, the intended use includes providing the diagnosis or treatment advice directly so suggestions are being made that's a substantially higher risk. It's actually, relatively speaking, a black box, which again, makes it a higher risk.

Here is another example which is the electronic health record and you can see here the risk varies a great deal by category with some things being, you know, much more at the high-end for example the intended use of an electronic health record might provide a diagnosis or treatment advice directly to knowledgeable users so that put it at the higher end of the spectrum but on the other hand it uses sort of relatively standard approaches in terms of network connectivity placing it more at the low end.

Several observations from going through these use cases and we went through a number of other ones which I'm not presenting today but are provided in the backup slides. And it was much easier to classify lower risk applications or attributes things that are standalone, have relatively narrowly designed functions, less variability in the way that there used.

Much harder to classify more complex software precisely. So it depends on how it's being used, it's dependent on the context of use if there is more complex software to develop lots of QA to do around it, much more effort to implement it, lots of interfaces to other systems and much greater reliance on QMS process and risk controls for known failure rates.

We think these things have several policy implications. First, we need to define clear criteria for stuff where functions that are not regulated but we should perhaps have labeling requirements to promote transparency for these. It would be useful to define clear criteria for stuff where functions that warrant greater regulation or at least greater attention and it's also going to be important and we'll come back to this to create a robust surveillance mechanism to track adverse events and near misses for most of software functions which lie in between the two extremes.

This slide just shows the current FDA medical device regulation and again I went through this last time but the slide is slightly revised so I'll highlight a couple of things that have changed in terms of enforcement discretion that can be used when risk is variable and where requirements are scalable, sometimes there are none, this is based on the FDA's authority to enforce regulatory requirements outside of traditional classification categories.

Within Class I there are a couple of levels lower and low. And for example, lower includes the general controls like adverse event reporting and facility registration and listing. Low within Class I is the same as lower risk, but there are more process requirements specifically quality system requirements for product development.

And you can read what's included here for Class II and Class III. Not until you get to Class III is – actually in medium Class II there is premarket clearance, also in Class III and for Class III they are much more detailed for both approval requirements. Okay.

So with respect to medical device regulation we went through and did an analysis of the relative pros and cons and some of the benefits of medical device regulation are that there are substantial process controls. So the medical device laws primarily are process control which describes how to create a product and in essence beneficial from the stand-point of flexibility. So by not dictating the end product it meets the innovation need to have flexibility and product functionality.

The good manufacturing process approach supported by the FDA regulation has had a positive impact on the quality of products and the results in confidence in the products produced through GMP. In terms of post-marketing surveillance the current FDA regulations already support gathering data about products post marketing and this has been really a key desirable element in the discussions of the Workgroup and in fact the discussions have been that it should be expanded and that this should be made more transparent so that there would be much more open access and exchange rather than just an approach that looks like product policing.

Some of the cons of the medical device regulation with respect to HIT include clarity. So, which software would be considered a medical device? Which Class would be used for HIT software and if it were subject to the law what specific requirements would be included to be in compliance? This approach is also geared to physical devices and as noted on the previous slide things like turnaround time, extensibility of software complicates using this sort of approach for HIT.

The blood bank example is quite an important one and the full application in the medical device regulation had a very negative impact on blood bank software vendors, at least that's the perception of the FDASIA group.

And there are also issues with what is called entry impedance and their two cases. First there is a learning and implementation curve for manufacturers or others who are trying to get into the market space so that's a real problem.

And a second use case is when software is developed, tested and implemented but without an FDA regulated process the product is then deemed to be subject to an FDA regulation. How can a past process be reconstructed to be FDA compliant? So that's a second issue.

With respect to – now over to ONC certification for electronic records, this group is obviously very familiar with this. The motivation is that there is a defined product and the government is funding a capital improvement to healthcare practice. So I will give you an example being Meaningful Use so that there is an obligation to promote good products and therefore we have certification for the products.

With respect to innovation, specification of specific software behaviors and specific tests does limit innovation. And in some cases can narrow solutions to problems to certain solutions. There can be issues of working to the test in which vendors strive to meet certification but they don't necessarily do some of the things that Farzad was talking about before which are really going to enable better management say of populations and that's why it's so important to have both the right goal post in terms of incentives as well as approaches like certification.

And so this sort of regulatory approach we believe is justified only when there is an overriding societal benefit. And examples would be interoperability or specific patient safety concerns. There have been huge benefits from taking this kind of approach.

And for example, when the railroads were implemented it was enormously valuable to have somebody specify the gauge. When I traveled in Europe as a student there were – I ran into the situation in which the gauge of the railroad was different between Spain and France so they had to design a special train to go from Madrid to Paris, that sort of thing, you know, does not exist anymore. And yet, you know, there are many times in which we want to avoid supplying too much specificity in terms of what should be done.

With respect to certification regulation, the group had a few specific recommendations to promote innovation one was that we judiciously use specific functional requirements and consider whether or not there is a specific public health or patient safety issue, when there is use those requirements otherwise try to avoid them.

The group also recommends using flexible compliance measures which again this group has talked about a lot and has tried to do in many instances. And to, for example, allow multiple approaches to achieve the desired end. And the ONC certification process of course does exhibit some of this approach. So, the certification standards for user centered design leave open the specific implementation.

We also suggest that avoiding requirements that empower a single external certification body. When there is a single body the usual issues occur when there is a monopoly. And finally, to try and increase predictability and to stage the definition of the requirements versus having a defined roadmap of features, and to make recertification criteria as easy as possible, again Farzad mentioned some points about that earlier. If there are things which are not really delivering that much value perhaps those would be best done away with.

If you compare these two approaches, so with medical device regulation there is a process control, with certification it's a product definition. With medical devices often there is premarketing approval. In certification there are best practice feature definitions. If you look at impact on the device side it can be positive when you're combining software from different sources but there can be lack of clarity which is the flipside of regulatory discretion and that can yield policy uncertainty and create things like entry impedance.

And there can also be continued overhead. There is a trade-off between a heavy process versus agile development which is often really useful in the software world. And medical device regulation, if fully applied to HIT and local implementation could be devastating to the market as we saw with the blood bank. You know, on the certification front some of the impact has been reduced flexibility. There have been issues of compliance innovation and it's less market neutral.

So next, I'm going to move into the regulatory area. And the regulatory area asked four primary questions. They asked, are the three regulatory agencies ONC, FCC and FDA deficient in any way with respect to how HIT is regulated? Are there ambiguities in those regulatory systems that need to be clarified so that vendors and others can proceed more easily to innovate? Do any of the three regulatory systems duplicate one another or any other legal regulatory or industry requirements? And then finally, setting aside existing approaches is there a better way to ensure that innovation is permitted to bloom while assuring safety?

And in some of the next slides given issues are classified using A's, B's or C's. A refers to ambiguous things that need to be clarified so not all ambiguity is bad. The ambiguities that are highlighted are things that the group believed needed to be clarified.

B refers to broken which means that the actual law is written whether codified in statute regulation or guidance doesn't fit HIT and there are many instances, not surprisingly, where the law really has not caught up with what is needed.

And then finally C refers to capabilities that can be underutilized. Things that we would like to see the agency make more use of because this is an effective approach.

So, here are the issues, the FDA issues that were identified with the group in terms of what wellness and disease, the group felt that there were many opportunities for improvement and that in particular the FDA needs to explain how to discern disease-related claims from wellness and should deregulate relatively low risk disease-related claims.

From the accessory perspective, the FDA, the perspective was that the FDA needed to explain its position on which basic IT elements are regulated when something is connected to a medical device. And then deregulate or down regulate those that are low risk.

With respect to the CDS software, there are many, many types of CDS software and it would be helpful to have the FDA provide more guidance about which forms of CDS software it's electing to regulate.

And then, with respect to the software modularization perspective, the recommendation was that the FDA needs to specify it's rules for deciding the regulatory status of software modules either incorporated into a medical device or accessed by a medical device.

On this slide we focused on the areas in which FDA regulation can be improved for devices that already fall within FDA regulation and believe that there are three main areas. Most devices subject to FDA jurisdiction have to meet the right requirements of the quality system. Unfortunately though, understanding how to meet those requirements can be really hard for standalone software. The regulation was written with physical products in mind.

And while the basic regulation is written broadly and can be interpreted industry would benefit from official guidance from FDA on how it should be interpreted for standalone software. There are private standards groups like AAMI that are working on this issue so this could be as simple as the FDA just recognizing that work.

Typically when a medical device manufacturer goes to the FDA and seeks clearance they are presenting a device with a very defined and intended use typically as a solo product. If instead the manufacturer goes to the FDA with what is essentially a compliment of the future unspecified network of devices the agency, not surprisingly, has a lot of uncertainty in terms of how to gauge risk and what kind of data to expect and it would be helpful if the FDA could come up with a paradigm that informs developers of these network components that demonstrate their claim of substantial equivalence.

And then finally when something goes wrong with a network of medical devices it's often very much unclear where the problem is. And often the problem is in fact between two devices at their interface as opposed to being the responsibility of one single component. But the laws currently state that FDA – the current laws were written with accountability in mind so their post market obligations like adverse event reporting and field corrective actions that are written though it should be clear whose responsibility it is when it just often isn't.

There are several current FDA program mechanisms that could enable innovation. The group recommended that FDA should affectively establish a policy of enforcement discretion for the lowest risk HIT where enforcement of regulations is inappropriate.

Second, the FDA should assess exemption for GMP for lower risk HIT that FDA should expedite guidance on HIT software, mobile medical Apps and related matters and I know that actually will be coming out soon.

The FDA lacks – the assessment was that the FDA lacks internal coordination on HIT software and mobile medical Apps policies and regulatory treatment, and more coordination around that would be beneficial.

We believe that the FDA should utilize external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA. And finally there may exist a need for additional funding to appropriately staff and build FDA expertise in HIT and mobile medical Apps which are obviously proliferating at a phenomenal rate.

With respect to ONC and around mandatory elements a challenge is that the current ONC program doesn't include the capability in law enforcement nor programs framed with mandates where it would sometimes be useful to do so.

With respect to safe configuration a note was made that safety depends on appropriate post installation configuration and they're not good means to educate or require compliance with documented and evolving best practices.

With respect to certification the group's recommendation was that ONC should avoid regulatory rules and certification test cases that endorse a specific solution or implementation.

And finally, ONC was commended in that it does a good job of periodically reviewing its programs and criteria and eliminating those which are no longer necessary.

With respect to FCC the challenges were that planning for deployment of wireless technologies is hard in the spectrum-crowded interference prone environments like hospitals. And the group believed that preclinical tests and evaluation tools in environments could help manufacturers and delivery organizations with an example being the FCC wireless test bed initiative.

And then with respect to post installation surveillance the challenge of spectrum management and identification and then diagnosing and resolving wireless coexistent EMC problems which affect HIT and medical device performance. It's again increasingly becoming an issue as people use more and more devices in these environments.

There were a number of cross agency issues that were identified. With respect to coverage of interoperability issues it's not completely clear, not surprisingly, since this is a new issue who exactly is responsible. For example, the ONC might regulate the HIT medical device interface, the FDA might regulate the medical device medical device interface. But the same medical device, like an infusion pump, could be used in either configuration. So it's not really clear then who is responsible for resolving a problem like that. And more generally, it would be helpful to figure out who will require interoperability when products need to be interoperable to be used safely.

With respect to FCC and FDA it was noted that the two agencies don't necessarily coordinate their review processes on converged medical devices that are brought independently before both agencies and coordination between agencies should be transparent and should help ensure consistency.

And then finally, with respect to the FCC/FDA conformity and assessment sometimes there is incomplete or missing clinically focused wireless conformity assessment tools that would facilitate safety in coexistence analysis.

With respect to adverse event reporting, when medical device system related adverse events occur it's often difficult or impossible to figure out exactly what the root cause of the failure was. Sometimes the data logs are incomplete, they're inaccessible, they're nonexistent or they're not in standardized format. Some of the recommendations that this group had that those sorts of things begin to be collected will definitely be useful but more needs to be done around that.

In addition it's not clear what the best model is for reporting and analyzing issues with systems or devices that span multiple agency related and non-regulated spaces. And our group surveyed a whole array of existing approaches and it was not really clear what the very best approach will be and we believe that further analysis is needed.

We did discuss the possibility of a new construct something like the Health IT Safety Administration or HITSA but it's not clear how much support there would be for development of an entity like that which would be a new entity.

And then finally with respect to adverse event reporting the current reporting pathway often doesn't facilitate timely resolution and we underscored again broader access to safety and performance data to enable timely improvements.

So, a specific requirement from this overall assessment and, you know, again the overall assessment was obviously quite detailed and critical but this is a big opportunity to basically rethink things and improve the overall approach in this area.

Our specific recommendations were that the HIT should not be subject to FDA premarket requirements except for medical device accessories which should clearly be defined by FDA except for certain forms of high-risk clinical decision support like computer aided diagnostics which is already regulated and for higher risk software use cases per the risk groups report including those where the intended use elevates the aggregate risk.

We did suggest that vendors should be required to list products which are considered to represent at least some risk if a non-burdensome approach can be identified to doing so. And then a major emphasis needs to be to develop better post-market surveillance of HIT which will include a collaborative process with lots of stakeholder participation and that should include both user self-reporting and then reporting from vendors and lots of transparency and then also post implementation testing to ensure that key safety related decision support is in place because it's clear that unless you do some post implementation testing you can't tell.

It turns out that all the vendors offer the sort of decision support that will result in improvements of safety but the users don't necessarily have to implement it and if you don't do some checking you can't tell whether or not it's really there.

In addition approaches are needed to allow aggregation of safety issues at the national level and there has to be federal support for doing that because if we don't have that it just will not occur. And the group recommended that which agency should perform the above will have to determined, and we did not make any specific recommendations as to which agency it should be.

But it's very clear that cross agency collaboration will be essential in this regard and we recommended that this approach would be provisional and it should be examined periodically. This is not a static area and things are going to change over time.

We also recommended that the following areas should be further developed and these could be accomplished, these are through private and/or public sector efforts and those include adoption of existing standards and creation and adoption of new standards which address key areas like interoperability. And second would be a public process for customer rating of HIT to enhance transparency which should be facilitated by an independent group using validated measurement results.

So, next we're going to turn to what could a new framework look like and the group that assessed this found some of the materials in the IOM report on Health IT and patient safety to be very valuable and began by looking at three areas of stringency, flexibility and information.

So, with respect to stringency the more stringent the regulation the less degree of freedom that you have for innovation and there's increased risk of not having innovation that's needed just to meet compliance. There is divergence of resources and there are missed opportunities.

With respect to flexibility the number of implementation paths to meet compliance, if you have more of those there are more degrees of innovation but if you're more prescriptive with respect innovation then there's less innovation.

And with respect to information if you have more information in the system then that increases the amount of innovation in the system.

So, some of the recommendations for a new regulatory framework were that certification regimens should be used judiciously and the innovation impact should be considered. There should also be transparency of results to supplement or replace certification. So, instead of a certification process to differentiate the market there's an opportunity to use transparency. The group believed that transparency in the marketplace is more efficient and it's richer in content than just requiring certification.

The group also recommended that national goals should be encouraged like the Joint Commission's goals, like Meaningful Use as they meet the flexibility test and set the problem agenda and not a product agenda. They do change and if well set can correct the market and create new markets and clearly where the market goes vendors will follow.

With respect to innovation requirements these can include developed software which can either be vendor or local. Another source of innovation is software set up which can be done through either customization or extensions. There can be integration with medical processes which clearly have to take into context the sociotechnical system.

And then finally, we have to be able to begin to combine technologies more than we do today and those include things like communication devices, sometimes these things are predictable like HL7 interfaces but sometimes they're not predictable like end-user combination of technologies for example involving software and hardware.

So, to summarize with respect to the new framework we think there should be national accountability that involves outcomes assessment rather than product definitions. We should when possible use international standards which are increasingly available for many things and if not national standards for quality process international and/or national operability standards to lower entry costs.

We should encourage configuration and extension to support process and solving of problems. We should encourage transparency of products and results, support the ability to experiment or iteratively develop, we talked about this last time Farzad brought this up at the last meeting around, you know, what should we do to develop a sort of fertile field approach. And then finally, there should be aggregation of safety issues that do occur so that they can be addressed and that should happen at the national level.

In addition there has to be some local control and local accountability. And we need approaches to enable design documentation and proving of local control systems. This could be co-owned with the vendor. There might perhaps be accreditation of stuff for implementation processes that could occur through an entity like the Joint Commission.

If you look at the examples of issues in which things went really wrong many of them involved poor implementations which has been a hard problem to address. And then there are a number of issues with respect to scope which are listed here.

And the IOM report discussed imagining a different regulatory framework and we have suggested that if we're going to encourage innovation and shared learning environments that the following general principles should be used. There should be a focus on shared learning. There should be maximal transparency that should be non-punitive. We should identify appropriate levels of accountability and clearly there should be minimal burden.

If you compare the current approach in a new framework, in the current approach there are often defined solutions and in a learning environment we'd like to see moving towards multiple solutions. Often there is a slow response to innovation and problems. The future would be continuous innovation. Under current regulations sometimes the results are opaque. In the future the notion would be that we'd move to continuous measurement of results. And current regulation in some instances discourages participation. We'd like to be encouraging participation.

So, to summarize overall we've described the taxonomy for considering what the bounds are for what is HIT and what might be considered for regulation depending on level of risk. We've proposed recommendations around development of a risk framework which may be useful for stratifying HIT by risk and then assessing what if any regulation is needed.

We've described the current regulatory framework, the potential new approaches and deficiencies, some of the ambiguities and deficiencies in current frameworks. We do think there is a substantial opportunity for the FDA in particular to try and resolve some of the ambiguities that exist today.

And we've described what we believe will be helpful to promote innovation in both the short-term and the long-term and to maintain patient safety and we've described with use cases all the above. We think that the definition of what should be included in HIT should be broad but we've described some exclusions.

We think that the patient safety risk framework and some of the examples we've given should be used as building blocks to develop a more robust and transparent framework which would allow the application of oversight by risk.

We suggest that the agencies should address the deficiencies and the ambiguities and duplication that we've identified. And we think that new frameworks with some of the characteristics aimed at stimulating innovation may be helpful.

In addition, we think that substantial additional regulation of HIT beyond what is currently in place is not needed and may not be helpful and therefore should be Class 0 except for, as we've discussed before, medical device data systems, medical device accessories, certain forms of high-risk clinical decision support and then higher risk software cases.

And for the regulated software it will be important for the FDA to improve the regulatory system to accommodate the characteristics that can make software development distribution and use different from physical devices and that new risk framework should report re-evaluation of what's currently regulated as well as new HIT.

And then in addition we believe that, as recommended by the IOM Committee, vendors should be required to list their products which are considered to represent at least some risk and that a non-burdensome approach should be developed for doing that. That better post-market surveillance of HIT is needed that's a really big gap clearly and that should include things like standardized formatting of reports, transparency of the results and then post implementation testing.

And that approaches are also needed to allow aggregation of safety issues at the national level including federal support and that the FDA and other agencies need to take strong steps to discourage vendors from engaging in practices that discourage or limit the free flow of safety related information.

And finally, how to organize the governance of all this should be addressed by a cross agency group and it should also leverage key stakeholders from the community like those who were involved in this subgroup. So, I will stop there.

Again, I want to just thank the members of the group that helped produce this, it occupied a large quality of the summer. But we hope it will be helpful to the involved agencies and to the government going forward.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Well and we want to thank you David for not only leading but managing this diverse process. So let me open it up for questions and comments. David?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
The final report, I really thought it fascinating and rich and deep. It raised a question for me which I just wondered if you thought about. As we look at the rest of our work today and the Meaningful Use Stage 3 discussion it seems like you've gone through an analysis of one particular set of applications and technologies through a risk framework. But where I heard you come out is with a fairly fresh look at how we think about HIT more broadly including EHR technology.

So the thing I heard you flag, you're advocating an outcomes oriented solution assessment process and post-market surveillance or other tools. You focus on interoperability as a key goal with public interest in these technologies as well as some of the risk areas that are posed.

You de-emphasize certification of assigned solution in favor of those observational metrics and tools. And it seems – and the post-market surveillance discussion it seems analogous to our use of quality measures as a means of assessing the impact of the technology not the functional requirements and certification criterion.

As you all worked through this great detail in this particular set of applications did you think about whether this framework would apply more generally to the work we're doing as a policy process?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
So, great question. I think it does have many applications to the work that we're doing more broadly. I think there has to be some evolution over time. At the beginning certification, I believe personally, has been extremely valuable because many of the records just did not include a whole lot of, you know, very basic things but over time, you know, all the boats have been listed and I believe that we should be trying to seek policy solutions that ask people to get to where they want to go. Again, as Farzad was describing before, we should seek approaches that are sort of minimally prescriptive in terms of how to get there. So, I think that that is a kind of a natural evolution.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
I will comment. I was thinking along some of the same lines. But the exception, and there are some that were described by David and the group was for example around interoperability where more stringency is, and I think Marc Probst has raised this point multiple times, more stringency can help increase innovation because – and that's something where you really want to increase the amount of testing and enforcement and transparency around a certification process. So, there are I think exceptions to that.

The other issue it made me think of was, you know, there have been calls for us to, for safety sake, standardize the user interface right? I just heard it on Friday from a doctor who said "I practice in three different places they use three different user interfaces why can't we just standard, why can't you just make everyone have the same user interface?" And, you know, I think that would be a phenomenally bad idea not because of the impact on innovation and on a competitive ecosystem where people should be able to develop user interfaces without us telling them that, you know, this is or is not usable.

But on the functionality, I think with some exceptions that members of the committee pointed out, we have been – and if we don't include the products and security, and interoperability requirements it has mostly been around us saying "you must have decision-support." We didn't say it should be a pop-up. We didn't say it should be this thing. We didn't say it should be an interrupt alert. There is, you know, have some form of decision-support.

We didn't specify how to do it and we left a lot of discretion on that. The balance is of course how do you then certify to that and test to that and enforce them and how do you keep that improvement but I think directionally it is very much in the direction that we've tried to be and maybe sometimes we've dipped a little bit too much into prescriptiveness, but as a whole I think it's directionally where we want to be with some exceptions.

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Can I make two quick comments in response to that? The user interface issue is a very interesting one in that there are some, you know, best principles around that. The UK for example had a common user interface set of work that went on for several years and they were able to identify a number of principles that do appear to work better than others.

At the same time I too would struggle with requiring people to use similar interfaces. This is part of why we suggested having approaches that really enable people to make comparisons between systems that should be possible to score systems according to how usable the interfaces are and those results should be transparent. So, that's another way of getting at that issue.

You know, around the decision-support issue is something that obviously this group has struggled with at great length and that's a place where I think some post-implementation testing is really beneficial because there are certain things that if you don't have, you know, it's not meeting the needs of the greater community.

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

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Yes, I'm not at all surprised but this was great David. A couple of things, one is on innovation. I liked agile development I thought that was really good that you mentioned that and along with agile development maybe it's somewhat synonymous, but just is the frequency of change it's not just innovation, it is the constant change that software goes through that if you have to have every piece of it overseen and certified it would tremendously slow down what's going on there. Maybe 100 years from now it will be different but at this point there is so much change going on that is good for the most part, very good.

Number two, international standards, I'm assuming what you mean in that is that we would work together with the international community not that we would import necessarily standards from Europe of standards from Asia. Because I don't know that I would say they're better or worse. They may be similar, they may be different. But my experience hasn't necessarily been that they've been better. Number three, but I think working together is fantastic because the world keeps getting smaller and people travel and interoperability in the end should not just be within our country it should be between countries as well.

Number three and this is just such a big one, changes by the user. What I see is that – several things one is you've seen one vendor system in one organization and you've seen one. You go to – I've heard so often users say "I use this system here and then I went there and I used this system there and I couldn't even realize it was the same system." And it's not just user interface it's what people turn on and not turn on. So, I'm wondering how do you test things when the vendor needs to get tested but the implementation may take quite a while as each organization tries to figure out what do we want for ourselves.

I remember many years ago the first tumor registry system I ever worked on, set it up thought it was good, got a second organization that wanted to use tumor registry, we showed them the first they said "well, that might be nice for them but it's not what we want." They wrote it totally different using exactly the same tools and the third one wanted something different from the first and the second. So, then what gets tested? I have not figured that one out. It's the setup, it's how you report on it and yet I think it's good. I think that each organization needs to do what is good for them in the end.

And the last thing I wanted to know was about high risk software use cases, the thing about decision support is I don't see decision support as a module. Decision support is threaded throughout the system, it depends on what you turn on and what you turn off, it depends on things like if you're going to have a drug-drug interaction what level are you setting it to sensitivity?

There are all sorts of things in decision support. It could be the order sets you have that is decision support in many ways because it helps drive you down and one group will pick different order sets than another group will pick.

So, I'm really interested in if it is decision support than how do we separate the concept of decision support as a standalone module from decision support as something that is threaded throughout because then you're getting into oversight throughout. And then what else is higher risk software use cases besides decision support?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
David, before you start, if I may also ask you, along the lines of Judy's next-to-last comment, you mentioned the systems related adverse events and you mentioned how root cause for some of the complex of Health IT is difficult because of its integration with medical processes and the sociotechnical system. In other words that it's not just the software developer and the software that gets shipped that is involved in the safety. It's the absolutely the issue of local accountability, it's also the response that safety can arise as responsibility and as a consequence of how the organization implements it, how they train, how they configure, what their workflows are and that whole piece.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Much different than a piece of equipment.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Exactly and I think the IOM group pointed out much the same. And I wonder if the group discussed that in addition to FDA and FCC, and ONC there is another set of activities around safety regulation in general in healthcare and processes for reporting of safety events and monitoring of them. You mentioned it when it when you talk about the local autonomy and JACHO style but could you talk a little bit more about how that broader view of health safety, health care safety and regulation of health care safety intersects with the device safety issue or the Health IT safety issue?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Okay. So, great set of questions. Agile development I agree with you I mean that's one of the things that this is just fundamentally different about software. In terms of standards, I agree with you there too. There are some instances in which there are good international standards. There are many others in which there are not. I think we should be approaching it the way that you described things.

Third issue, that's one of the most complicated problems in Healthcare IT and I think it's still sort of fundamentally unsolved and it will have to be something that we continue to monitor and try to figure out. If you don't let people configure things at least a little bit then they won't use them. But if you do let them configure them too much then you get all sorts of problems. And part of the reason I think post implementation testing is so important is that it's at least one way to help get at a small part of this but it's something that we'll have to kind of watch and tackle over time.

To get to Farzad's question about this, if you look at other issues from the broader context of safety regulation, you know, I would say that the mechanisms that we have are kind of okay but not that great. If something is a never event you are required to report it to the Joint Commission, you are required to report it to the state.

There will be many new safety issues that are created by HIT and many of them will be predictable. And we believe that it will be possible to eliminate many of those if we can identify good solutions at some places and then disseminate them. So we feel like there is really sort of a special responsibility to deal with, you know, with these issues because they're likely to happen in many places all over the country at the same time.

We don't know exactly what the magnitude of those will be but the existing approaches for safety more generally have not been I would say really terrific at addressing those issues. There have been some examples of successes and then many other examples of problems just continuing. So, we think that there is a role for some, you know, particular approach in this area.

If we can find out what the issues are by aggregating problems across the country then I think some of those other broader sorts of mechanisms like the Joint Commission can be leveraged to get hospitals to pay attention or the analogous organizations in the ambulatory setting. Around the high-risk software use cases let me ask Paul to make a comment. Do you have a thought about that?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Well, let's see this is contributing from the Risk Subgroup that matrix was developed to try to help people think through and it does illustrate, it points out – there is a big green band about the way things are implemented and recognize how important that is as a contributor both the benefits but also the risks.

And you could almost look at it as being there for whether it's the provider organizations to look at its own risk profile in implementing anything HIT in EHRs or a regulatory agency that's considering where does regulation need to apply and maybe they only pick up one piece like the process not only the quality process of developing the software but the quality process of implementing the software. And maybe that goes to the private sector as David had pointed out.

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Yeah and Bakul or Bill do you want to comment about what's already considered high-risk? I mean, there are certain things that you already consider.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
I can talk about some of the things in software that we currently look at and I think you alluded to David is the computed detection device software.

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

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
And that, you know, we talked about it last time in the post committee meeting or post committee meeting. There are other things in the radiology world, there are other things in the EKG analysis of the – that happens that's purely software and it's just – getting from a device and then analyzed for higher variability or other aspects of that, so those are the kind of examples that are currently being regulated by FDA.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
I will also add an observation that comes off of the FDASIA Workgroup's report but also the IOM Committee and that's the how do we address this implementation problem? And I think one of the major points that David made was the transparency and sharing as well as aggregation and analysis.

So it's really I think there could be so much more learned or the pace of learning quickened by more ubiquitous sharing of experiences both good and bad, and I think David's group alluded to the fact that sometimes there are some restrictions or impediments to sharing. Any other comments on this? I'm going to go to Neil. Neil?

Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health
So, this is amazing, David for somebody who has been not a part of this stuff it's so understandable and it's yet so comprehensive and I think it's just an incredible piece of work. So one of the things that's probably outside the scope but I think is really critical is the issue of what happens with users and I think we haven't even like touched on this.

I think it was at the very first Policy Committee meeting I said "well, who is responsible for making sure that people are using software appropriately" and we really haven't done anything significant in that area. So, a couple of thoughts.

So, first of all, you know, we're dealing with the safety issue like this is automobile safety but we're not dealing with licensure in terms of what does it mean to be able to operate one of these things. And I think, you know, we've moved from a point where 5 percent of the people were using EHRs to where they're ubiquitous and every single person is going to be doing all of their transactions in these systems, you know, if it's not happening already, you know, we're really close.

And so I think that moves it into sort of a different mode, you know, everybody is going to be driving one of these and yet we haven't really figured out what it means in terms of standards yet for people in a number of different areas.

So one other sort of regulatory thing we might look at is something related to professional licensure. You know, we have requirements in New York State that we have to be certified to do child abuse detection and reporting, infection control stuff, but, you know, there's nothing in relationship to anything that people need to know about safety or appropriate use of electronic health records.

And similarly, you know, in medical school we still haven't really approached the issue of medical school and residency training and the kinds of curriculum things that have to be developed in order for people to come out with competencies in this area.

And the other piece that I think is important is we really haven't specified a level of accountability for the vendors in terms of what training really means when a product is dropped in an office. And, you know, we've seen all the spectrum of stuff from people, you know, requiring extensive training to people basically, you know, drop shipping systems and having people open up boxes and follow instructions on how to, you know, put them in their office.

So I think that the idea of trying to understand what the vendor responsibility is for either certifying a level of training that people need to have in terms of being able to use the systems or sort of moving forward and at least requiring that the production of some products and things that help people at least get through the basics of what it means to operate these systems safely.

I mean, you can see when you look at not only different, as Judy said, not only different users, different organizations using the same software, but you can go into an office and go from room to room and find five different providers using exactly the same implementation in five different ways and some people bypassing critically essential parts of the software.

So, I think that there is, you know, in my opinion there's probably more errors and more mistakes, and more danger, and more safety problems in relationship to use then we're going to discover in relationship to how the screens are set up or any of the other things that we might look at.

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
So, great point and we did discuss that a bit and our suggestion was that that should be delegated to local groups and that it should be done jointly with vendors and Judy I'll come to you in a second because you have experience with this.

But, I agree with you Neil, you know, I just came from Switzerland and in Switzerland you are required to actually go through about a month's worth of training to be able to have a dog which I was kind of shocked about. But, you know, in other parts of the world there are more requirements around licensure.

Neil S. Calman, MD, ABFP, FAAFP – President & Cofounder –The Institute for Family Health
For a kid it's only a week.

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Yeah, so Judy do you want to comment about this?

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Yeah, sure a little bit on the training. I think there are several things to consider also with the training because I absolutely agree training is critical and in some areas people are able to self-train and in other areas they're not and that's interesting to observe as well.

But what we have found a problem is that if you get trainers who come and get trained and then they train others unless they've had real hands-on experience and been involved with those who are actually using the system getting teachers who are separate from real life use having them take four weeks of courses and go back and train all the med students and nurses is not real good and that's one of the problems I think we've run into with training that if you haven't lived it you don't really know how to do it. It's sort of like sitting in the passenger seat while you're driving, if you haven't ever driven it's not the same thing.

The second thing is that the nurses has to train well and I absolutely agree with that, but second to that is very often it's the organization that continues the training and that is where we have seen a lot of the breakdown as well which is sometimes the vendors are going to be actually be more critical of their own trainers than the organization is because they've pulled their own people, they've told them you're now going to be a trainer. These people go out and do the training but maybe they're not really the best trainers. Maybe they're trying to meet Meaningful Use dates and they are just shoving the systems in too fast in order to meet those dates and as a result training gets, where I see 10 or whatever, training gets not done very well because of the speed of trying to do things.

I've heard situations where people have said, yes I'm – training a little bit we're going to come back later and finish up but the later never happens. We also hear that with turning things on we're going to turn on more later because we have to get this in fast and later doesn't come around.

And so really nifty things that can help such as if you install some of the capabilities of making sure that you handle sepsis appropriately and save many, many lives, a number of our customers have done that, I'm sure other vendor's customers as well, but not everybody does it, because they have other things going on, maybe they're putting in an ERP system and they don't get back to putting in the sepsis control.

So, those are other things I think with training and setup that happen that are a bit outside the vendor's responsibility. But, I think training – the organization quality of training is also absolutely critical.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
David, you mentioned in the risk framework the likelihood of a hazardous event and that obviously is one of the most important parts of doing this risk assessment, right? And I was thinking about also your discussion of entry impedance and supporting the ability to experiment.

I'm wondering if you could take another look at that of how you're giving examples of that likelihood of something happening and incorporating the concept of the prevalence or the number of installations or the number of people exposed to it obviously has a relationship to the total likelihood of a hazardous situation existing.

And I think it's that principle is already in the FDA's framework around, you know, allowing limited use and experimentation and so forth with ability to monitor. But the way you have it now is, you know, per life years and so forth and that normalizes it down, but it doesn't include the concept of the prevalence of the total number of personal lives of exposure as it were. So, that maybe just one pointed area where you can incorporate the idea of prevalence or how widespread the use is.

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

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

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you very much and I just think this is an amazing piece of work and it must have taken you – you must have spent the entire summer doing it, it was just unbelievable. But one of the things that I really want to talk about a little bit and maybe ask you to expand a little bit more on is this transparency section and we've talked perhaps more technically on other areas, but to me the transparency is one of the key things that's going to drive the improvement in the system.

And unfortunately, I think you've got three different bureaucracies here, you know, some of which I think the FDA is probably the most insular in prescriptive and difficult, if you've ever dealt with the FDA on various issues, those who do understand, but perhaps the ONC has a little different mindset in being less prescriptive. So, how do you balance?

And then the FCC I'm not sure exactly the role that they would be playing, but if you're going to have the transparency, if you're going to have some reporting mechanisms how are you going to balance all of that with different philosophies within agencies and who is going to have the ultimate responsibility?

My thought is you really need the private sector involved in this and public/private kind of endeavor if you're going to set up some kind of mechanism to promote the transparency and the reporting and making sure that you have – that you're not going to be so prescriptive, that you're going to allow for innovation to happen. So, what was the group's feeling on that? I don't see a recommendation on that per see.

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Well, there are a number of examples given around communities that have been set up in which people, for example, could share experiences about devices or applications, or tools that they've used and that enabled people who were consumers of those things to get a very rapid sense of kind of what was working well, what was not working well, in ways that would typically not be possible if you're waiting for something to sort of disappear into a federal database and then come out later.

And I think kind of how to make that happen is a considerable challenge, but the FDA for example, at the last hearing, I can't remember who shared some of the examples about this, has some new approaches which are focused along those lines. I can't remember who –

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I would question though if you're going – those are your antidotes, how are you going to analyze? Who is going to be charge of doing the – of really looking in a broad spectrum across the country and what are the liability implications of that when you start down that road and what types – who is going to be going to use that information to do what with?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Right, so there are a variety of different consumers of the information. I mean, our feeling was that if the information is made available to the public that the public will make good use of it and that the market will move in ways that are beneficial. You know, how to set it up, how to organize it is again a substantial challenge. And I don't know, does someone from – Jeff do you want to make a comment or – ?

M
You know, these are going to be challenging issues as you have heard too also the concept of shared responsibility makes these issues about liability even more complex. So, it's something we will have to look at and I think particularly also with the FDA as we've been moving to the deregulatory one of the flip sides is that actually for a number of the products that are regulated by us they get federal liability protection. As we deregulated they will no longer have federal liability protection. So, it's another issues for us to talk about in the group.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
The liability issues are huge.

M
Yeah.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare
Thanks and again, this is a great report. And this is probably an easy question. As you went through the process and I seems to me regulations happen at a point of time, you know, and we can only deal with that point in time. In this space there seems to be a lot of convergence between, you know, what we might classify as HIT and what we might classify as a medical device. I mean, one of these days my Fitbit is going to be an HIT I think and provide all kinds of decision support. Did you have that conversation and how that might be managed looking forward?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
We did talk about that at some length and you're right I mean there is this continuum that goes all the way from, you know, from your Fitbit to something that's implanted in your heart and one of the big challenges that we tried to take on was how could you come up with an approach that is sufficiently broad and flexible that it would really allow you to deal with that sort of spectrum. You know, there are always instances in which some device, in which you can imagine substantial risk coming from a device.
Let's say you have a device that's measuring the weight and the weight is then sent to someplace in your medical record and then the weight is used to dose a meditation that you're getting that could be a substantially risky thing when initially you were just measuring the weight.

So, I think it is a big and broad question and any regulation has to attempt to deal with that really broad spectrum. We won't get everything right at the beginning. We should try to be fairly broad and this will have to be revisited periodically.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Was there a question on the phone?

Paul Egerman – Businessman/Software Entrepreneur
Yes, this is Paul, can I ask a question?

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

Paul Egerman – Businessman/Software Entrepreneur
Sure, first I wanted to add to what everybody else has said, David this is really spectacularly good work with your report I'm really impressed with it. First I had a couple of observations one is people tend to say negative things about the FDA, but, I do want to point out the FDA plays a very important role in protecting consumers on issues with food and drugs, and other devices and I've dealt with the FDA and they are good people who are earnestly trying to do what they think is the right thing.

On the issue of software and showing software as a device that to me is almost at the heart of some of this FDA regulatory issue because I listened to it, you know, Judy talks about in terms of how different users use the system differently perhaps customize the software differently. There is a point where the software is really not a device but it's really like a business process or a work process and that's not the same thing as a device, it's not something that – business processes are not something that necessarily can be easily regulated by the FDA or by anybody else. So, those are just a couple of observations.

The question that I have on the presentation, on one of the previous slides there was a recommendation for basically a customer evaluation or rating of HIT systems or EHR systems. My question is, don't we already have that from an independent agency with things like Gartner reports and Klas reports?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Yeah, so both good observations and in terms of the evaluations our belief was that we are aware of those of course and we feel that they are necessary but not really sufficient. They are typically expensive. The approaches taken to get them are proprietary and not necessarily open and our feeling was that having a more open sort of approach which was more broadly accessible would be valuable.

Paul Egerman – Businessman/Software Entrepreneur
Okay, thank you.

Charles Kennedy, MD, MBA – Chief Executive Officer, Accountable Care Solutions – Aetna
Another question, Paul?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Go ahead who is this?

Charles Kennedy, MD, MBA – Chief Executive Officer, Accountable Care Solutions – Aetna
It's Charles.

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

Charles Kennedy, MD, MBA – Chief Executive Officer, Accountable Care Solutions – Aetna
Earlier in my career...first of all I want to say this is very thorough and very detailed work and I just want to echo everyone's comments there. The comment and question I have is early in my career one of the folks who was training me said you can never separate the data from the applications, from the software and his point was that if the underlying data is fairly clean and fairly representative of the purpose you are building the application for in fact you can provide a high-quality application that people will use, but that if the underlying data is dirty or inappropriate for your objective no matter how high quality the application is you will end up with a poor result.

And as I look at this work, I don't see much discussion around the challenges of the underlying data sets and I know that may be hard to conceptualize in such a regulatory framework. But I was wondering if the Workgroup had any deliberations on that and what role data might have in this regulatory framework?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
So, great question. It will definitely be a very big challenge as we move forward especially as more data start to move around and organizations are asked to take in data from multiple other sources and I guess the place that we focused around this really had to do with the need for standards and interoperability.

If we have really robust standards we'll be a lot better off. Some of the early examples of personal health records for example though illustrate that given what we have today there are very big challenges with the quality of the data that exists in various systems today.

So, I think that is likely to be a significant problem for some time, it will gradually get better as we evolve, but it's something that we'll have to live with for a time. And we need better solutions to be able to deal with it, it's one of the things we don't really have great solutions for today.

Charles Kennedy, MD, MBA – Chief Executive Officer – Accountable Care Solutions – Aetna
Yes, just as a follow-up, I agree with you that personal health record space patient entered data is certainly one area where, you know, the data quality can be bad but even when we're dealing with things as basic as, you know, the output from a lab system and understanding the conditions with which the particular lab test was done, you know, many of the systems out there today don't deal with that level of variability very well and those can have fundamental impacts in the quality of the information that is provided. So, I do think this is an important challenge and something that we've got to address if these regulations are really going to help promote patient safety.

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

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Thanks. Matt final question?

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
I think this will be a good final question. It's been a real pleasure working with the Workgroup and the other agencies on this and this has been really constructive and, you know, as the three agencies set out to write the report that will be the recommendations to congress I view this as a unique situation this doesn't happen very often.

And I'm sure that congress will take all of our recommendations we wrote and just implement them, but if there were just one or two problems that we sought to have addressed with these recommendations and actions that we thought would address them and then looking back three or five years from now and saying did this happen? How would we know? Is there any thought around that? So, what are the top one or two problems and how to address them?

David W. Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Sure, so I think that we need better listing of products so that we can figure out what relates to what and then much more robust post market surveillance so that we can figure out what the problems were and then say this I where they came from and if we do that I anticipate that we'll be able to aggregate them and then work on improving the system.

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology
I just wanted to make a final comment. I wanted to personally thank David Bates for all of his hard work. This was the largest Workgroup we've ever had and very diverse, lots of different input as you can tell by the length and detail of the product. It was a lot to pull together and David did an excellent job and I also want to personally thank the Workgroup members who came together over the summer during vacations calling from all over the country and the world while on vacation to participate in this, it really was stupendous work and a lot of effort went into it and I just want to personally thank you.

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

Applause

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
So, should I just take that as a yes vote? We do need to approve this for its passing on to three agencies. I'll entertain a motion to approve?

W
I move.

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

W
Yeah, I'll second.

W
Third.

W
Fourth.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And all in favor?

M/W
Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And opposed or abstained? Okay, thank you very much David and thanks for that report and thanks to the whole Workgroup for the effort. Okay, we're going to move onto the Meaningful Use Workgroup update. Okay, we're back at you after last month. And I want to thank Michelle and Elise for their help in preparing some of these slides and for the Meaningful Use Workgroup that met many times by call to work out the issues that you raised – the questions you raised last time.

So, what are we going to do today, we want to review what we heard from you last time, we want to outline our new outcomes oriented framework and really connect the dots which is what you asked us to do, review the plan for analyzing deeming framework and that really fits front and center with Farzad's opening comments, and seek your approval of the framework and priorities not the detailed objectives we'll come back to you later on in the fall for those.

So, what we heard from you, now we heard a lot of things, but here are some top-level things. One you said, look we've said Stage 3 is to focus on outcomes, how do you connect the functional objective recommendations link? How do they link to outcomes? So, we're going to explain that to you hopefully.

How does it relate to – how does Stage 3 relate to the HHS initiatives such as the National Quality Strategy, Million Hearts, ACOs the things that Farzad mentioned in his opening remarks. We hope to walk you through a scenario that shows that linkage.

You said that the deeming pathway is a good direction but we need the appropriate clinical quality measures in order to make that a good program and you wanted us to address the need to reduce disparities more. So, we hope to do all that for you in this presentation.

So this is the now famous swath where we go from Stages 1 and 2 where we capture data and exchange it to the places where the patient needs it to go. Our focus on Stage 3 is to improve outcomes. So, we've built a framework that does emphasize the health outcomes and we're going to walk back from there and show how that traces itself back to the Meaningful Use Program.

So, health outcomes, first you have to measure it that's probably one of the most important things, people feel it, individuals, patients feel that they're better off but we don't really have a good way of measuring that, we still don't. We know that's a sore spot. A lot of the measures that are in current use are based on available data which happen to be claims. So, we need to do a better job of getting measures that matter to individuals.

So, we also know, and we set out from the very beginning to say this Meaningful Use Program under HITECH its purpose is to improve health outcomes of individuals and the population. But Meaningful Use has to do with software. So, those are the tools, the software itself doesn't make people feel better or get better, it's the professional and the patient and caregivers as intermediaries, as human intermediaries that apply these tools to getting better outcomes.

So, let's work backwards from the health outcome measures, the true measures of health outcome which the EHRs and PHRs do not do and work that backwards and what should a Meaningful Use HIT incentive program do to improve outcomes?

We're going to derive from those priorities what should Meaningful Use Stage 3 set as functional goals in order to help humans improve outcomes for patients?

And finally we will get to the functional objectives that's in the Meaningful Use Program so that you can see how this works backwards from the problem is solved, measuring and improving health outcomes all the way to functional objectives and hopefully a parsimony set that are reflected in HIT.

Today's discussion focuses on this really washed out green I think, right? It's focused on those two things, the Meaningful Use Program priorities and the Meaningful Use Stage 3 functional goals. Okay, so let's work back from one of the HHS priorities for the country the Million Hearts Campaign and just to reinforce the point, the outcomes are measured by these electronic clinical quality measures but the programs themselves, the software, doesn't touch it. It really in directly affects it.

The clinical decision support mechanisms of various type interact with say let's computerized physician order entry or provider order entry and the human takes that input and makes decisions that do help contribute to better outcomes.

So, Million Hearts is there because the goal is to reduce heart attacks and stroke by a million over I think the next four years. Right now there are a million and a half heart attacks and strokes every year causing 1 in 3 deaths, lots of deaths, lots of disabilities and lots of cost. And it is a great contributor to racial disparities in life expectancies an important problem to address.

So, let's walk backward from how would software impact that. Now we're going to begin with the population. So, it's often known that usability is not considered until after the software is written. Quality is not considered until it goes through QA. Let's put population thoughts at the beginning instead of the end. So, instead of measuring it after the fact 1.5 years later let's think of managing population health at the beginning.

So, we would like to have as providers, and patients, and caregivers tools that would help us identify people who are at risks for these deadly illnesses, strokes, heart attacks, people who still have uncontrolled blood pressure despite having good drugs to control them, people who haven't gotten beta-blockers after their first heart attack and people not on aspirin. Why would we want to know that? To know how well we're doing, how well we're performing as a health system.

The other reason to do that is to reach out to people not just when they come into the office but reach out to them while they're living their lives or in some cases have them come into the office because their blood pressure is not controlled or because they're not picking up their medicines which would indicate a lack of medication adherence.

So this is taking a very proactive view of population management and you heard that's front and center for people in the new payment model, for people who are managing populations like in ACOs they need this. They didn't have this before and probably most of them still don't.

What about pre-visit? This is before you're actually in the exam room, could providers, in a real-time basis or near real-time basis, know at the beginning of the day when you're in your huddle how am I doing with my panel today and who am I seeing today or who could I be communicating with today to improve their health. That would be the kind of information we need that we don't have and going back to Farzad's comments.

Patients, patients who are in the game, what could they be doing today considering their health? What could they be doing in preparation for a visit? How do they communicate so they don't even have to come in for a visit and secure messaging for example? So, there's a lot of things that happen outside of the confines of the bricks and mortar.

What about check in? Hopefully there's not much waiting going on anymore but there still is that's where we can collect some very important things that impact care and social determinates of care in particular. What about all the things that influence even the decisions that are going to be made, their race, their language, their preferred means of communication, literacy a lot of these things impact the health and healthcare. So we could be collecting that during the administrative check in period.

And in the exam room this is the time to understand what is going on in this person's life. What things do they need help with an order to prevent a heart attack or in order to prevent a stroke? What are the evidence-based tests or treatments that we should be applying to this patient? How do we avoid unnecessary tests? How do we prescribe medications that are cheaper, have the same effect that could be cheaper? So you see how you're affecting the health, the well-being, the health care and the costs associated with healthcare.

And finally, after a visit when they're not in your office, there are a lot of things that could be going on to both monitor and educate patients about their own personal health condition. Data can be uploaded to the PHR, other members of the healthcare team can be alerted, notified about any particular visit or event such as an ER visit and the information shared from one visit can be shared with others. So, in short, hopefully we're showing you the way that you would link these tools and the people using these tools to improved outcomes for health, i.e., reduced strokes and heart attacks.

What about – another question you had was what about this alignment with the National Quality Strategy? Fortunately, but by design they align very well, the reason is because both programs really derived their domains from the same place which is the National Priorities Partnership a multi-stakeholder group sponsored by the National Quality Forum.

So, you'll see the list on the left is basically the same, a little bit of lumping and shifting to the list on the right with the exception of us not including affordable care in our initial domain or initial category. We'd like to include that as we move forward. That's why that's in light green.

And the other thing we did was what we know as category one, improving the care, the quality, safety and reduce – improving quality, safety, efficiency and reducing healthcare disparities was all in category one. We've broken out reducing disparities to a separate box here so that we can pay special attention as we go forward and you'll see how that plays out.

So, let's now connect the dots and work backwards as I said from the health outcomes to the goals we have for Stage 3. So, for example the Meaningful Use HIT Incentive Program has as its outcome the following state that patients would receive evidence-based care, they wouldn't be harmed by their care and they wouldn't receive inappropriate care. So, that's the goal of the Meaningful Use Program.

The functionality goals, the functionality for EHRs in particular to achieve in Stage 3 in order to support the right most box with the Meaningful Use outcome goals are the following. All relevant data would be accessible through the EHR. The clinical decision support would support timely, effective, safe, efficient care and prevention and that it would help avoid inappropriate care. So, those are the functionality goals we'd have for EHRs that would support the outcome goals, outcome of the Meaningful Use Program goals on the right. Just for comparison we listed some of the functional objectives already in rule for Stages 1 and 2.

The next one is engaging patients and families in their care. If the world were a better place the following outcomes would be true that patients understand their disease and treatments, patients participate in shared decision-making and that their preferences are honored across the care teams. The functionality goals in order to achieve that would be the following. One that HIT provides patients and caregivers online access to health information. Two that patients have the ability to contribute information to the record including patient reported outcomes and that patient preferences are recorded and used throughout their whole caregiving process.

In the next domain in care coordination our goal would be that all members of the patient's care team that includes the professional side and patients and caregivers, as authorized, would be participating in implementing a coordinated care plan not just accessing but implementing it in a shared way, in a coordinated way.

So, the goals we have for Stage 3 would be that relevant patient information is shared amongst the healthcare team and the patient especially during these handoff periods, these transitions, that we have shared goals, care plans and interventions and that they are tracked so that we can coordinate with the entire team.

Under population and public health our outcome goals would be that providers know the status of their patient's health, their panel and that we would have bidirectional exchange with public health systems so that we can not only know things that effect each patient in our communities but also can submit information that can be used in public health administration.

So the functionality goals for HIT in order to support those outcome goals are the following, that we have efficient and timely means of defining and reporting on patient populations so that we can identify areas for improvement and that we would share information with public health agencies in a bidirectional fashion.

For affordable care the first thing we'd want to do is eliminate duplicate testing. So, there is absolutely no gain in doing the same thing to an individual. We want to make sure that we use cost-effective diagnostic testing and treatment strategies and we'd want to minimize inappropriate care whether that's overuse, under use or misuse any of those affect the actual cost and maybe detrimental to outcomes.

So, the Stage 3 functionality goals to support those outcomes, that the clinical decision support in its many flavors would avoid duplicate care, duplicate testing, that it would avoid unnecessary or inappropriate care.

And finally in reducing health disparities the outcome is that we would eliminate the gaps in quality of health and healthcare across multiple disparity variables. So, the functionality goals that would support that is that we are cognizant of those parameters, those individuals, the things that make us individuals and make sure that we recognize them and consider them when we are making care and health decisions.

So, let me move over to the deeming framework and the status of the electronic CQMs. What's the background? As we mentioned, one of the biggest probably criticisms – people acknowledge that Meaningful Use has done a tremendous amount, essentially going from 0-60 percent or 80 percent in hospital cases, of getting people to have these tools available.

But as part of this program one the concerns and criticism is that sometimes the burden of reporting is actually more than what it took to implement something. So the idea of deeming is to provide an optional pathway, an alternative pathway that allows us to reduce the burden of having to report, rewards good performance and gives people the flexibility to increasingly innovate so it addresses a lot of the things that we talked about earlier today.

This would in short be a program that allows high performers whether they're performing at a top-level or significantly improving from year-to-year that they have already met, and this is an important clause, that they've already met the functional objectives in Stage 1 and 2. We already know from history people do not go back so there is no sense in keep on asking people to sustain the reporting burden when they're doing a good job, especially when they're doing a good job.

So, the proposal is that for people who are indeed doing a good job or significantly improving that they would be deemed in fulfillment of a subset, not all, but a subset of Meaningful Use objectives. And especially note that this is an optional pathway so for example if you do not pass the thresholds for deeming that does not affect your susceptibility to MU penalties, in other words there is no downside risk here to put it in ACO terms.

Now potential elements that we have in our design and we have to flush this out, one what is a high performer? We have proposed the top core – what's a high improver, we had proposed 20 percent improvement or reducing the gap between where you are and where the high performers those are just examples and that it would be based on your prior 12 month report.

Second that there would be some measures of high-priority areas that's TBD in both the ambulatory space as well as the inpatient space and that there will be some flexibility built in. So, we're trying to recognize all of the good attributes of a regulation. So, we don't want to be prescriptive, we want to bake in flexibility and that people would pick let's say two quality measures upon which they wanted to base their deeming from each of two high-priority categories.

And finally in order to work on the disparities that they pick one of those four measures and reduce the disparity gap in that area. So, those are sort of the elements of the deeming framework as we laid out to you last time.

I mentioned up front that one of the Achilles' heels is that, well we're – do we have the right measures that would access how well is someone doing, what's their well-being, their sense of well-being as well as what is the state of their health? Well the answer is "no" we don't have enough.

So, we've charged a couple of Workgroups, one Tiger Team in particular that is made up of members of both the ACO as well as the Quality Measure Workgroup to look for HIT sensitive outcomes oriented eCQMs that could be used not only for deeming but also for Stage 3. So, they're charged to come back to us in the next month or two with those attributes of these outcomes oriented measures and some exemplars.

They have divided up their work into the following ways. So, for measures that currently exist in the CMS programs the Quality Measure Workgroup would be looking to identify those. For measures that are in the pipeline or where there are measure gaps this Tiger Team is to develop both the attributes and some exemplars or the kinds of measures that would be useful both in deeming as well as the Meaningful Use Program.

So, the next steps would be that we would develop – as far as deeming we'd look through those high-priority categories, we'd try to suggest thresholds for participation and we'd identify areas where we would like them to reduce health care disparities. Hopefully, we will have the recommendations back from this Tiger Team by October so that we can incorporate those into our final recommendations later in the fall.

So, just to repeat in terms of what we're trying to accomplish with this presentation and the feedback we're looking for from you. So, working backwards starting at the health outcomes and the health outcome measures on the right we proposed a set of priorities that align well with the National Quality Strategy and the functional goals, not the objectives themselves, but the goals that we outlined that are connected to those priorities that would drive improved health outcomes.

And our proposal, just to emphasize the fact, this is what we're seeking approval for today, and that upon your endorsement or approval in that direction, it's not noted above, but your endorsement of this direction we would go back and vet and developed the functional objectives for Stage 3 to propose to you let's say November or at least late fall so that we could move on with the program and that we are counting on both the Quality Measure Workgroup as well as this Tiger Team to come back to us with recommendations surrounding the quality measures that matter to individuals. So, that can be our milepost that can be the prize that we're shooting for.

So that's our presentation for today and we're seeking endorsement of those two green areas so that we can move on to the actual final functional objective recommendations next time.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Gayle?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you very much and I absolutely agree that trying to make it simpler and easier for people to meet Meaningful Use is absolutely the direction we need to go. My question really deals with small providers and small community-based hospitals, individual providers. How would someone who is not part of an ACO be able to use a deeming mechanism?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
That's a good question. So, it wasn't – so it is motivated by the ACO model, which says let's consider essentially the total population as well as the total cost and not just drive it on volumes, a lot like Farzad was mentioning this morning that applies to practices and hospitals small and large. So, you don't have to be in an ACO but you have to be – we are shooting towards the direction of where we're considering the health of individuals in a community and what does it take to promote that and to address that and so the tools needed that we don't have today, this real-time dashboard of how are my patients or how is my community doing? Those are the tools needed to move in that direction, but you don't have to be part of an ACO. We're just trying to give you the tools.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, Gayle, maybe the implication of your question might be that the measures, the eCQM measures used for the deeming should include not only ACO measures but also measures that are part of the other value-based purchasing and reporting programs that providers are subjected to?

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

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Got it.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
And for instance, how would a group of ophthalmologists or a group of orthopedists be able to meet Meaningful Use through a deeming process? I think as you look at this we need to look across a spectrum of the providers out there. How do I as a single ophthalmologists be able to deem to meet Meaningful Use through deeming? How would I, as a gastroenterologist, be able to do that?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
So, let me give you a couple of examples, one is for the orthopedic surgeon for example, clearly, they have measures like postop infection rate for example. What about postop walking and lowered pain that's the kind of measure we would like to use as deeming and you can see how that applies there.

And we'll admit up front, as we have acknowledged before, that there aren't as many measures of that sort for specialists as we would like and one of the objectives here by putting in this program is to actually cause more to be developed in that direction. But, that's an example where a measure that is more of the outcomes orientation, like the functional status, can apply to specialists equally.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I think as we move forward Farzad this would be very much a part of what we build into Stage 3, you know, we're anticipating Stage 4, Stage 5, you know, we have to make sure that this continues on after our existence or whatever because we want continuous improvement.

But, you know, the original program was developed to be three stages. So, by the time we get to Stage 3 and our goal is to improve outcomes let's make sure that we have a process in place that permits all providers to reach that presumably through a deeming mechanism.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thank you. On the phone – oh, sorry, Deven?

Deven McGraw, JD, MPH – Director – Center for Democracy & Technology
Yeah, so I have a question on slide 21 where the functional goals and outcome goals are identified under the population and public health bucket, so we've got – one of the things that registries can be used for is not just public health reporting but also population health analytics generally that contribute to a learning healthcare system and it feels like what's missing is the sort of the population analytics that don't deal with direct reporting to a public health agency but again contribute to the learning healthcare system.

So, I would just suggest that there might be a missing bullet here that has to do not just with how well you manage the patients in your office or how well you do public health reporting that's either required or recommended but in fact are you also contributing such as through the use of registries to learning generally that isn't tied to public health.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC
So, you're saying that the original objectives we showed you may be missing, but isn't that – that's what we meant by that first bullet, efficient and timely means of defining and reporting on patient populations not reporting to public health agencies, it doesn't say to public health, so that is the registries right there. So, does that cover what you're suggesting? That was our intent.

Deven McGraw, JD, MPH – Director – Center for Democracy & Technology
Yeah, I mean, I thought it was our intent, I think maybe – I mean and we can work this through, approach completely acknowledged and I believe it is was what was intended, it just wasn't entirely clear.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC
So, you're saying make sure that when we translate this bullet to functional objectives that it's not just to public health agencies?

Deven McGraw, JD, MPH – Director – Center for Democracy & Technology
Exactly, thank you, George.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
– all right, go ahead.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Yeah, so back to that same one the MU outcome goal seems more like a functional goal this bidirectional reporting so that we might want to reword that to be more parallel to the first bullet there which is maybe, you know, public health or population health managers know the status of their population.

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

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
David?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
Thanks. Thank you Paul and the Committee for working on this for months and trying to get it to where it represents everything we need. I think the clarity of this framework is really good and you've done a really nice job as you did working backwards from the goal to the structure.

I think in general the framework we've had for 3 or 4 years, which we've talked about as of late but under a more crisp and graphical way which is good and I think the fact – you mentioned that the action is on the outcome measures their availability to drive this process everything else is an estimate or an approximation of what's relevant to the outcome measures. Absent the outcome measures we're still kind of in the same suit and I think the pressure on the subcommittee as you talked about is very significant to develop something.

And I think that raises the question of if the measures are essentially newly introduced to the program which captured the outcomes you've flagged we don't have data on performance yet so what are we deeming? We're essentially deeming something from the old measurement world which may or may not be correlated with the outcomes we're trying to accelerate and improve so that's a little troubling to me.

I just want to make a couple of points about the model so far. I think the recommendation that CMS should survey the landscape for CQMs whether we support the pipeline both are valuable, we might do a little more to specify the criteria that represent successful measures that support the outcome goals we've talked about so that when the scanners for measures scan they'll know when they find a winner and I think we've had some proposed outcome measures that have not been very good at measuring outcomes and we need to be clear about what it is we're looking for to populate that far right of the diagram.

Secondly, I think we should distinguish performance on outcomes that you haven't measured from performance on older process measures that we know don't always correlate to outcomes improvements and I'm hesitant to deem organizations on performance of older established measures which may predate the Meaningful Use Program and therefore they get waived into Stage 3 Meaningful Use because they used this for 20 years successfully on HEDIS and other measures that we're still taking through the system.

Thirdly, I think measures don't correlate to infrastructure or that is our ability to specify a worthy measure doesn't mean we have the capability of measuring it and going to Gayle's point there will be many providers who may be very important in the chain of producing a good outcome. The surgeon in the operating room is important to the successful ability to walk six months later but it's not the only contributor to that outcome.

We're going to have to be thoughtful about whether to attribute the performance of all the providers who may not be linked through contracts or ACOs or otherwise to the attainment of an outcome which they all contribute to for this program. So, we may all agree, I would agree, on functional outcome measures for orthopedic surgery as a desirable outcome whether it's appropriate to include that as a metric for deeming in the Meaningful Use Program is something we should talk about.

And secondly, I'm concerned that we don't have the infrastructure to capture that outcome measured today. We have not certified in the EHR program the capability of capturing those outcome data in the EHR product and we haven't been very thorough yet in specifying registries or other data intermediaries who might capture all the data across the continuum of care to support an outcome measure.

So, I think this model gives us an assignment in a way as a Committee to work equally hard on interoperability and intermediaries to support outcome measurement in the e-enabled world recognizing Gayle's point that a lot of the individual contributors to this are not representing themselves as ACOs or HMOs or rather parts of the continuum of care or episodes.

So, I think that's the main thing I'd like us to give to some thought to is this by itself has kind of a structural flaw in it around our ability to capture the outcome data and then hold everybody contributing to that system accountable in the sense of economic penalties and rewards through the Meaningful Use Program.

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

So, good questions David or good comments. Your first one has to do with well how would we recognize a good CQM if we saw one and there are two things. One is your group about over a year ago put together some of those attributes when you came up with some of the concepts and that's one of the charges to this Tiger Team is to go look at that list of concepts and the other is a more explicit charge to the group is to come up with those attributes so we would recognize one if we saw one all in the space of then next, I think, four weeks.

But, at any rate we're trying to both enumerate the attributes of a good CQM and some exemplars of like what would one look like actually recognizing that most of the thing is going to be forward looking or future looking.

You did point out the quandary of, well how are we going to get the improver function if we don't have the new measures yet? So, Stage 3 is at least a few years off and so our hope is that we provide some of the motivation to get some of the measure development and testing underway so that it could come out before Stage 3 or before the deeming program comes into existence because "yes" you'd have to have something to measure against or even to benchmark in order to get top core. So, those are some of the Catch-22's but if we don't start now we'll obviously never get there.

Your last point about the structure is sort of interesting that's the important part of that diagram showing that the Meaningful Use Program only applies to the left-hand side of that line. It doesn't regulate, yes it does regulate in some sense the Meaningful Use of these tools, but it doesn't cause good things to happen by itself and you pointed out the other pull that we're counting on, if you remember the handoff, the tunnel we talked about early on is this talks with getting some of these tools in place and by golly we've been doing a really good job of doing that.

But we're relying on the pull from like CMS Programs and ACOs to tackle that last mile of getting the data created, captured and moved around. So, we're going to try to tackle the interoperability with Stage 2 for example and set it up for Stage 3 outcomes, but I think it's the motivations that you talk about that are going to have to actually do the pull, but we're hoping to at least reward good performance in that direction.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, David, just to capture kind of the actionable implications of what you said, one is you agree with the concept but the devil is in the details and we should not allow deeming – that there would not be functional equivalence of the objectives for measures that are the old process heavy measures. So that if we do deeming they should really be things that capture the full intent of what we're supposed to accomplish.

And the other point I take from your comments is that this does not exist in a vacuum and we have to connect this work and these measures to the broader conversation around how healthcare reimbursement is shifting to reward outcomes. And if we can be certainly aligned with, but if in fact an accelerant to getting measurements that matter for those other quality programs, and I think that is certainly the spirit within which Patrick Conway and Kate Goodrich and others at CMS see this, then these programs can be mutually supportive of each other rather than in isolation to each other.

I will point out that the physician value modifier for example starts with large physician groups 100 plus, right? And then there is a plan for it to then go to 10 and over and then the smallest practices later in recognition of some of the attribution and other challenges that you mentioned, but I think it's going to be very important, it's very fortunate that the drafters of the regulations are going to be at CMS, our colleagues at CMS where both of these trains are headed to the same destination and keeping those connections I think will be important.

My final reflection, David, is the measures need not be all collected or I will ask whether the measures need necessarily be collected in the EHR to be used for deeming. So, if we have a claims-based re-admission adjustment that is being used for measuring coordination of care, whether that might be an appropriate measure to be used for deeming of transitions of care for example and I'd like your comments on that.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
Yeah, I think those are really good points and appreciate your comments Paul. And I guess that goes to what I was suggesting about registries and data intermediaries. To the extent we can begin to talk about another layer of data capture which could permit us to assess outcomes and then in turn make Meaningful Use rewards based upon performance measures elsewhere that's good.

I haven't seen an explicit sort of allocation what's in the EHR, what's in another platform to capture the data of interest and If I'm a potential – if I'm the user how do I know which platform I'm talking to to get the validation of my performance. So, that infrastructure should be made more clear in the next couple of years.

To your point, Farzad, I think we and my purchasers are very concerned that to succeed with the payment changes and the structural changes we're advocating we need this data platform to be widely available and we're in a Catch-22 now where which comes first the payment incentives to pull people through or the platform that enables people to be measured and rewarded and we've got to sync them up really tightly, I know you are working on that closely with CMS.

But, my concern about this model is really how does it really get played out in the operational side of certification and data intermediaries.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Let's go Marc and then Judy, and Gayle.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
And Farzad, if I could get in the queue?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
All right, you'll be right Gayle.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare
I think I skipped the line but that's okay. I thought one of the premises that you talked about Paul was that the tools were in place and that people don't go backwards and that is where you're going right? I mean, some of the measurement requirement would hopefully diminish because, well, for instance, I'll just use CPOE and it's not a great example, but – well actually, I'll use a wrench.

You know, if you're working under your car sometime and you're trying to pull a bolt off and its stuck the right thing to do would be to grab the hammer and loosen it, but you know, you have the wrench in your hand it's just as easy to bang it with the wrench and at times I feel some of the Meaningful Use requirements to date are a little too prescriptive but if we do have the tools in place and if CPOE is the right thing, you know, hopefully people are using it. So, part of this is definitely looking at how we minimize that measurement component and move into just outcomes.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thanks, Judy?

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
A few things here, I'm a little confused about deeming. Do people get to do deeming in some things and not others or is it deeming across the whole thing? Do you substitute deeming for doing MU3? So, in other words if I'm really good in orthopedics do I get to deem for orthopedics? But if I'm not hot in diabetes do I not deem there? Do I have to be good in everything?

And even within them in orthopedics maybe I have really good hip results but not so good spine or in diabetes I'm really good in adults but not so good in pediatrics. How do we handle that? Is the definition of doing deeming meaning you have to be passing everything or not everything?

And what about the things in Meaningful Use 3 that have nothing to do with quality, clinical quality measures? What about things like keeping certain data elements? What about things like interoperability requirements or sending things to registries, or patient engagement things? So, I guess I don't understand really is deeming, you pick this and this, and this, and you get your choice or is deeming, it replaces MU3?

Then how does an organization know its high-performance, maybe they all think they are or some of them do and how can they measure that and again, you get down into well pediatrics versus adults or which part of ortho? And so that's my second question.

My third question is we were kind of thinking of it as for the larger well known high-performing organizations, but if they can substitute deeming for Meaningful Use, and I'm not arguing one way or another I'm just thinking it through, then shouldn't that be available to others who may not fall into that category but still are excellent in this piece or that piece?

The fourth thing I have is does deeming mean that vendors need to create two sets of things? One thing is for all the measuring of performance for Meaningful Use and the other thing is for measuring all the deeming evaluations that need to be done because that's going to be significant?

And then the last thing I have is, and I have some analysis of all the SGRP number things and there's a lot in there I would recommend that we focus on that have to be things such as what requires standards that says the EHRs should do this but really the standards aren't there to do this, because I think we can actually get into more of a mess if in fact we don't put the standards in first which is the Maslow's hierarch, I think, bottom set first you have the standards and then you apply them to what you're doing.

Then if we say to all the vendors go do this but there are no standards to do it against and all we're doing is creating stuff that later on the vendors won't be able to interoperate well. So, there's quite a few things that I think were in there that didn't have the standards first.

And another thing I think we have to look at too is when is it not an EHR. So, for example there was something on labs, what was it, EHRs must have the ability to identify abnormal lab results. Well, the lab systems define what's normal and abnormal not the EHR. So, is it clear when something is – when we should be saying take from the lab systems rather than do itself. So, there's a lot of those subtleties in there that especially the setting first of standards that I think have to be addressed.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Do you have solutions for those, Judy?

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Well, you know, it's really interesting, if you take the fact that there about 120,000 data elements and it took two years – we're getting faster now, but two years to do about 4 of them, so you divide – that's 2 a year, you divide 2 into 120,000 that give you 60,000 years.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
I think we do a little more than four. Just in terms of the guide post for the conversation today, Judy we're taking a step back from the SGRPs of the abnormal lab results and what's the scope of that.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Right.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Particularly for this reason, right? We want to get the broad understanding of why these things, that I think was lacking last month where people said, how does this relate to the need for new models of care? How does this relate to quality? We're moving it up a level, we don't want to go back down Judy today.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
No, I'm okay with that but I don't want it to be a mandate to go ahead with things that won't work because we've approved a high level.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, we're not asking for approval today of like the abnormal lab results and the implications of that.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Okay.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, Paul, maybe you could address some of the questions about the deeming.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Right, thank you for that. So, one is in the ideal world we would have a measure for everything and for every specialty for every case from the nose to the hip. But we don't have those so we're looking for proxies with what we do.

The analysis I might make is Toyota is known for its quality but we don't have a measure for its speed, speedometer and its left locking mechanism you just say they want to get good products out there that customers like. Similarly we're expecting, counting on providers who say they like to deliver high-quality care and have their patients write good things about them and they'll figure out what it takes to do that.

So, if you pick some exemplars, some important exemplars of good quality – the outcomes of good quality process management then it's a proxy for saying these are high performers and they're probably not going to slack off on the – because they do kidneys and that's about the only thing we can do in the absence of really good quality measures.

We talked about the problem of do we want better ones? Yes we do. So, people would not be expected to have a thousand measures through all aspects of their care even if they're a specialist to be deemed and also they would not be deemed for all of the functional requirements just for some subset that can be reasonably assumed that a high performing organization would be attending to without actually proving it.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
So, I'm not quite getting the answer.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Just one little short – so remember the spirit of this is we're trying to reward good behavior and also we're trying to reduce the burden of having to work with this program as we're passing it off to other incentives like payment models that reward the good behavior. So, given that context maybe.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Paul, Judy had asked is it that if you do well on a certain quality measure you're deemed from all of the Meaningful Use requirements or for a section?

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC
So, I would recommend we not split up the deeming program. So, you get deemed – so it's one program you deemed or you – this is my recommendation, you get deemed or you don't. So, we have a minimum set that's broad enough that we say you are deemed and then what you get deemed for is a subset of the functional measures. There are some that don't get deemed because those are the ones we're pushing forward and we don't believe they're deemable or because there is such high priority. There are different criteria by which we would not deem it.

But I wouldn't break it up into now you're deemed for patient engagement, now you're deemed for population health, if that's where we want to go I would incorporate that into how we would define the objectives instead because the program will get too complicated to have exceptions for objectives and then have deeming for objectives. So, we either deem as a whole for a subset of all the objectives or you don't get deemed that would be my recommendation.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
But, I guess that's part of what needs to be worked out yet.

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

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Is what we – I think if folks have suggestions for how we can make this deeming approach stay true to the intent but yet be feasible and implementable, this is the time to give that input to the Workgroup. What we're doing today though is we're not seeking approval for any specific approach to deeming, but the concept that if we can find the right measures that matter that there would be an ability for folks to get away from having to document the specific functional measures that they are doing. I will note specifically Judy mentioned data elements, keeping data elements.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Yeah, that's some of it.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
And I think to go back to what Marc said, yes the idea is that if you've been for four years or five years you've been collecting problem lists or medication lists then you're unlikely to stop doing that once you're a Stage 3 user. So, yeah, part of the idea here is to simplify back around, you know, keeping track of data elements and focus more on the later parts of the curve.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
So if you divide it into several things. One, it's all clinical areas rather than individual clinical areas you're saying it's all clinical areas. Is that correct? Not the individual clinical areas?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, if you look at the slides from slide, what is it, 18 through 23 it has in different categories, it lists the – where we have the current Stage 1 and 2 functional objectives and the Meaningful Use outcome goal that we're trying to get to. So that's where, you know, there's a certainty here and I think this is very useful for people who say, you know, how do these individual requirements how do they go together, how do they work together? So for safety there may be a series and if there is –

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Okay, so each of these is its own category?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
These are the six categories.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
And you can deem against those categories?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, we haven't figured –

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Is that –

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
To be determined, to be determined.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Not decided. Okay, to be decided.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
To be determined.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Okay, so then you have those six areas that you'll decide whether to be deemed against and in addition there might be other areas that you can't deemed against? Am I understanding that correctly?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, privacy and security for example is a –

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Yeah, right, exactly, lots of interoperability, yeah, okay, thank you.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
We're trying to make it simple.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And just to answer one of your specific questions Judy, no we aren't expecting vendors to have to do another thing, because these would just be quality measures that people are already reporting on they just now have a benchmark.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Before we go back to Gayle, anyone on the phone want to make a comment?

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC
Christine was after you.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Christine?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Yes, do you want me to go now?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Please.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
So, thank you Paul and thank you Michelle for putting together the great conceptualization of the outcomes oriented approach. I just wanted to confirm and express my support for what I think I heard Paul say which is that the Workgroup will go next to looking at making sure the criteria we have to support the goals and are robust enough.

The reason that I say that is I because as I am listening to your presentation, Paul, I think there are some areas like disparities and the care summary, and consumer upload of data where we do have some work to do. On the consumer upload front we did receive a letter from a number of patient advocates in support of that and also I know the Consumer Technology Workgroup of the Standards Committee has been making great progress. So, I think it is a good time to sort of go back and do a double check and I wanted to first ask if that is what I heard and make sure that is the case?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Yes, we're only seeking endorsement of the goals points.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Right, right.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And then we have to re-vet the objectives.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Great, okay. So, on the second piece on deeming, I agree very strongly with the concept. I do have some concerns that we'll be able to operationalize it, but, you know, we'll see. I think we're doing all the right things but I do agree with David that we should be hesitant to use some legacy measures as I might describe them.

I think with respect to David's comment of Gayle's earlier point about being thoughtful with respect to how we hold people accountable where they may not be the only player, I'm actually okay with that and the reason is I think even if they're not part of an ACO, the deeming pathway is voluntary and I think providers are likely to only select it and to select specific measures that they feel they can have an influence on.

So, I think that's good and I think, you know, we're not necessarily talking about having them be perfect performers but improvers. So, if they think they can, you know, as a primary care physician help improve a patient's functional status because they've got an integrated practice that can support that then great. So, I'm actually okay with that.

I think the one thing that I remain concerned about and I know we're not talking about it here is the list of what gets deemed and I just wanted to remind folks that we did receive a different letter from 17 different consumer groups who were very concerned about deeming the patient facing criteria. So, I just want to put that in the parking lot list of things to address as we try to operationalize the deeming pathway. But again, I do support it's concept and I support the outcomes orientation that we've described here. Thanks.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thank you. Gayle and then David?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Yes, thank you very much. Maybe this is little too much in the weeds if you're trying to look at this at the, you know, 40,000-foot level. But as we move forward and get down into those weeds and think about operational, how you're going to make deeming work? I think we have to really consider how you're going to do that and what analytics are going to be available to do that. Are those analytics going to have to be built into the EHR? Is that something we are going to expect our vendors to provide?

Because at that point it becomes, I would think, rather expensive and are you going to...does that become a choice then if I'm a little provider and I just – you know, I know I'm just going to try and meet Meaningful Use and I don't want to pay for the expense of a module that's going to do deeming or are we going to have independent deemers out there who do – you know, who analyze – who are going to do the analytics, especially if we move forward if a physician is responsible for other providers out in the community, the orthopedic surgeon is then responsible for the physical therapist who is not part of their organization and they don't have an electronic health record. How is the system going to work?

So, as you think of deeming, you have to think through the whole system as a continuum and make sure that the tools will be there in order to do it and what is the cost of doing it and are you going to have outside providers, vendors selling the analytics to do it. So, what's the goal and how are you going to operationalize the entire process?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
It's a great question Gayle. This would link to an important tool that in our initial proposal for Stage 3 we had included, and that's this notion of a near real-time dashboard. So, I would observe that in a lot of these value-based, pay-for-performance kinds of programs the providers pay attention to that in the remaining quarter of the year and then they work on in.

The purpose of the near real-time dashboard is literally almost every day you have a huddle for a number of reasons, can't you huddle and understand where do I sit today in January rather than December and say, what can I do to be better, that's the critical tool that is totally missing and if we had that, and that is one of the things we're going to be considering, I think that would not only help people achieve the high performance, but actually a very good intrinsic reward system for the individual providers who just would like to know am I doing better today than yesterday?

It can work or observe it to work magic. So, to answer your question that is a new functionality that could be an example of a Stage 3 functionality that I think would be instrumental in helping people to achieve high performance and then we'd like to have the deeming program reward them for accomplishing that. That's how it would work in the ideal case.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
And Gayle, I think the point – I was talking to a small practice doctor 10 days ago who said, you know, if there is one thing you could do, why do I have to put in these G-Codes? I spend half an hour a day putting in G-Codes and I said "oh, but your reporting quality measures through Meaningful Use?" She said "yeah" I said "well, you know, they can't for PQRS."

So, part of what we have to do is we have – working with our CMS colleagues at CCSQ have created a framework where we're moving very rapidly towards the concept of report once, use many times. And the minimizing burden and minimizing costs will really rest critically on how well we can get to that point where the same quality measures that they have to report any way for PQRS, the same quality measures that the hospitals are reporting for IQR, the same measures that are frankly going to be used for ACOs and the same measures that are going to be used for the value modifier which may be more money actually at stake on those then the Meaningful Use, those are going to be the same measures that we need to I think coalesce towards.

I'm not saying it's a one way street, David, that whatever those measures are that Meaningful Use will use them too. I think it's a two-way street where Meaningful Use can be in some ways the point of the spear towards more accurate, more reliable collection of quality measures, the intermediaries may be an important means of getting new measures reported but any reporting should be able to be used multiple times for multiple programs. I think you have the administration's commitment on that. David?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
I wanted to kind of clarify what we are going to vote or consider here today, the green boxes on our slide. In the material you went through in more detail Paul there are the bullet points inside each green box inside each priority area and are those meant to be substantively what we are asked to endorse going forward, those bullet points if you like?

And how does that mesh with, going back to Christine's point, the concerns we heard from people at the previous presentations about some of the elements – in the previous point in the development of this we were looking at specific quality measure examples that might be used for deeming. We got some feedback from some of the groups indicating they didn't think those were the right metrics to test appropriateness for deeming for example on patient engagement. Is the consideration at this point to put aside the questions of the previous examples of measures pending the further reporting back of the new subgroup?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yes.

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

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
And we'll come back to that question of which measures link to which outcomes, etcetera later.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yes.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
In November or whenever that is. So, today we will take, and I think probably all of us could tweak the wording and the bullet points and whether the right concepts are reflected there. I have my own concerns about some of them. But conceptually you would like approval of that structure and those bullet points, but there is still some opportunity to revisit those later on?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yes. So, with that can I move the Committee to approve the framework laid out here today? All in favor?

M/W
Aye.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Abstentions? Judy. All opposed? Okay, thank you.

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you I want to personally thank George and Paul I have seen the number of hours that they put in and e-mails at all hours of the day and just want to thank them for all of the hard work that they have contributed to the Meaningful Use Workgroup.

[Applause]

Public Comment

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
With that it's now time for public comment. If there is anyone in the room that would like to make a public comment, please come up to the table. As a reminder, public comment is limited to three minutes and operator while we wait for people to come up to the table if you could please open up the lines.

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute
If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Janet Marchibroda, MBA – Director, Health Innovation Initiative – Bipartisan Policy Center
Hello, I'm Janet Marchibroda, I direct the Health Innovation Initiative at the Bipartisan Policy Center. My comment is in reference to the earlier discussion about FDASIA. We commend the Workgroup for all of its hard work and effort it was amazing how much time they spent. We concur with the Workgroup's observation that a new framework would be helpful and should be explored.

The BPC convened about 100, more than 100 consumers, clinicians, hospitals, technology companies and PSOs to develop principles and recommendations for such an oversight framework which reflect many of the things that the Workgroup laid out learning environment, reporting, reporting, reporting, education, training and the like and we say, for the record, as part of this meeting, we encourage policymakers, the administration as you consider and develop your final risk-based regulatory framework for Health IT that you take into consideration the BPC report.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you.

Lindsey Hoggle, MS, RD, PMP – Director of Informatics – Academy of Nutrition & Dietetics
Good afternoon, my name is Lindsey Hoggle I work for the Academy of Nutrition and Dietetics and I just wanted to applaud the work that you're doing. I see how many hours you've put into that and especially focusing on initiatives such as the Million Hearts Campaign.

One thing that we have done for the past four years is to listen to the proceedings of these meetings and have develop standards within HL7 for diet order, nutrition messaging it is under a one year draft standard for trial use which means it will be ready for Stage 3. I know this is the Policy Committee but I understand the relationship between what has to be out there.

We also have also worked on allergies and intolerances and have that as a draft standard, the main analysis model right now. So, I just ask that you consider those for Stage 3. I see this as an opportunity, a rare window of opportunity to put in nutrition were sometimes we put in medication. There are a lot of times where we can modify the nutrition for an individual and it changes the direction in the course of their treatment.

An example was last night a friend of mine, a college roommate called, 55 years old and has a blood glucose of 120. Her plan was to monitor the blood glucose, report it to her doctor, try to lose a little bit of weight and try to delay the process of medication at the age of 55 for high blood sugar. So, I just think there's a lot of opportunities there and I would ask again that you include nutrition for Stage 3. Thank you.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thank you.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Is there anyone else in the room that would like to make a comment? We do have another comment on the phone. Wes Rishel.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated
Hello, this is Wes Rishel from Gartner. I like everyone else am excited about deeming and recognize the cautionary comments particularly from David Lansky and Gayle with regards to two issues. One is, well they tie together because small practices, particularly specialty practices are out of control of many of the factors that affect the outcomes of their patients and that they are data starved because of the lack of access to the necessary information to measure the outcomes of their patients.

At the same time, I think, we as a country are struggling with the informational and clinical integration and all kinds of issues associated with isolated practices that are not part of organizations that can put in place long-term measures and make long-term measurements.

Given that deeming is an optional path, I think that it would be a shame to deny that path to entities that do have access to the data and clinically integrated because there are some entities that are not so fortunate and it may have the reverse direction of if those options are available to entities that are data starved, they may become advocates for health information exchange with a level of intensity that they have not been so far. Thank you very much.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you, we have no more public comment.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Okay, thanks everyone. So, we will adjourn for lunch until 1:30. Thank you.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
If everyone could take their seats, we're going to get started in a minute. Operator, can you please open the lines?

Operator
All lines are open.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you. Rob Anthony are you on the phone?

Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid
I am.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Okay. Paul do want to get us started or do you just want to hand it off to Rob?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Sure, I'll get us starting by handing off to Rob. So, thank you Michelle.

Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid
Well, after that illustrious introduction, I will dive right into this and I know that you guys have a busy agenda today so we're keeping this one short. So, we'll just go through the overview of the registration and payment data. One of these things that we will not go through today is the attestation data. I think that a lot of high levels of performance that have leveled off. However, if you visit the data and report section of the CMS EHR Incentive Program's web page anybody who is interested in that information will be able to get it.

So this shows active registrations for July. As you can see we have a sizable number of folks who are actually registered for the program. If we move onto the next slide and we do include Medicaid here every month that we can show that breakdown between AIU and MU the adopt, implement, upgrade payments and the Meaningful Use payments, one of the things that I like to highlight is this increasing trend that we are seeing with Meaningful Use under Medicaid and you can see that we have over 19,000 eligible professionals who have actually achieved Meaningful Use on the Medicaid side and almost 1700 hospitals that have achieved Meaningful Use and obviously many of those hospitals are duly eligible so they are achieving under both the Medicare and Medicaid, but we're definitely seeing that curve happen with Medicaid Meaningful Use. Next slide.

So, as of the end of July and I am sorry that we were not able to get more recent August figures for everybody with the Labor Day holiday but we were at nearly $16 billion in incentives paid. If we move to the next slide you can see that we have over 315,000 unique providers who have been paid in the program to date. You can see that that includes almost...we are so close to 200,000 Medicare EPs and also very close to 100,000 Medicaid EPs, over 4000 eligible hospitals under that as well. And again, this is as of the end of July. Next slide.

So, in the interest of time I combined a couple of different slides that we have eligible hospitals as of the end of July. So, that means we have about 90 percent of all hospitals that are actually registered to participate in either the Medicare or Medicaid programs or both. We are at a little over 80 percent of those hospitals actually having received a payment under Medicare/Medicaid or both. Next slide.

And, this illustrates where the registration and paid eligible professionals are under Medicare and Medicaid. You can see that we have a sizable majority of eligible professionals registered for the program about 77 percent obviously not quite as many who are being paid at this point in time, but you can see below that we are very close to about 60 percent of all of the EPs who are eligible to participate in the program having received a payment Medicare or in Medicaid. Next slide.

This is an illustration of the number of Medicare EPs by specialty. We are now at 63 percent of all of the Medicare EPs who are Meaningful Users are non-primary care and this is just a breakdown of all of the different specialties but you can see that there are many that are represented here.

If we go to the next slide , you will see that August, as I had predicted last month, was somewhat of a slow month for us as far as payments being made about 2400 Medicare EPs were paid, 4000 Medicaid EPs and about 175 hospitals, so a little over 6500 providers, these of course are estimates and we'll have hard figures towards the middle of this month. But next slide.

We illustrated this for July as well. June, July and August tend to be among the slowest months historically within the program. You can see where those levels are here and obviously as we look at November, if you look at November 2011, if you at November 2012 you can see how that graph starts to the rise and certainly in January and February and so on we see a sharp spike as more people come into the end of the year. So, it looks like 2013 will proceed with that same type of curve and we'll start to see in a few months more Meaningful Users come in.

We're also at a point where we have a large number of people who have already been through their first or second year so they'll be doing a full year of Meaningful Use and we obviously won't see any of those people come in until January or February either. There is less of a population of first-timers coming in during that space. Next slide.

So, at this point in time we have over 220,000 Meaningful Users through the EHR Incentive Program, about 3300 hospitals, about 19,000 Medicaid EPs and a little over 200,000 Medicare EPs when we look at both individual Medicare EPs and those who are participating with the Medicare Advantage Organization.

And then if we go to the next slide, this is just for folks who need it here is a link to where the data and reports page is, you'll be able to find a full slide deck there in just a couple of days and we will be updating those August reports relatively soon as well and if anybody has any questions I'm more than happy to field the Committee's questions now but if anybody has any questions separately please feel free to e-mail me.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Rob, Jennifer or Steve?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology
Ladies first.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator
Okay, great I'm just going to zip through some of the usual updates here and then Steve and I are going to present some new data on progress to certification under the 2014 edition. So, starting off to look at comprehensively across all of the incentive programs and the Regional Extension Center Programs you can see that a large majority of hospitals have attested to Meaningful Use as of July 2013 and the vast majority are engaged with either the EHR Incentive Programs or the Regional Extension Center Program and the penetration of Meaningful Use is even higher if we look at this in terms of the percent of hospital beds or discharges in the country.

Looking at the latest trends in attestation by hospital type we can see similar trends to what we saw last month with some disparity by size and critical access hospital status. We've seen a little bit slower growth among critical access hospitals in the most recent several months then we have among some of the small rural and other larger hospitals but as we saw at the end of 2012 we're hoping that we'll see another spike in their participation towards the end of the program year.

One thing that I wanted to highlight here is the percent of hospitals that had attested by the end of program year 2012 so just over half of all hospitals had attested at that point ranging from 43 percent of small urban hospitals up to 60 percent of small rural and larger hospitals. So this is the group of hospitals that will be moving to Stage 2 in 2014.

Shifting to the professionals, we can see here looking across all of the programs that the majority of eligible professionals are engaged with either the Regional Extension Center or the CMS Incentive Program and about 45 percent of all EPs have attested at this point with an additional 15 percent having received AIU payments.

Again, looking at the trend time over time, as Rob pointed out, here this is among just the Medicare professional. We're in the slow stage of the reporting year so we haven't seen a whole lot of growth in the most recent months, but again just wanted to highlight that as of the end of the program year 2012, just over half of Medicare eligible professionals had attested to Meaningful Use. So these are the folks that are going to be moving to Stage 2 in 2014 as well. And with that we'll move into the 2014 certification update.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
All right, thank you, this is Steve Posnack. So, I'm going to cover four points to remind folks of the sort of policy overlay, the shift that occurred in, I believe, our rules published a year ago today or less, yesterday. If you want this day in regulatory history Stage 2 and standard and certification criteria, final rules were published and that will hopefully give you some additional context for the numbers and metrics that Jen is going to be leading into as she takes the baton back.

So, one of the biggest changes that we made and that I covered with folks when the rules came out was the change to the definition of certified EHR technology and we made this a more flexible, dynamic definition if folks remember the bull's eye diagram that I showed to be driven by the stage of Meaningful Use that a provider seeks to achieve.

So under the revised certified EHR technology definition eligible providers need to have EHR technology that satisfies what we call the base EHR definition which is a minimum set of core capabilities plus at a minimum anything else that they needed to support their achievement of the stage of Meaningful Use that they needed to meet.

So EPs that are seeking to achieve Stage 1 don't need EHR technology certified to support Stage 2 requirements until the point in time when they reach Stage 2. So, that will change fundamentally hopefully how certifications are scoped and how vendors seek to get certifications going forward which will mean, hopefully, we will see a shift towards more EHR module certifications that, as I've also discussed in other presentations, what I like to call right size certified, closer to what the eligible provider or eligible hospital needs to use to demonstrate Meaningful Use based on what they're trying to accomplish.

So again, what that means is that complete EHRs from a certification regulatory perspective that designation still exists we've seen a lot go forward and get certified to that, but its relevance will diminish to a certain degree as I think we expect more EHR technology to be presented for certification to a more appropriate scope for the type of customers that are out there.

So teasing into what the certified HIT product list is and we call it the CHPL and nondenominational. So, the CHPL is a listing of all products and subsequent versions that have been reported by the ONC ACTBs under the temporary certification program or now under the ONC ACB, Authorized Certification Body, so it's a cumulative list of all certified products that have gone through the pipeline not the list of unique products that have been used for attestation and not the unique numbers.

So, if folks use the top line numbers from the CHPL they will be significantly overestimating the actual number of products that are really out there. So, that's an important point to keep in mind as Jen starts to tease into the data that they have.

And then the one thing that I have found particularly interesting that I have somewhat tracked which will also feed into some of the pie charts for the ambulatory setting 40 percent of the vendors that have a product listed on the CHPL have never been used in an attestation and it's 50 percent for the inpatient setting. So there's a lot on the CHPL that has never been used for a single attestation.

And so that's important to context to keep in mind that when you look at the broad numbers of thousands of products, thousands of products represent iterative versions that vendors have brought forward to keep their certification current and products that someone brought forward seeking an opportunity that never came to fruition that they weren't able to secure the right, you know, customers, etcetera.

So, there is a lot that I think we will see shake out as part of the 2014 edition certification some of it being folks that never had products use will, in some case, likely not come back. So, now I'll turn it over to Jen who will start from that lead in there.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator
Great, thanks Steve. So, where are we in terms of certifying products to the 2014 edition? This slide here shows the progress from the lens of professionals. So, as Steve pointed out, if you take a look at the CHPL as a whole you'll find 991 vendors that have any certified products to the 2011 edition and the vast majority of these vendors only have a product in the 2011 edition and do not have products certified for the 2014 edition yet.

So 6 percent of those 991 vendors have a 2014 edition product available, 16 of these vendors have a product that meets the base EHR criteria for 2014 and another 40 vendors have a product certified to the 2014 edition but not one that meets all of the criteria for a base EHR.

But, as Steve pointed out these vendors are not necessarily being used by providers to attest. So if we whittle this down in the next pie in the middle to there to the number of vendors that have actually been used to buy an EP as their primary vendor for attestation in Stage 1 we see there are 469 vendors that have served this role, but again a small percentage of these vendors have products certified to the 2014 edition at this point, 14 of them have a base product certified for 2014 and 7 have a product that doesn't meet all of the base criteria.

However, if we look at this in terms of the number of EPs that have attested we see that 66 percent of EPs are covered by one of these vendors that have a 2014 product available. So, 54 percent of EPs attested in Stage 1 with a vendor that currently has a 2014 edition product available that meets all of the base EHR criteria. An additional 12 percent of EPs that have attested have a product or use a vendor that has a 2014 product that doesn't meet all of the base criteria yet. So these are vendors that are signaling they're on the path to getting their product certified but they don't have all the base EHR certifications yet.

So, on the next slide we look at the same thing in terms of the perspective of hospitals. The first pie there starts off again with that whole universe of the 991 vendors and when we look at the middle pie we can see that for hospitals just 56 vendors have served as the primary EHR vendor for hospitals that have attested to Stage 1 and of these 27 percent have some sort of certified EHR product for the 2014 edition right now and these vendors cover 64 percent of all hospitals that have attested to Stage 1.

So, again just a slightly smaller share 46 percent have a vendor that has a base EHR certified for 2014 and an additional 18 percent have a vendor that has another product certified for the 2014 edition that doesn't meet all the base criteria. So, we can see that while it's a relatively small number of vendors overall that have products in the 2014 edition list at this point they're covering the majority of both hospitals and professionals that have attested to Stage 1 so far.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC
Right on time.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thanks, Jen. If you could go back to the slide that shows the percent of hospitals by group and how many had attested by the end of FY12, this one, thank you. I think, Jen mentioned it but it's easy for it not to register that line is significant because even though we talk about 2014 being the time for people to step up to Stage 2 and we've heard a lot of concerns about whether people will be able to get to Stage 2 by 2014 because there is a personal escalator built into Meaningful Use the requirement to go to Stage 2 is predicated on when you entered the program.

So if you first attest by FY12 then after two years of being in that status then by 14 you need to step up to Stage 2 and this represents the share of hospitals and different categories that will be in Stage 2 in 2014 versus in Stage 1. And so, for example, the majority, slight majority of hospitals who are in those small urban categories will not need to be in Stage 2 until 2015 and by extension, according to the rule that we had in the final rule, they also wouldn't need to go to Stage 3 in 2016, they would be due to go Stage 3 in 2017.

So, basically if you're in the more advanced half of hospitals or doctors and you were able to go earlier, you were able to get more of the money because the money was frontloaded. So, if you're in the more advanced half of the universe of hospitals and doctors you were able to go earlier but that means that you would also have to step up to Stage 2 – and according to what we put out in the final rule Stage 3 in 2016.

If you're in the lower less ready half of hospitals and EPs then you would not need to, according to the rules that we put out, need to step up until 2015 for Stage 2 and 2017 at the earliest for Stage 3. That's just helping explain why we drew that line there and brought the numbers, because we do hear a lot of concerns in terms of the readiness of folks to step up to the Stage 2 requirements.

Now this is the Meaningful Use requirements, you still need to use 2014 edition software but the concerns that we're hearing in terms of some of the tougher measures around patient engagement, around transitions of care, public health reporting and so forth many of those don't kick in until Stage 2 requirements. Is that clear? Okay, Gayle and then Art?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you, I had asked last month about the small urban hospitals and I was looking for some analytics on that as to if you had taken a deeper dive into who those hospitals are and can give us a better profile, and perhaps some reasons why we have such a small number, you know, 55 percent now have attested and we're well into the program. Can you give us a little bit better understanding of these small urban hospitals?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator
Sure. So I actually included a bit of information on this in the appendix. I didn't want to frontload it here for time considerations, but on slide 10 here I show the breakdown of hospitals according to their attestation status. So, you can see on the middle bar here the breakdown of hospitals that have attested in terms of those categories that we've looked at before critical access hospitals and then the rest of hospitals by their size in urban/rural location.

And the far right bar is the hospitals that have not yet attested. So, you can see that the small urban hospitals make up 17 percent of those hospitals that have not yet attested critical access hospitals and medium-sized hospitals making up the largest chunks of hospitals there. And then when we take a look at some of the characteristics of these different types of hospitals that have not yet attested there is sort of a lot of information here but I wanted to give you just, you know, sort of a sense of the characteristics of these hospitals.

You can see that the majority of critical access hospitals that have not yet attested are enrolled with the Regional Extension Center, so again, signaling that they're working towards Meaningful Use, but looking at the small urban hospitals in particular, you can see that they are similar to other hospitals that have not yet attested one key difference being that they're much more likely to be a for-profit ownership status.

So, 48 percent of the small urban hospitals that haven't attested are for-profit compared to 17 percent of all hospitals that have not yet attested. So that's one place that they are unique relative to some of these other categories. And happy to answer questions about any of the other data that's there too, but that's sort of one of the highlights I would say.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
And less likely to be part of systems, less likely to be teaching hospitals also contributing to that.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
There also seems to be a geographic barrier there too with a large number of them being in the South.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
In the South, yeah, these are the smaller and some of these I think our colleagues have looked at this as a certain portion of these are also specialty hospitals that maybe don't do kind of full-service. They maybe specialty orthopedics or eye surgery, or other hospitals that maybe less – more – to be for-profit but less likely to be achieving Meaningful Use.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Can we get that breakout as to which ones are the more specialty, you know, what percentages are specialty.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yeah, we can try that.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Versus general or acute care hospitals.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yes we can try that. Sometimes that's a little hard to nail down but we can try to get that. Art?

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Yes, thank you for the presentation. I'd like to go back to the slide, it's 7 in your deck there, the one with the pie charts, right. So, you mention here that there are 991 vendors that are registered at the CHPL, right? How many of those have been used for Meaningful Use attestation? Did you say that? Have all of them been used?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator
Only about 60 percent of them have been used for attestation.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Right. So what happens to the others 40 percent are they in the game for Stage 2 or are they – do we think that they'll drop out?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
I guess I'll take this one. I mean, we have no way to know necessarily depending on what they – they may have sought an EHR modular certification for something specific and they may be trying to enter the market again. They'd have to recertify to the 2014 edition requirements. But, it's hard for us to say whether or not they'll come back.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Right, so they could be 40 percent that aren't the primary EHR, but they could be a module used in the other 60 percent? Am I understanding that correctly?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Not on the 2011 data.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Not on 2011. So they were not included at all?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
They've never been used for a single attestation.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
And attestation would include all modules as well?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Correct.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Okay. So, then I just wondered what's the risk for those that have a vendor that's of low penetration in the 60 percent for Stage 2? Is there any idea about that? Whether someone has invested in an EHR and now their product isn't going to be in the second box in the dark blue color? Do we have any estimate of that?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
We don't have that.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
The point of this analysis is to say that those vendors that have a disproportionately larger share of actually getting people to attestation are much more likely to having achieved the 2014 certification that's kind of the main thing that comes out of this.

There are, undoubtedly, vendors who intend to enter the market even though they didn't have any in 2011, they didn't have a single attestation in 2011, I'm sure there are some who still want to do this and they're going to go ahead and they're going to get the 2014 certification as well and maybe they'll get some customers as well.

And there may be some who got the 2011 certification and they have some number. I don't think it's going to be a huge number, some number of customers in one who don't make it to two and those customers are going to need to find another product to meet their needs. Undoubtedly, that will happen but my hope is that it's going to be a relatively – and based on these indications it's probably going to be a relatively small number.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Farzad this is Christine I'd like to be in the queue?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Go ahead?

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Great. So I think my question is fairly similar to Art's, you know, I think it was last month at the Policy Committee we heard, I think it was AHA, mention that there were very few, maybe 8 or so certified products available, but I think what I heard in this presentation is if you at eligible hospitals whatever the number is now, they cover almost 2/3 of the market and then for EPs they cover a little more than half of the market for 2014. Is that – first of all is that right?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator
Yes, so for both EPs and EHs about 2/3 are covered by a vendor that has some type of product certified to 2014 and it's about half that are covered by a vendor that has a base EHR certified for 2014 at this point.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
The one thing that we should reiterate is that this data is a month old now it's from our last analysis point from August 8th and so I think we would expect to see an upward trajectory in the past month that will increase these numbers on both shadings of blue.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
That make sense to me I think for, you know, two reasons, one is that, you know, we recommended and CMS and ONC implemented the extra year for vendors to have more time before Stage 1 started, but also, at least I know that the RECs recommend that as a best practice in contracts if you have a clause about regulatory compliance and being certified and meeting Meaningful Use. So I would imagine, and that was really my second question was, you know, that we would see that there are in fact probably several products that are in the pipeline.

But, to that point are there any holdups that we should know about? I know that last month I had sort of a hallway conversation with a very large vendor who said they wouldn't be delivering their products to the customer until at least mid-October because CMS hadn't finalized the quality measure specifications. And they are a very large vendor. So are their holdups like that that we should know about or is there anything that we could be supportive of moving forward?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
This is Farzad I'll just note that the fact that there are vendors representing 2/3 of the market that have already gotten certified I think indicates that there are no holdups that would bar a vendor from achieving, I think it's more a function of the resources that they've put into it, the degree to which they had already began this process and how close their product was to meeting the certification and to some extent their agility of their development processes in terms of being able to meet the new requirements.

I will note that while there have been some associations that have said, you know, we can't hit the timeline because the whatever thing wasn't ready or it's too quick. There are other vendors who have actually said no, no, no we want you to keep the timeline because we worked hard to meet those timelines we're going to be ready our customers are going to be ready, don't change the timeline. So, I think it is to some extent a function of who the vendor is, what their architecture is, what their readiness was as well as what the ecosystem has been doing.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
And I just want to emphasize while this is one metric that we have available to us that we can use to give us a window into how EHR technology developers are performing relative to the certification criteria, how much coverage of eligible providers there is based on the ones that have been certified that isn't meant to discount the real implications of having – you know, once these products are listed on the CHPL, the 2014 edition there's still a lot of work that needs to be done, right?

It needs to be rolled out, there needs to be training as we discussed this morning. All of those changes need to occur and so we don't have, you know, implementation schedules and rollout schedules for all of that. But those are other metrics that other industry players might be able to help illuminate for us as well so that we can kind of merge all of these together so we that we have a decent basis for some situational awareness, but this is the one that we can bring from our vantage point immediately to help shed some light on the situation.

Christine Bechtel, MA – Vice President – National Partnership for Women & Families
Well, that's really very helpful and I appreciate that a lot and I completely agree and understand the implementation timeline issues. I think it would be extremely helpful, you know, there's this other conversation happening around the timing of Stage 3 and I think it would be helpful to understand in a more data-driven way what the cycle time is for the development of or the I guess refinement of the products.

We have a new certification criteria for Stage 3 and then the time on average that is going to take different entities to implement and to train and to change their workflow. Because that's really, I think, essential to having us understand from a policy stand-point is this a two-year cycle as we've set up or is it really more of a three-year cycle and I think we just don't quite have the data that we need to weigh in on that and that's going to be important.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Let's go to Marc, David and then Judy?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare
Okay, so I have one of these questions that probably goes to a different vendor group. But I was going to kind of look at Judy. As you look at 2014, you know, the edition, and actually, well one comment is, so if I read the chart right it's 50 percent of the 50 percent of hospitals that have an EHR in place, right? That's what this pie chart suggest is 25 percent of hospitals have a vendor that has a 2014 ready edition of the software?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Well, the analysis only speaks to those who have attested to Meaningful Use by that time.

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

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, it may be that many of those who have not attested also have the same product.

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

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
It's not –

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
We don't have any of the 2013 attested yet.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare
Okay, so now the question, it really had to do with the workforce associated with getting to the 2014. So, if we're getting down to a relatively few number of vendors, which is kind of what those pie charts suggests. Do we have the workforce, you know, do the vendors have the people required to get everyone up to the 2014 edition or your thoughts on that? I mean, you have thoughts as well, Steve, you might, I don't mean to just ask Judy but I know she is dealing with it.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
It's huge and part of my thinking about this is that what about the number of vendors who did have a certified product what number is that and did they drop out of this business? Because that would be an interesting thing. Of the ones that people aren't attesting for are they dropping out of the business? And as each Meaningful Use stage gets harder do we see vendors leaving the market and then, is that a good thing or a bad thing? And is the entry – the barrier to entry high, so high that new vendors can't easily enough come in?

And it would be interesting to be able to get some of those statistics of who is leaving the market so that – and I think there's two ways to do that. They may be leaving the market, closing shop or they may be leaving the market and not selling to any new customers yet they're being good at supporting their existing customers, but what's their future?

So, I think that somehow what you're saying Marc plays all into that and if we could look deeper and I don't know if that is easy or not easy, into those – but we can give you a certain number of months for it and...sorry –

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
I think, you know, we see, just like most of you do in the trade press, etcetera when there are mergers and acquisitions and some of that could be attributed to some of the shifts and changes others could be I've heard, you know, you couldn't have your product on the market unless it was certified regardless if you were selling to people that were going to achieve Meaningful Use and so we saw a lot of, you know, EHR technology developers coming forward to get certified because it was good thing and maybe they're used for other purposes but for Meaningful Use attestations that where numbers shape it.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
The other thing as far as context I think that's important here is that prior to HITECH there were not 900 certified vendors. So –

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Well, the CCHIT had a certification program with 100 and some certified products and I think after HITECH, we know, right, there was a real influx of people trying their luck, trying their hand and that's a good thing and some of those are now part of those who account for a great majority of attestation. They're the new innovative and new companies that have succeeded.

And I think what we – what has been seen in almost every other industry, you could start from the auto manufacturer on down, has been that there is a period of consolidation after, you know, a big expansion, lots of different people try it, some succeed, some don't. So, I don't know that it's necessarily a good thing or a bad thing I think it just is.

My expectation would be that we are going to see many, many, many dozens more products certified to the 2014 criteria which are more rigorous and let's not kid ourselves here, right, 2011 certification was a lot easier it was the temporary certification program. We were getting things, there were fewer standards that we could require, we were, you know, fewer testing tools and so forth.

Anyone who has gone through the 2014 certification process knows it is more rigorous and there is much more, I think, in the way of consumer protection built into when you buy the system, you have a reasonable assurance it can do what it's supposed to do and meet interoperability and security requirements.

So, you know, in a way I think this is going to be an unfolding story. It's a little hard to draw kind of moral conclusions from it I guess is what I would say. It's something that we need to observe more and see if there are some of the concerns that people have are going to emerge or not. David?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
I'm interested sort of in the market segmentation and the viability of the market more broadly and the part of the market. And maybe you don't have data for this, so maybe just put this on the parking lot somewhere, but particularly because I think there is a political concern that some of the provider types are having a hard time getting access to the products or installing the products or training of the products and that while a certain segment may have had difficulty it could lead to a political pressure to slow down or alter the whole program and I think that would be very unfortunate.

So, I'm wondering if you're seeing enough activity in the market that will address the needs of certain provider types let's say the small urban or the small rural that we're looking at here on the curve or if the modular approach meets their needs differently or if a cloud-based approach becomes more accessible to them and whether as you look at product types, which are displayed here, in this sort of fertile market that Farzad described, is there anything we can do to ensure that the market is more differentiated in a sense and that we don't create a huge, you know, monolithic certification program for that defined solution David talked about this morning which becomes a barrier to entry for people who really could solve the problem in a way that they make money.

I've heard for example some rural hospitals have had the feeling that vendors don't want to go out there it's too far, too expensive, not worth it, not enough market in supporting those institutions. Is there anything we can do to make our program more adaptive to those requirements?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
So, Jen and I were just huddling here. I mean, I think we can definitely do the backwards analysis as I would call it, you know, taking this, the last pie chart there and splitting it by, you know, for eligible professionals, the types of eligible professionals that's in the categories and seeing what those miniature pie charts look like for each of them.

There may be a dominant player in a particular specialty and if they are certified on the 2014 edition then that makes us feel a lot better. If they're not then it could raise some other concerns. I think the same would be true for the hospitals we can kind of work our way backwards to see what each individual segment looks like from a support coverage perspective.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Judy?

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
I was just wondering whether it would be possible as Meaningful Use 3 comes on to look at the different things that the vendors have to do and weigh them. What we do when we evaluate projects is we look at all of the things but one is criticality and the other is length of time. So, if something is very critical and takes a week it gets done. If something is not very important but is going to take 10 years we're not going to do it.

I wonder whether there is a way of evaluating, it might be different from each vendor, but I think for the most part even though the actual number of hours or day, or weeks, or man-years is going to be different it might be that it's similar and yes this one is very hard for most vendors and this one is very easy for most vendors and then add that onto the different items that have to be done so that as you look through it you might say, we have lots of easy ones, we can add some more or we have an awful lot of hard ones which ones aren't as critical.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
You mentioned that it may not be the same for different vendors and I think some of the analysis that Christine was asking for along the same lines of when are you going to be ready and how long does it take, right? How long does it take to implement this? There is going to be potentially pretty big variability between different vendors depending on their architecture but also depending on, as David mentioned, cloud-based for example as one example right? How hard is going to be to roll out those upgrades to different people who've already installed them, obviously very, very different depending on the approach.

And I guess one question I would want the Policy Committee to discuss and advise us on is what is the appropriate pace of change? Is it one where we titrate to the middle of the pack or to the slowest large vendor? Do you understand what I'm saying? Because if we – yeah, so love your thoughts on that and I don't know if – I don't think this is necessarily a data question it's more of a policy approach in terms of titrating the speed of that regulator.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Well, we are scheduled to talk about timing of Stage 3 between now and let's say November that's one point. The question you asked Judy is a good one and we've asked how we can get that information. Is it possible that EHR association could give us some guidance? I mean, you already have some of our proposals from last time, last month, you could give us some kind of indicator.

I mean, I think we would appreciate it. We would certainly consider it, but it would be most of you that has that information and you would be reflecting a combination of development as well as your customers implementing it is the question that Farzad asked. So, it's a combination of what Christine asked about the vendors and what Farzad asked about the implementation.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
Okay.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
That would be very useful I think.

Judy Faulkner, MS – Founder & Chief Executive Officer – EPIC Systems Corporation
I'll propose that.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Other questions or comments? Yeah, go ahead Art?

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
So do we have an idea how much consolidation there really has been for like the 40 percent or even in the 60 percent that have been used? How much change there has been among the purchases to have to go to a new product? And, you know, how does the market deal with that and how do the successors have a strategy for that when they buy out another company, you know, is that something we know about? Are there anecdotes about that? Is that something that ONC is trying to evaluate or provide guidance to those that have been certified?

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Well, I think two things, one is in terms of what's appropriate policy Art I think one of our goals has been to use multiple policy levers including certification but also working with the EHR Association to make it more feasible for people to switch if they choose to switch. It's not a decision where they have to switch, right, but if they choose to switch can they for example get their data out and the EHR Association Code of Conduct was very helpful in saying, we believe that if you want to go to another product we will help you get your own data out.

What we've done with certification around portability I think is also a step in the direction of helping people migrate some of the information from system to system and there are guidelines in terms of what should be in a contract. So we put out some helpful, I think, information about if you could, before you sign a contract these are things you should consider and one of them is being able to migrate and get my data out.

But in terms of, you know, is there anything else that we can do, a lot of this is what's happening in the market. There are certainly indications and there are some surveys of varying quality with response rates that, you know, we should take with a grain of salt about the number of providers who believe that they're going to change/switch systems over the next period of time and it's not an insignificant portion I think by any means, you know, ranging from the teens to 30 some percent think that they over the next year or two or three they may switch systems.

So, it is a significant issue, again it's hard to describe a moral judgment to it. It may be a good thing if they're moving to better systems. It may be a bad thing if they're forced to because the perfectly good system they had is no longer going to be supportive and it's hard to get to that using the data that we have.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
I just wondered if there are some lessons that could be gathered by ONC to share with those teens to 30 percent what you should be looking for or what points to avoid in the next go around, you know, you want to be sure that you're not doing that a third time, right?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
And that's something again with time that I think we'll be able to see as we go into 2014 through the attestations, you know, it will be retrospective at that point which providers attested using a different vendors products and maybe as a proxy for how much change we've had in the attestations versus people that were on the 2011 edition and met Stage 1 and then shifted to a new product either at Stage 1 or Stage 2 using a 2014 edition product. So, I think we're a victim of that not yet occurring in the attestation data yet.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Thank you.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Gayle?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
This is Gayle I think I'd like to add to that conversation. I think as we move forward, especially going onto Stage 3, these are critical concerns, because if you have providers out there having made huge investments in software and in implementation and changing workflow, and the whole process of implementing an EHR and we are – certainly we are down to that point where you have market shrinkage, you have consolidation we read about it all the time but there are real world consequences of that and that needs to be part of our timing considerations that you have workforce issues with companies going out of business and then other additional companies, then you're looking to buy a whole new system as opposed to an upgrade and something that you have to relearn and reteach.

So, these are considerations that the numbers will be very important coming forward to see actually how many of those vendors do actually attest that do actually meet certification requirements for 2014. And that would be very critical to our timing to make sure that providers are capable of meeting Stage 2.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
So, Jen maybe next time we can have this same analysis repeated for those who are in the earlier half who would have to step up to Stage 2 to see if the patterns hold there or if they are any different?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator
Yes, sounds great.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Great, on the phone? Great, thank you. In data we trust. We are very late on our – this is what happens with data. So, maybe Seth and Lauren we can speed this up.

Seth Pazinski, MS – Division Director, Planning and Operations – Office of the National Coordinator
We'll do the lightening round.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yeah, sorry about that.

Seth Pazinski, MS – Division Director, Planning and Operations – Office of the National Coordinator
Okay, Seth Pazinski I'll just do the policy and program updates. Six items to talk about today I'll just jump right into the first one. First ONC is hosting the third annual Consumer Health IT Summit. It's going to be on September 16th. The focus of the summit is going to be on accelerating the Blue Button movement. The registration is currently full for the summit but you can still register to get on the waiting list and then there's also the option to participate via webcast as well.

The second item, just following up on, you've heard before about the request for information around options, policy options to accelerate health information exchange. ONC and CMS in August released a paper on the principles and strategies around accelerating health information exchange. There is a website there available on healthit.gov and there is also information there beyond the paper on things like guidance for states on how to leverage Medicaid to accelerate health information exchange as well as information on the recent rulemaking from CMS and OIG around the – kickback rules for donation of EHR software and services.

ONC released a progress report on the Federal Health IT Strategic Plan 2011 through 2015. The diagram on the slide there is based on an article that Dr. David Blumenthal wrote while National Coordinator trying to highlight how different federal Health IT initiatives and investments have been targeted at and aimed at influencing the Health IT marketplace around adoption, exchange and Meaningful Use.

The next item is to let you know that there is going to be an ONC, CMS and NIST pilot, This is specific to the Meaningful Use Stage 2 transition of care measure number 3 and this is where exchanging a summary of care record with another provider that is on a different EHR system. There are two options under that measure so one is, which we think most people will do, which is through their natural course of business will exchange with another provider but in the circumstances where that's not a possibility they will need to test for the CMS designated test EHR. ONC is just about wrapping up the recruitment of EHR vendors to participate in this pilot which we anticipate will launch in the middle of this month and conclude in October.

I'll skip this, this is just that healthit.gov would meet a number of resources available around case studies and success stories that we've been collecting from providers as they implement EHRs as far as Meaningful Use.

And then the last item here is actually back to the EHR contract guidance that Farzad mentioned a few minutes ago. This is part of our implementation of our Health IT Safety Program and the focus here really is on EHR contract terms that could affect continuity of business operations or patient care. So it does talk about termination and wind down as one of the terms that's covered in that. Any questions?

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

Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator
That was really fast I don't know if I can match that.

Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator
So, Lauren Thompson in the Office of Science and Technology in ONC, I want to give you a little bit of an update on the standards and interoperability framework activity and I'll really touch on some of our highlights. There we go.

So, I think you've seen this before just some updated metrics. We just got some statistics on the last few months. We have – people have logged close to 2500 hours in the month of August on various initiatives and that is growing month-to-month. One of the things that we're hoping to do is illustrate some of the trends with the S&I Framework overall as well as some of the initiatives we weren't able to have that available today, so I think we can share that with you next time.

This slide and the following one is just a snapshot illustrating all of the initiatives and the lifecycle of an initiative. We have provided details on all of the initiatives in the materials and I'm not going to go through all of the details. I'll highlight a few things focusing on some of the more active initiatives right now. This illustrates where we have pilots located across the country.

So, just to highlight a couple of things on a few initiatives, some of the newer initiatives that have gotten kicked off, structured data capture is focused on the functionality required in a form or a template. We have two implementation guides that are being developed focused on REST and OAuth, and SOAP, and SAML, two work streams working here one around forms and one around standards both have kicked off in the June and July timeframe and we're developing implementation guides presently.

Data access framework is one of the newer ones. This is focused on getting provider's access to data both local data access, meaning access to their own patient's data within their health organization and targeted data access for known individual patient's data from an external organization, this was kicked off in July and the consensus on the charter was achieved just last week. So, this is very new, use cases and user stories are being developed as we speak. So, there will be a lot of activity between October and December around this.

Another new initiative is the European Union, US eHealth Cooperative Initiative. This was kicked off very recently and this is a collaboration of the US and the EU focused on eHealth exchange. It was launched in June, two work streams working here one around workforce development and one around various aspects of interoperability. Community meetings began in August and they're meeting weekly on this initiative.

Longitudinal coordination of care, this initiative has been underway for some time. There are some key developments that I just wanted to highlight. The C-CDA is being revised to support the transitions of care and care plan exchange and it's being balloted right now in anticipation of the HL7 meeting in a few weeks. We're trying to align with the care plan exchange efforts of the various HL7 Workgroups and also identify potential pilots for launch later this month.

Public health reporting initiative is soon going to be entering the next phase of activity. It's a full community initiative at this point. They'll be focusing on phase two with new use cases soon. Blue Button Plus, I think everyone is familiar with this focused on the consumer, two websites have been put up one around push one around pull, API documentation and the focus of this initiative right now is on adoption and supporting the current reference implementations that are available.

HealtheDecisions, there are three work streams here. Work streams one and two are focused on the initial use case and their work stream two was the pilots, pilots are being completed. Feedback from that are being incorporated into the standards and the use cases being updated based upon the feedback that we are getting from the pilot.

Work stream three is focused on the second use case and two aspects of that, one around decision support services with an implementation guide being developed there and the virtual medical record logical model and implementation guide also being developed.

So, with HeD we've submitted an off cycle ballot to HL7 last week as well. So, a lot of activity right now, that HL7 meeting is upcoming towards the end of the month so we're really trying to get a lot of things packaged up for that.

Data segmentation for privacy, the IG for Direct and exchange are being validated through HL7. The RESTful IG has been accepted by IHE. Five pilots ongoing, a sixth pilot has been identified and will be starting. So it's been – this as well has been transitioned to a community led effort with the pilots and the SDO balloting as the focus of the initiative.

The other two initiatives here, laboratory results interface and laboratory orders interface. I won't spend a lot of time on. These are focusing on the pilot efforts and those were the highlights that I wanted to share with you. Also in the materials are some details on the other initiatives that are not quite as active or have concluded at this point. So, with that I will open up for questions.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
All right, thank you Lauren and Seth for expediting your presentation, appreciate that. Members want to ask any questions or comments on this? David?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
One of the little ones about Blue Button Plus, what I think you said it's primarily around the supporting adoption of Blue Button generally. Where are we at with cataloging the Apps either how users, how consumers can get access to a downloaded text or PDF Blue Button file and how do they know about finding the Apps that let them do that either process something to download themselves say from CMS or that they are using an App directly to access it on their behalf?

Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator
I can't answer that specifically, but Farzad is raising his hand.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
There should be a place where you go to learn if your provider, your health plan, your hospital whatever is one of those groups that makes that available for you. The question is where should that be housed and maintained and we are working with our Consumer eHealth Program with Lygeia to think about creating that, what we call the hub, where you can go and become aware of that. So, I do think that's something that's lacking now. A lot of people, more people have access to the Blue Button than they realize have access to it.

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

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
The second piece though is just the awareness of the whole concept. We had a Blue Button meeting at the Indian Treaty Room at the White House with predominantly folks on the outside developing these applications and almost to a person they said the biggest problem we're facing now is actually not standards, the biggest problem we're facing now is awareness and raising a kind of understanding that it is available. So, I think that's something that we look for the private sector to step up and do more around even as we do our share.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health
Well my impression going to the CMS site is that once could download the raw data from CMS but they don't – they were uncomfortable pointing you to any resources to make sense of it, but public agencies might have some opportunity to figure out a solution to help people process, find the Apps that would get them to that solution.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
You can search the App store, but yes.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Any other comments? Thank you very much Lauren and Seth for your report and very interesting projects. Okay, I'll go through some quick announcements. We have a couple of hearings and a new charge that you should be aware of. One is we're having a virtual hearing on advance directives finally and this will be September 23rd 9:00 to 1:00 p.m. Eastern Time, as you know this is one where a lot of people have vested interest but it tends to be a very complex topic so that's why there are four panels to talk about the legal, the state's issues, the implementers, patients and patient advocates let's flush out some of the details were all those devils are and to make sure that we can come up with some way of incorporating that into Meaningful Use if it makes sense.

A virtual hearing on accounting of disclosures, another complex issue, one that was intended to, I mean, the whole concept is to give patients more awareness and better control over their data, but it too has a lot of details that cause operational challenges. So, we're going to hear about that from large and small healthcare providers, health plans, patient advocates, users of technology and non-health technology solutions to this challenge.

So the first one on advance directives we're going to hear a report out next month and the accounting for disclosures we'll hear a report out on November, the hearing itself is going to be September 30th from 11:45, I don't know why 11:45, to 5:00 p.m. Eastern Time.

And there is a third charge to the Certification Adoption Workgroup and it has to do with the missing players, you know, congress had HITECH and there are some folks that are not eligible for Meaningful Use funds for example like long-term care and so one proposal is could they be included in a voluntary certification program so that would at least raise the – you know, try to facilitate the exchange of data where it needs to go even if they can't be by statute participants in the Meaningful Use Program per see.

So, a lot of good information and hearing material to come later on this month, actually. So, I wanted people to be aware of that. Any other questions or final comments before we open to public comment?

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
When did you say the Certification and Adoption meeting was?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
That actually is not a meeting that's just a new charge to the Workgroup.

Arthur Davidson, MD, MSPH – Director – Denver Public Health Department
Okay.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Yeah, sorry about that. Okay, can we open up to public comment please?

Public Comment

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Operator, can you please open the lines? And while we wait for the operator to open the lines if there is anyone in the room that has a public comment please come up to the table. As a reminder for public comment there is a maximum of three minutes for public comment.

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute
If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Mari Savickis – Assistant Director, Medical Affairs – American Medical Association
Okay, thanks very much, this is Mari Savickis with the American Medical Association. I would just like to reiterate that we submitted a letter in conjunction with the American Hospital Association on July 23rd and for those of you who haven't seen a copy of it I'd just like to give you the website first, so get your pens out, write it down, because we have some, what we think are fair and reasonable recommendations, it's ama-assn.org\go\meaningfuluse you can find the letter there and I'm just going to highlight again some of the points that we made and hopefully you'll take these into consideration given the pending October 1 and January 1 deadlines.

Our members share the administration's commitment to the widespread adoption of EHRs. However, we believe that the best way to move the program forward and to ensure that no providers, particularly small and rural are left behind is to realign the Meaningful Use Programs current requirements to ensure a safe and orderly transition to Stage 2.

We are concerned that the vendor community is not ready for the challenge to move to Stage 2. The compressed timeline puts providers in a position of rushing to implement creating conditions that prevent them from optimizing the use of systems and possibly introducing a risk to patient safety.

We are concerned that the current timelines will exacerbate the digital divide. Given this complexity and level of difficulty a program with an all are nothing approach in which failure to meet any individual part of the objectives or missing a threshold by a small amount leads to an overall failure in meeting Meaningful Use is overly burdensome and we made four recommendations, I'll read them quickly to you, being short with my 2 minutes.

Allow providers at Stage 1 to meet the requirements using either the 2011 certified edition or the 2014 edition. Number two, establish a 90 day reporting period for the first year of each new stage of Meaningful Use for all providers similar to what was done for Stage 1. Number three offer greater flexibility to providers in meeting Stage 2 to ameliorate the all or nothing problem and recognize that the level of change in Stage 2 will take time to accomplish. Number four, extend each stage of Meaningful Use to no fewer than 3 years. We think these are fair and reasonable approaches and I urge you to take a look at the letter. Thank you.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you. Is there anyone else in the room that would like to make a comment? If not we do have another public comment on the phone. David Tao?

David Tao – Technical Advisor – ICSA Labs
Hi, thank you David Tao from ICSA Labs, Bob and Steve, and Jennifer's presentation on Meaningful Use and certification statistics were very well-done and useful. It would be great in the future if both the CMS Meaningful Use attestation data and the ONC certification data could be combined and analyzed together so you could have stats such as a chart of the last time statistics from the certification data products to the start of the first actual attestation using that product so that would help answer the question I heard today of how long does it take realistically to get from the time a product is listed on the CHPL until it's really used for Meaningful Use. I think we know that products sometimes may appear on the CHPL but not actually be ready to implement for weeks or months after that. Thank you for listening to my comment.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
We have no more public comment at this time.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
Well, good, thank you. Well, Farzad we've managed to end precisely on time. I want to acknowledge your last HIT Policy meeting and towards the end of your tenure as a very successful National Coordinator thank you so much for all the help and all that you and the office and the country has accomplished.

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Thank you.

[Applause]

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation
And thanks for a very productive meeting. We approved the FDASIA report. You gave us permission to go delve down into details for the Meaningful Use Stage 3. We heard some very interesting and both challenging and provocative data about the Meaningful Use Program that's generated a lot of questions and I think we're going to get more detailed data so that we can use it as input as we go consider for example Gayle's question about timing and I think these are all important things to know. So, thank you so much for a very productive meeting and we will see you next month in a face-to-face.