

HIT Policy Committee Transcript August 7, 2013

Attendance

The following members were in attendance:

- Madhulika Agarwal /Terry Cullen
- David Bates
- Christine Bechtel
- Paul Egerman
- Judith Faulkner
- Scott Gottlieb
- Thomas Greig
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Farzad Mostashari
- Aury Nagy
- Marc Probst
- Joshua Sharfstein
- Alicia Staley
- Paul Tang

The following members were absent:

- Neil Calman
- Patrick Conway
- Arthur Davidson
- Connie White Delaney
- Latanya Sweeney
- Robert Tagalicod

Presentation

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

Thank you. Good morning everyone. This is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. This is the 51st meeting of the Policy Committee. This is a public meeting and there will be time for a public comment. There will be time for public comment before lunch and at the end of the meeting, and public comment will be limited to three minutes. As a reminder, please announce yourself when speaking as the meeting is being recorded and transcribed. For those of you who use Twitter, the hashtag is #HITPolicy and I will now 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 and Technology Officer – Palo Alto Medical Foundation

Here.

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

David Bates?

David 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

Good morning.

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

Neil Calman? Art Davidson? Connie Delaney? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

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

Judy Faulkner?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

Here.

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

Scott Gottleib? Gayle Harrell?

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

Here.

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

Charles Kennedy? David Lansky? Deven McGraw?

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

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?

Joshua Sharfstein, MD – Secretary, Department of Health & Mental Hygiene – State of Maryland
Here.

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

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

Latanya Sweeney? Madhu Agarwal?

Madhulika Agarwal, MD, MPH – Department of Veterans Affairs

Here.

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

Patrick Conway? Thomas Greig?

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

Here.

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

Rob Tagalicod? With that, I will now turn it over to Farzad.

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

Well this Policy Committee meeting holds no special place for me. I announced – the Secretary sent out an e-mail that was very kind, announcing my decision to step down from position of National Coordinator for Health IT, in a little while and yesterday was very humbling for me personally to see the reaction that I think was largely undeserved. But I think shows an appreciation for the progress made in Health IT, which I think symbolizes something larger, certainly larger than my departure, but the faith that we can do big things. We can still do big things in this country and that we've been doing something pretty big and pretty important, something that really matters in this community. And that the way in which we do it, requires – truly requires a partnership between government, smart government as well as the private and non-profit sectors.

And that's how we get big things done is government having a critical, but limited role in convening, in coordinating policies and engaging with the field and where necessary, setting standards and establishing a floor. That's been the work of this committee and the openness that we've conducted our business up until now, I think, has been an essential part of in general, moving in the right direction. Not always – we're not always going to be – we're human, we're not going to be perfect in our policymaking, but we always considered all of the information that we could gather. And we always thought it through with the best intentions, with no agenda other than to get it right. And I think that's reflected somewhat in the comments that we received yesterday. Just to reiterate a couple of things, I know there are probably a bunch of people who are you know, "beep"-off I want to tell you, who may be called in just because they're curious. I'll just reiterate what I say in the letter.

I'm bit going to anything that I know of right now, it just seemed like the right time. In a way the right time because things were going well, I didn't want to leave if things were not going well. And we're between rulemaking cycles, so there's a certain good timing there. But more than anything, it was just my – highly unscientific term – my heart said it was time and it felt right and I've had no regrets since communicating that decision to the Secretary, and that's a good sign, I think. But I know that I will continue to feel passionately about the mission of improving how our system knows its patients, how our health system cares for its patients. And the difficult, but necessary transition we have to go through, we have to go through, to deliver care differently, to engage with patients differently, to pay for care differently. And the indispensable role of data – of information, of insights and actions that are fueled and supported by Health IT. So, I'm going to be in your camp, I'm going to be continuing to cheer on the efforts here, even as I leave this role. So, I just want to say that, and we can go to the – today's, as usual, amazingly packed, informative agenda. Thank you

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

So, I don't think you can get off that easily. I want to pay tribute and give an enormous thanks for the leadership you've shown in really negotiating a transformative change, as you described. It has to do a lot with the information, but that's the underpinning of the change that we need to do in the whole health system, that's underway, and partly enabled by the work that you and the department have done. We're enormously grateful.

One of the things you've always inspired us by is your ability to keep your eye on the prize, and your feet sort of close to ground, and moving us always with that intent. And I think – for me, I also agree with you that this committee, the people and the people who work on the workgroups always look at it that way, without being as parochial and really looking for the right thing to do. It's not easy, but it's always a balance. It's been fantastic to work with you; you're a fantastic visionary, tireless, dedicated and always passionate. So, that's been just so inspiring. And if you look at the two years we've been, let alone the four years you've been here, we've really gone from zero to 60 in no – in ways that would not have happened without both the enabling legislation, but the work that's been done by you and David Blumenthal and the Department and – assisted by some of these FACA committees. So, really, really appreciate it and so thank you so much for your leadership.

All right, as Farzad said, we do have a very full agenda and there's a lot of both timely and important discussions that are going to go on, some as an introduction for more feedback before we go to some final recommendations for approval next month. So we'll start with a workgroup report from what we called the FDASIA Workgroup, which was called for by Congress, in terms of looking at this new world, HIT is different, it's different from devices, for example, that come pre-packaged and delivered and it stays the same, pretty much. This very somewhat amorphous thing called an information system and the software that powers it is a different kind of animal, and it requires – potentially requires new ways of looking at it, both in letting out the door and watching what happens to it. So that's the purpose that Congress asked a group, and the Department to provide it with recommendations on a framework for how to deal with this thing called HIT. So, FDASIA Workgroup was charged under the HIT Policy Committee to dedicate time to look at it, and they're going to present their first view of that today, for feedback, and then we'll get their final recommendations next month, before we turn it over to you.

Next we'll hear from the Privacy and Security Tiger Team who is going to, at long last after their hearing, talk to us about that third scenario, which is the non-targeted query. They'll also be talking about recommendations on meaningful use attestations for security. We will have a lunch, let me see, I think we have a little time for lunch, and then hear back from CMS with their data update. We will be charging into the Meaningful Use Workgroup with its initial presentation of the final draft, and I don't even know whether I should call it final – its initial recommendations. You have heard from us before, but you're going to hear an update, after we've digested your input and the input of the public and come up with some changes we'll present to you this afternoon. Again for feedback before we also come back to you next month with our final recommendations.

And then we'll close the formal presentations with the Information Exchange Workgroup, which we heard from last month, and we asked them to do a little bit more work related to provider directories and data portability. So, we'll be hearing from them for final recommendations. And then we'll close with public comments. So that will take us all the way to 4:30, so, it is a long day, but there's a lot to be done over this summer. Any questions? So let me ask also the minutes from last time were distributed and let me hear any comments or motion to approve.

(Indiscernible)

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

Okay, second?

W

Second.

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

Any further discussion? All in favor?

Multiple speakers

Aye.

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

Opposed or abstain? Okay, thank you very much. So we will start out with David Bates, which is chair of the FDASIA Workgroup, who's going to talk to us about their initial thoughts in making recommendations about a fra – or providing input on a framework to ONC – ONC, FCC and FDA.

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

I will, before David starts, I do want to acknowledge the work of this FDASIA Workgroup that David has tirelessly kept moving forward. Very different tribes who have come together, I think, for some for the first time, to really deeply hear each other's perspectives and views, and it's been, I think, a testament to David's skills as a chair that he's been able to keep the group moving forward. We do have with us our good colleagues from FDA as well with Jeff Shuren and Sally Howard, from the Commissioner's Office. So welcome Jeff and Sally. Josh doesn't count – stay out of it Josh. And we want to turn it to you David.

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

And before that, we forgot to introduce new members –

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

Ah, yes. And our new member introductions, and I think also, for Scott, Dr. Gottleib, the first time where we're in person and want to welcome you as well. But Alicia Staley, is our new member. And she is in the – appointed by GAO for the patient and consumer advocate position. If you could, Alicia, tell us a little bit about yourself and then Dr. Aury Nagy, who I believe is on the phone. Dr. Nagy?

Aury N. Nagy, MD, FAANS – Las Vegas Neurosurgery & Spine Care

I'm here.

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

Okay great. So let's first hear from Dr. Staley

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

Sure. My name is Alicia Staley, I'm a three-time cancer survivor, 22-year cancer survivor. I live in the Boston area. I've been a patient at Tufts Medical Center since 1991, they've basically followed me for long-term care. I'm involved there as a member of their Patient and Family Advisory Council. And I have a background in information technology and engineering. So as a patient with an IT background, I'm honored to be able to work on this committee and help provide the patient perspective in everything that you're doing, because unfortunately I've been a professional patient for too long, but whatever I can do to help, I'm very honored to be here. So thank you.

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

Thank you.

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

Dr. Nagy?

Aury N. Nagy, MD, FAANS – Las Vegas Neurosurgery & Spine Care

Hello. My name is Aury Nagy. I'm a neurosurgeon in Las Vegas, Nevada and have been active in the community here for several years. I serve as the Committee Chair for the Neurosurgery Committee at one of the local hospitals and I am presenting the perspective from the medical healthcare provider community. Thank you for allowing me to be of service.

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

Thank you and apologies for the Hungarian pronunciation of your name. David?

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

So, thank you Paul and thank you Farzad. Could I have the next slide? So this slide just shows the composition of the committee. I want to thank them for a lot of very hard work over the summer. As has been noted – so I can advance? Okay. Good. I did not notice this. That's good. Okay. As has been noted, the committee had very broad representation, we had a lot of spirited discussion. There are many people on this group who are very knowledgeable about the current regulatory processes. Many of the folks who are listed here are either here today in person or on the phone.

We were given a big task and had a short timeline. There are many issues that came up, there was lots and lots of discussion and I'll be highlighting the key points today. But I would just like to note at the beginning that there are several sources of backup, so there are some notes on the slides. There are some additional slides that we have circulated and we're also going to be producing some additional textual material, which will explain some additional points. We did not agree about everything, not surprisingly, but we did agree about most things and I will be trying to highlight areas where there both was and was not disagreement. These are the subgroups that we broke up into. We had one group that focused on taxonomy, which attempted to sort out what was HIT and what might not be considered HIT, and that group was co-led by Patty Brennan and Meghan Dierks. Then the risk and innovation group was co-led by Keith Larsen and Paul Tang. And the regulation subgroup was led by Julian Goldman and Brad Thompson.

Our charge was as follows: So the FDASIA Act calls for the HHS Secretary to post a report within 18 months, that means by January, 2014, that contains a proposed strategy and recommendations on a risk-based regulatory framework pertaining to Health IT, which has to include mobile applications, has to promote innovation, should protect patient safety and avoid regulatory duplication. And we did not have to develop the framework ourselves, that will be done by the Agencies respectively, the FDA, ONC and FCC, but we were asked to make recommendations which will guide the development of the framework. The process was that we had three months of deliberation, which again, was a short interval to discuss all the issues that there were to discuss. We had one in-person, face-to-face meeting, we had the three subgroups, we had dozens of conference calls both in the subgroups and in the larger group, and there was a lot of processing through online approaches.

We considered much of the prior work that had been done in this area. Although there has been lots of work that has been done, but one especially important input was the IOM Committee recommendations in this area. We had a great deal of input and support from all the three involved agencies and we also solicited public commentary and got a lot of very useful public input on things we should address. Now the backdrop here is that the literature suggests that HIT clearly appears to improve safety overall. And we now have many studies that strongly support the safety benefits. However, the literature also provides multiple clear anecdotes that Health IT creates new safety risks. While the magnitude of harm and the impact of Health IT on patient safety overall is uncertain, because of the heterogeneous nature about Health IT, because of the diverse clinical environments that exist and workflow and the limited evidence in the literature. We do believe overall that Health IT is beneficial, but it could also clearly create new problems. And we felt it's important to address this. Now the FDA has had the authority to regulate Health IT, but in general it has not done so, except in limited ways, which we'll go through.

Here are some examples of problems, which have been associated with Health IT. In one study that was published by Han, et. al from the University of Pittsburgh, the mortality rate that when up from 2.8% to 6.3% percent in children who were transferred in for special care after introduction of a commercial computer order entry application. I'll not that the same application was subsequently introduced at a couple of other centers, which looked at their mortality rates, and they showed that it actually went down.

Another study which highlighted some deficiencies was a study that was done in which a flight simulator computer order entry was developed and when 63 hospitals around the country used this, they identified only 53% of medication orders which would have been fatal. In addition, there's a clear problem that's emerged of writing electronic orders on the wrong patient, because providers sometimes can't tell which record they're in. And finally, when even serious safety-related issue with software occur, there has not generally been a central place to report them to, and they typically do not get aggregated at the national level. So, it's been hard to have a learning healthcare system.

One example of an adverse effect of regulation is as follows. So in closed loop systems, one application can drive another process. And for example, oxygen monitoring could be used to tell an intravenous device to stop delivering narcotics if the oxygen level goes down or hypoxemia is detected. And traditionally there's a been a very high regulatory bar for any closed loop approach at the FDA that may have prevented some beneficial closed loop approaches from being implemented, and we give an example here of a death that occurred that could potentially have been prevented by integrating sensors with infusion technology.

So, on to the work of the subgroups. The taxonomy group suggested that we should have several guiding principles and that basically those could be used to assign HIT to one of two categories, either HIT that requires risk-based regulation or a category in which risk-based regulation is not needed. And the key principles were that all entities addressed by the risk-based regulatory framework can be described by a set of defining characteristics. That framework would have to be sufficiently robust to meet future undefined needs, because we just do not know where things are going in all directions, and many of these applications are going to interact with each other in the future in ways that are unpredictable. We wanted to avoid creating an inclusive inventory for determining what is regulated and this – we're recommending a decision-tree approach which emphasizes functionality as a primary scoping criterion. The notion is that functionality will help distinguish between two similar innovations, one which might require risk-based regulation and one which might not.

The defining characteristics of what should be included as HIT were divided into these domains. So, we looked at user type, phases of the product lifecycle, developer and manufacturer type, distribution model, conditions of use, intended use, product categories and then we included a miscellaneous category to cover anything that was not included in the first seven categories. And there are a lot more specifics regarding what the group believes should be included as HIT in the additional slides, but there's just not time to go through all that material today.

So here's one example of the sort of description within a domain. And this happens to be for product types. We picked this just because there were a number of things that were listed as being in-scope and a number of things that were listed as being – that we decided were probably out of scope. So in scope would be things like electronic health records or hospital information systems of systems, decision support algorithms, and you can read the rest of the list. Out of scope were some other things like claims processing, like health benefit eligibility, like practice management scheduling systems and inventory management. And there's a further list. And one could reasonably make an arguments that some things which are on one side could potentially be on the other side or vice versa, but in general we felt that this was a useful sort of approach.

On this slide, this slide illustrates the decision tree approach. And I will note that we determined late last night, that yes and no have been reversed here, which we will correct in the next iteration of this slide. But, so the example is, is the use intended to inform decision-making about initiating, discontinuing or modifying care interventions or personal health management. And if the answer is yes, it would be potentially in-scope, if no, it would be out of scope, and we'd defer to the existing regulatory framework.

Another group worked on developing a risk framework. And the patient risk framework enumerates a number of important factors which influence the risk of software systems. It doesn't weight and doesn't calculate any specific risk score for a given product, it's intended rather to serve as a framework to help assess factors to consider when thinking about the potential risk of patient harm arising out of the use of a software system. And while the matrix, which we'll show you in a minute, characterizes a relative risk, these are intended to serve as directional guidance only. There are exceptions for each condition. Some of the things which end up being scored as higher risk, actually may be safer than what is currently being done – the example being the closed loop systems, which I gave you before. We also included a number of basic definitions which are – these are international definitions. I won't go through and read these,

But here is another set of definitions. We included definitions, for example, for purpose of software, for the intended users. That's an important one, these are the intended users of the software as declared by the developer; in addition, the severity of the injury, likelihood of a risky situation arising, transparency of software operation, data and knowledge and content sources, hazardous situation, the ability to mitigate harmful conditions. So these are some of the key underlying definitions. In addition, complexity of software and its maintenance, complexity of implementation and upgrades, complexity of training and use; and you can see, as we get further along, we're trending towards more things that are related to complexity and interactions. Use as part of a more comprehensive software and/or hardware system, and then finally, network connectivity.

And this is the matrix itself. There will be a few reversions to this matrix which were developed after we had to go to press yesterday afternoon, and they'll be incorporated in the next iteration of this. But in general, this is what it will look like. And the notion is that an individual item could be classified as lower risk, medium risk or higher risk, based on thinking about how it scores with respect to these parameters. And those are, for example, the purpose of the software product. So if something is information only, the purpose is transparent and clear; that would be low risk. Medium risk would be an instance in which it makes recommendations to the user. Higher risk would be something that involves automated decision-making. Intended user is another category, and you can read the dimensions here. Severity of injury is an important one with higher risk being things with more life-threatening potential. The likelihood of the hazardous situation arising, definitions given here again.

Another key category is transparency of the software operations and data and included content providers with one extreme being black box, the other extreme the software output is easy to understand. Another important dimension is ability to mitigate harmful conditions. In addition, the complexity of software and the maintenance, the complexity of implementation and upgrades, complexity of training and use. Use is part of more comprehensive software system. And then finally, down at the bottom, things relating to connectivity and security. And I'll next take you through several use cases, which I think make it much kind of easier to understand how this might be used.

So this is an example of an mHealth nutrition app. This would score as lower risk really across the board, so it's information only. The targeted user is easy to figure out. The likelihood of a hazardous situation arising is very low and just across the board, this appears to be low risk. Here's another example, which is of an insulin pump and this is clearly much higher risk and you can again see at a glance that this has a different profile. So, there's automated decision making involved, there's diagnosis or treatment advice which is being given directly to a knowledgeable user. There's life-threatening potential it is black box. So all of those characteristics make it relatively higher risk and that probably deserves more regulatory attention.

This example is for an electronic health record and health record makes recommendations to the user, its providing diagnosis or treatment advice, it has a life-threatening potential. It is used a lot, so it's used commonly and so on; again, much higher risk than the first set of things that we considered. So a few observations from applying the use cases to the risk framework. First of all, it's much easier to classify the lower risk applications that ended up being fairly straightforward. Often their standalone, they have narrowly defined functions, there's less variability in the context of use. It was much harder for the group to classify more complex software precisely. Often things depended on what the specific circumstance was, much more dependent on the context of use. There's much more complex software to develop and to do quality assessment on, more effort and expertise required to implement it. If you implemented it badly, really could have adverse consequences.

The events in Pittsburgh were probably related to poor implementation and there are other descriptions of poor implementation leading to what were probably adverse consequences. Much more effort and expertise required to – many more interfaces, more reliance on a variety of process controls and risk controls for known failure rates. And when there is a failure, often it's hard to determine exactly why it happened. Sometimes you can't even tell right away. So this has a few policy implications we believe.

First of all, we think that it's important to define clearer criteria for software functions that are not regulated, but that may have transparency labeling requirements. Second, it would be useful to develop clearer criteria for software functions that may warrant regulation, or at least greater attention. And in addition, all this has to be supplemented by a robust surveillance mechanism to track adverse events and near misses for most of the software functions which are in the middle. So we believe that there are these two extremes, one where you don't need to do very much, one where there needs to be a close eye, but that most software probably lies right in that middle area.

Okay, so now I'm going to talk about regulation and I'll begin by discussing current regulation. Many of you may be familiar with this, but some people who are on the committee probably are not as familiar. The FDA currently has three levels of – three classes for medical device regulation, Class I is low risk, Class II is medium, Class III is high. Within Class I there are two levels, one is Class I, which is that there's a quality system requirement and Class II there's no quality system requirement. And quality system requirements change the manufacturing operations in ways beyond some of the normal ISO quality standards, and there are also fairly substantial paperwork requirements. So, you have to do adverse event reporting and the facilities have to be registered and listed. I should have noted that FDA also can classified some things as Class zero, in which they – the risk is low, they retain the ability to regulate, but they don't actively enforce anything.

For Class II, again there are two levels. Software typically can't go on the market until the manufacturer proves to the FDA that it's substantially equivalent to other software on the market and the review cycle is 90-180 days. For Class III, the bar is higher, it's the same as Class I, but there's also premarket approval. You have to develop clinical evidence and the FDA review cycle is substantially longer, it sometimes takes two-to-five years.

This slide describes the pros and cons on the medical device regulation. There are a number of benefits. First of all, some of the benefits are that there is good process control. Second, the good manufacturing process which is supported by the FDA regulation has clearly had a positive impact on the quality of products and has improved confidence about the products produced through it. And third, post-marketing

Surveillance is reasonably effective, this already supports gathering data about products post-marketing, and it's been a really desirable element. Some of the cons are that there are issues around clarity, there are often questions around which software is subject to the medical device regulation. Which Classes will be used for HIT software? If it's subject to the law, what are the specific requirements for being in compliance? Second, this is geared a bit to physical devices and turnaround time and configuration and extensibility of software makes it harder to apply this to HIT.

The blood bank example is one that we discussed a lot, and which has received a lot of attention. And the full application of the medical device regulation has had a significant negative impact on blood bank software vendors, or at least strongly perceived negative impact. And this example has again been cited numerous times, and we provide a citation for this in the notes. And then finally, entry impedance is an issue and there are two cases here. First is one in which the learning and implementation curve for manufacturers or others who are trying to get into the market space is difficult. And the second use case is where software is developed, tested and implemented, but without an FDA regulated process, and then the product is deemed to be subject to FDA regulation. That becomes complicated because it's hard to understand how a past process can be restructured and there's not a well-defined ability to bring current software into compliance, as the FDA regulation defines the process to create the software in the first place.

With respect to ONC regulation, this group is obviously quite familiar with that. The motivation for ONC certification has been that the government is making an infrastructure change in the medical sector. And then there's some obligation to ensure that the products that are purchased in the infrastructure are good products and meet the overall goals of the infrastructure change. The certification regulation has been implemented because of a series of specific software behaviors, which are reinforced by some specific test case behaviors, and this has changed the software and narrowed the differences between software, and obviously a lot of that has been very positive. But, there are also significant issues with working to the test or what's sometimes referred to as compliance innovation.

The group made a few specific recommendations to try and promote innovation in this area and it is suggesting trying to increase the flexibility of compliance to try and take an approach of defining desired features, avoiding implementations in the descriptions, trying to increase the flexibility of compliance certification. Trying to avoid requirements which effectively depend on a single source with the notable example today being Surescripts. To try and increase predictability so that requirements are well defined versus having a defined roadmap of features. And finally, having an easier approach for recertification so that that should be better defined and relatively limited.

This slide compares the approaches of current regulation, medical device regulation and certification regulation. And one uses a process approach, the other takes a product definition of approach. Of these two, process control approaches have less negative effects on innovation. Product definitions, on the other hand, reduce flexibility more, and this is noted in the impact statements under each of the regulatory methods. This difference is the core of the differences between the two systems. And for the certification approach, how the software was developed doesn't matter, it only matters whether it can run test scripts at the certification point.

The regulatory group addressed four main issues. First it asked, are the three regulatory systems, those of ONC, FCC and FDA deficient in any way with how HIT is regulated? Second, are there ambiguities in the three regulatory systems that need to be clarified so that HIT vendors and others can proceed to more easily to innovate? Third, do any of the three regulatory systems duplicate one another or any other legal, regulatory or industry requirement? And finally, setting aside the existing of approaches, is there a better way to assure that innovation is permitted to bloom while safety is assured?

Now in some of the subsequent slides, given issues have been classified using an "A," "B" or "C." "A" means ambiguous in the sense that there are things that need to be clarified. So while not all ambiguities are bad, the ambiguities that are highlighted are things that we think would benefit from being clarified. "B" means broken, which means that the actual law as written does not really fit HIT. And finally "C" refers to capabilities that may be underutilized, things that the agencies might use more because this represents an effective approach. So, this is the assessment of the group with respect to the FDA.

For wellness and disease, the borderline between disease related claims on one hand and wellness related claims on the other hand. The FDA has jurisdiction over disease related claims, but if you instead make a wellness related claim, then that's not regulated and there are simple rules in this space which the group felt sometimes lead to over-regulation. Second issue is the scope of what constitutes an accessory to a medical device? And the FDA has had a longstanding rule which says that anything that's intended to be used as an accessory device, is itself a medical device and then gets regulated to the same extent as the device it accessorizes. But there are lots of generic accessories that are relatively low risk and probably should not take on the regulatory classification of a product that they accessorize.

Third is the scope of clinical decision support software that the FDA regulates and the FDA has long regulated certain forms of clinical decision support software like computer assisted diagnosis software in particular, used with medical imaging. However, the FDA has never been really clear on the contours of its regulation for this broad category of software and the vendors believe it would be really helpful to have a little more definition around this. And finally, software modularization is an issue and the feeling of the group was that development of software involves a high degree of incorporating existing modules into larger software programs that might have a medical purpose. But many of the individual modules are very generic and not necessarily intended for medical software. So does the FDA regulate those modules or not, how is that issue handled?

The next slide focuses on the areas in which FDA regulation can be improved for devices that fall within FDA regulation and there are three main areas. First of all, the first – the vast majority of devices subject to FDA jurisdiction have to meet the requirements of the quality system. However, understanding how to meet those requirements can be hard for standalone software. And this regulation was written with physical products in mind and while the basic regulation is written broadly and can be interpreted, the industry would benefit from official guidance on the FDA on how this should be interpreted for standalone software.

Second is a premarket requirement for interoperable devices. And typically when a medical device manufacturer goes to the FDA and seeks clearance, they present a device with a very defined intended use, and it's typically a solo product. If instead they go to the FDA with what's essentially a complement of the future unspecified network of devices, the agency has trouble trying to gauge risk and what sort of data to expect. And the industry, we believe would benefit from if the FDA could come up with a paradigm that could inform developers of some of these network components, about how to demonstrate their claim of substantial equivalence. And finally, with respect to post-market requirements for networks. When something goes wrong with a network of devices, and now today everything is networked, it's often unclear where the problem came from and the problem may, in fact, be related to one of the interfaces between the these two products as opposed to the responsibility of one single component. But the laws have been written in a ways that are focused on accountability and there are post-market obligations like adverse event reporting and field corrective actions that are written as though it should be clear as to whose responsibility it is. So those would benefit from being updated.

The next area focuses on current FDA program mechanisms that could enable innovation. And the group believed that the FDA should establish a policy of enforcement direction for lowest risk HIT, where the enforcement of regulations is inappropriate. Second, the group believed that the FDA should access exemption from GMP for this lowest risk HIT, that it should expedite guidance on HIT software, mobile medical apps and related matters. The assessment of the group was that the FDA does not have as much internal coordination as it should around HIT software and mobile app policies and regulatory treatment and it would benefit from more coordination. In addition, that the FDA should utilize an external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA. And finally, that there may be a need for additional funding to appropriately staff and build that expertise in HIT and mobile medical apps. And clearly the development of those apps has just skyrocketed, it's really been a challenge to keep up with them.

With respect to ONC, there were several areas that were identified. One is that there are a number of – with respect to mandatory elements, the current ONC program doesn't include capability in law enforcement, nor does it have programs with mandates in some places where that might be useful. Second, around assurance of safe configuration, the concept here is that there's ambiguity that safety depends on appropriate post-installation configuration and there are not good means to educate or require compliance with documented and evolving best practices. With respect to the certification program, the recommendation was that ONC should avoid regulatory rules and certification test cases that endorse a specific solution or implementation to a specific, desired feature. And then finally with program review, the FDA got some kudos as it does a good job of periodically reviewing its programs and getting rid of the programs that are no longer necessary. And that is something that it would be good to do more of.

With respect to the FCC, an issue with ambiguity related to pre-installation, there's a problem at planning for deployment of wireless technology is difficult in spectrum crowded, interference prone environments, which are most hospitals. And the notion was that pre-clinical test and evaluate tools in environments could help manufacturers and healthcare delivery organizations, an example being the FCC Wireless Test Bed Initiative. In addition, with respect to post-installation surveillance, there's also some ambiguity issues here with spectrum management and identification with respect to diagnosing and resolving wireless coexistence and electromagnetic compatibility programs that affect HIT and medical device performance. And that's especially relevant in healthcare facilities and mHealth environment.

Cross-agency issues included coverage of interoperability issues. There's a challenge with exactly who's responsible for ensuring needed interoperability. The ONC regulates – appears to regulate the HIT medical device interface and the FDA regulates the medical device medical device interface, but sometimes the same medical device, like an infusion pump, could be installed in either configuration, so who's responsible for resolving that? And in general there are a lot of issues like that that have tended to come up as we get into a more complex, networked sort of world. With respect to review, the FCC and the FDA don't necessarily coordinate their review processes on converged medical devices that are brought independently before both agencies. And coordination between those agencies would be useful and then transparency around that would be helpful in terms of eliminating a number of hurdles. And finally, with respect to the FCC and FDA conformity assessment, sometimes there's incomplete or missing clinically focused wireless conformity assessment tools. If those existed, that would be helpful with respect to safety and coexistence analysis.

With respect to error and adverse event reporting, it's hard to obtain data for systems performance analysis and while medical device HIT related – system related adverse events occurs, it is often difficult or impossible to find the root causes of the failure because data logs are sometimes incomplete, inaccessible, sometimes non-existent or not structured. In addition there are issues with root causes of events being – which span sometimes regulated and non-regulated spaces and it's unclear what the best model for reporting and analyzing issues with systems and devices that span multiple agencies. The group surveyed an array of existing approaches and couldn't really land on one, but the feeling was that is further analysis of this is needed. We did discuss a new constr – potential new construct, like a Health IT Safety Administration. It was clear that it would be useful to have broad stakeholder involvement in whatever is done in this area. Finally, adverse events should be accessible both early and broadly and the current reporting pathway doesn't facilitate timely resolution and broader access to safety and performance data to enable timely improvements was emphasized.

So specific overarching recommendations in this area, first of all the group recommended that HIT should not be subject to FDA premarket requirements except for some specific categories; first, medical device accessories which would benefit from clear definition by FDA. Second, certain forms of high-risk clinical decision support like computer aided diagnostics, which we think should be regulated. But again, that would be helpful to have a clearer definition from FDA. Higher risk software use cases as per the safety working group teams report including those where intended use elevates aggregate risk. And then finally, 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. Many of the current approaches to registration do involve a substantial amount of regulatory burden.

In addition, we felt it was very important to develop better post-market surveillance of HIT through a collaborative process which again, including broad stakeholder participation. That should include spontaneous reporting, also post-implementation testing to ensure that key safety related decision support is in place. Often that is available, but it's not turned on. And then finally, approaches are needed to allow aggregation of safety issues at the national level, and there has to be federal support for doing that or it won't occur. Finally, we felt that this approach would be provisional and should be re-examined periodically. In addition we recommended that a couple of should be further developed, this could be done either through private and/or public – public/private or public sector efforts and those include adoption of existing standards and creation and adoption of needed new standards . Obviously there's a lot of that going on now. The FDA just made an announcement yesterday about a large number of new standards. And in addition it would very helpful to have a public process for customer rating of HIT which would improve transparency.

Next we looked at regulatory impact on innovation. And a starting off point around this was the Institute of Medicine Report, "Health IT and Patient Safety," which included a study on the impact of regulation, which was in Appendix D of the IOM report. And that appendix discussed the innovation dimensions of regulation and suggested that there were three main domains, stringency, flexibility and information. If you have more stringency there are fewer degrees of freedom for innovation, there's increased risk of disruptive radical innovation to meet compliance and you get divergence of resources and missed opportunities. With respect to flexibility, there are more paths you have to accomplish compliance, the more degrees of innovation you have and the more prescriptive the regulation is in describing or even moving from describing to specification a desired behavior, the less innovation you get. And in the extreme the software is designed by regulation. And then finally, with respect of information, if you have more information in the system, you tend to get more innovation.

So, we made some recommendations for a potential new regulatory framework. Some of these were that certification regimens should be used judiciously and when specifying implementations, the issue is that they can narrow creativity and innovation to a specific or narrow list of solutions. There are some instances where narrowing choices is highly desirable, of course, like interoperability standards, but there are others in which it's better to specify a goal and then let people get there in different ways. Some of the innovation impact here can be channeling energy into working to the test, which I mentioned before and channeling the discussion to definitional terms rather than meeting market needs.

In addition, there should be transparency of results, and that could either supplement or even potentially down the road, replace certification. Transparency in the marketplace can be quite efficient, it has been in many other areas and it's richer in content. Certification just reveals that a system has passed a certification test and all vendors typically are able to eventually pass certification tests. And then finally, national goals should be encouraged. Examples are the Joint Commissions goals and Meaningful Use goals. They meet the flexibility test, they can help set the problem agenda and not the product agenda, they do change and if they're well set, they can help the market correct and create markets and where the market goes, the vendors will follow.

Some of the – some sources of innovation within the sociotechnical system can include developed software which can either be vendor or local, software set up, customization and extensions, which can be integrated with medical processes. And then combining of technologies, that is often done with communication devices, but – and sometimes involves predictable combinations like HL7 interfaces, but sometimes might involve non-predictable communications, with an example being an end-user combination of multiple available technologies involving hardware and software. It would be valuable in a new framework to have national accountability and outcomes assessment as much as possible, as opposed to product definitions. This also ought to include both national, and to the extent that they're available, international standards for the quality process, which would again be measurable and transparent. The notion would be that national interoperability standards would lower the entry cost through full participation of affected stakeholders, and this would encourage configuration and extension to support both process and then solve problems. There would be transparency again of products and results, this would support the ability to experiment or – develop. And in addition, we'd need to be able to aggregates safety issues at a national level so that if there are multiple problems in isolated places, these can be all brought together and you can figure out whether it's a systemic issue or not.

There would also be local control and local accountability so that local groups would design, document, improve their local systems. There would be accreditation, perhaps, of the software implementation process that might be through some entity like the Joint Commission today. We're seeing people implement in ways that are not necessarily desirable. With respect to scope, there are a number of issues including local configuration of software, local extensions, the ability to iteratively develop, implement and measure changes, integration with medical processes, training of end-users, sharing of lessons learned, surveillance by the organization and then post-implementation testing. The IOM report – it should be imagining and not imaging, a different regulatory framework suggested that if we're going to encourage innovation and shared learning environments, that the following principles should be included. There should be a focus on shared learning. There should be more transparency. This should be non-punitive. There should be appropriate levels of accountability and the idea would be that you'd minimize burden.

The comparison between current approach and a new framework, in the current approach we have defined solutions and in a learning environment, we'd have multiple solutions. Today we often have a slow response to innovation and problems, the future would be continuous innovation. Today we often have opaque results, the idea would be to move to having continuous measurement of results. Today a regulation often discourages participation and the idea would be that in a learning environment we'd encourage participation.

So, this was a lot, but overall what we've done is we've described a taxonomy for considering what the bounds are for what is HIT. We've proposed some recommendations around development of a risk framework, which we hope will be useful in considering whether or not regulation is need. We've described the current regulatory frameworks, some potential new approaches, some of the deficiencies of current frameworks, some of the ambiguities and duplications that exist in current frameworks. We've also tried to describe what we believe will both be helpful to promote innovation in the short term, but then also in the longer term. In the longer term, that would involve moving to a new framework. And we tried, to the extent possible to illustrate some of these things with use case examples. We have more of those, but again, couldn't fit them all in.

In addition we believe that the definition of what's included in HIT should be broad, but should also have some described exclusions. We think that the patient safety risk framework and the examples that we described should be used as building blocks to help develop a more robust and transparent framework; that the agencies should work together to address these deficiencies, ambiguities and duplications that have been identified. That new frameworks with some of the characteristics aimed at stimulating innovation may be helpful in advancing the marketplace. That substantial additional regulation of HIT beyond what is currently in place is not needed and would not be helpful, that is to say, it should be Class zero except for MDDS, medical device accessories, certain forms of high risk clinical decision support and then higher risk software cases. And for all of these situations in which there is more regulation, it will be very important for the FDA to clearly define them and then to improve the regulatory system.

Finally, we believe that as recommended by the IOM Committee, the vendors should be required to list their products which are considered to represent at least some risk and that would enable this post-market surveillance. And that a non-burdensome approach should be developed for doing that. Clearly better post-marketing surveillance of HIT is needed. That should include things like standardized reporting of the involved reports, some post-implementation testing and then approaches to allow aggregation of safety issues at the national level, which again would involve some federal support. Finally we believe that the FDA and other agencies need to take steps to strongly discourage vendors from engaging in practices which discourage or limit the free flow of safety related information. And I will stop there.

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

Great, thank you David. Comments or questions from the Committee? Scott?

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

That's excellent. I mean, it's clear that there's a lot of good thought that went into thinking about the risk-based framework, particularly thinking about a third-party certification process. There are lots of things in commerce today that don't undergo premarket review that present certain risk to consumers, but go through some kind of certification process or need to be built to certain specifications. I want to rearticulate just some of the framing that you talked about upfront, when you talked about FDA has the authority to regulate IT. I think you meant to say FDA has the authority to regulate certain IT, and it would be useful, probably, for us to look at the definition of what constitutes a medical device here and also think about that risk-based framework that you articulated in the context of intended use and what does and doesn't fall into the context of being a medical device. Certain healthcare IT tools can certainly be used in ways that make them medical devices, but that's not the intended use of the product and thus, there's no implied intended use there, there doesn't become a regulated product just because a physician or a patient can use it in a certain way that wasn't the intended use of the product. So I think it's important to think about intended use in the definition of a medical device and it presents certain challenges to some of the frameworks we've laid out here. So for example we talked about FDA to issue guidance stating it's enforcement discretion in certain cases for low risk Health IT products. Well I would argue that for a lot of the low risk Health IT products that you talked out in terms of how you framed them here and how you framed the intended use of those products, they're probably not medical devices under the plain language of the statute, so FDA couldn't issue guidance articulating that it has enforcement discretion. It could say that even if we had the power to regulate these products, we would use our discretion not to regulate them, but I don't think that the agency would feel comfortable saying that it's exercising enforcement discretion over things where it's ambiguous about whether it is or isn't a medical device. And so I just – it's a long way of saying – standing framework, I would just go back and look at it in the context what clearly does and doesn't the classic definition of what is a medical device. Because I think it's going to opt certain things clearly out of the bucket that even was in your framework as low risk and potentially regulated.

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

I mean, what we said was actually, what we meant, perhaps Bakul or Jodi, do you want to comment about this?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

So thanks Dave and thanks Scott. I think you're raising a point of things, and maybe examples may help here in terms of what clearly does not fit the definition of a medical device versus what could fit into a definition of a medical device. I mean the statute is broad, and if you look at the diagnosing, treating, mitigating of disease in humans, but clearly scheduling of patients in a hospital is not a medical device. I think the team went and looked at some of those sort of glaring examples and put that in perspective. Perhaps a discussion off-line or with the team would be helpful for understanding things you're thinking about in terms of where it would fit or not fit the definition.

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

Could – I thought that actually your first part of the taxonomy discussion of what's out of scope, claims processing, population management tools, general purpose communication applications, those are, I think, exactly what Scott's – it's in the spirit of what Scott's talking about, that not everything that's Health IT is what FDA would exercise discretion over. There are some things that, in the taxonomy, would be potentially outside –

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

Right, I mean, there's some ambiguity as to what's in and what's out.

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

I mean there's a lot of ambiguity. You're talking about the second reference in the statute to what defines medical devices. The first reference, an instrument, apparatus, implement, machine, contrivance, it's not clear that some of these things, depending on what the intended use is, even fits that. I mean the FDA can probably speak to this in more – better detail that I can, but I just think it's important when we look at the risk-based framework, to think about it in the context of what is the intended use of the product. Because I see a lot of things here that can be used in different ways that could opt them into regulation, but since it wasn't marketed for that purpose, it's not going to fall into the definition.

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

And I guess what I heard David describe is, there are two separate issues that you're raising, both good points. First, let's be clear about kind of what's in bounds, what's the scope; and second, even within things that are in scope, let's have a risk-based matrix for deciding –

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

Right, exactly.

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

– the intended use being an important one, but not the only one –

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

Right.

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

– that fits that definition.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

This is Jodi Daniel. I just – Farzad, you introduced a couple of folks around the table, I just want to make sure everybody knows who all's at the table. So from FDA in addition to Jeff Shuren and Sally Howard, we have Bill Maisel and Bakul Patel. Bakul is one of the people who sat on the FDASIA Workgroup from FDA, and also from FCC we have Julie Knapp and Matt Quinn, and Matt was a member on the workgroup as well. So, I just wanted to make sure folks know, so that when folks speak up, they know what the perspective is they're coming from.

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

Thank you. I think Paul Egerman was next.

Paul Egerman – Businessman/Software Entrepreneur

Sure, thank you. And first I want to say David this is really excellent work. It's an impressive presentation and also it's great to see Jeff Shuren and Bakul Patel here again, I was able to work with them on a safety related workgroup a couple of years ago, and cooperation with the FDA is really a very positive thing. So I just want to compliment them.

I had a few simple observations I like your report, I like your recommendations. You have a lot of comparisons between ONC and the FDA and certification as a regulatory process. There's one fundamental difference comparing certification with what the FDA does, and the fundamental difference is that certification is voluntary, as a vendor, I don't have to certify my product. If I want to, I could create an EHR system that is non-certified, I can skip the whole thing and I can take it to market and I can sell a non-certified product. If my product is regulated by the FDA, I do not have that option, I cannot take it to market without FDA approval, and that's a very fundamental difference between the two regulatory processes in a lot of ways.

Another observation I would make about certification is, you talk about David the importance of not being too, I think – I don't know if you used the word too prescriptive, that you talk about solving a problem as opposed to talking a lot about how the problem is solved. And I just make the observation the certification process has to be objective. In other words, you have to have – it should be in any way subjective, so you have to specify with enough detail that the software simply passes a test. That there's no judgment involved in the certification process and so that's one of the reasons why there has to be some amount of specificity in what's in a – at least a federal certification process. I mean there are, of course, non-federal – non-government certification processes where people are making judgments as to whether something is a good thing to do. I don't think we want the federal government making judgments about that in terms of software capabilities.

One thing I liked about this presentation was when you talked about safety and adverse problems with EHR systems and HIT systems, you made a distinction between data and anecdotes. And that is an important distinction. I mean there are a lot of anecdotes about these systems, but there are a lot of anecdotes about all computer systems and so that distinction is important. The FDA would not, I hope FDA would not jump to conclusions about any particular healthcare product based simply on two – a handful of stories or a number of stories, no matter how clear those stories were. What the FDA does is hopefully does a lot of work with getting data and evidence and so the recommendations about gathering that data is particularly important in this process. So those are my comments, great job David, really appreciated it.

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

Just a couple of brief responses. I will note that even though certification is voluntary, you can't get Meaningful Use dollars unless you use a certified record, so that would make it hard for a vendor to be successful in the marketplace.

Paul Egerman – Businessman/Software Entrepreneur

But it's still a choice.

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

Right, you do still have a choice. One issue with certification is something can be certified and it may or may not be very good.

Paul Egerman – Businessman/Software Entrepreneur

That's also correct.

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

Josh ?

Joshua Sharfstein, MD – Secretary, Department of Health & Mental Hygiene – State of Maryland

Thanks. First let me say how great it is to see some of my former colleagues from FDA and to say how great they've been doing on so many different issues. So, that is – it's really fun when you leave FDA, Scott can probably speak to this, it feels like you don't leave because so many things are in the news all the time about FDA and you kind of remember. But every time I hear about the Device Center, I hear a lot of great things. So, congratulations to you all. I have one question both for Dr. Bates and for the FDA colleagues, which is, applying more of a public health lens to this, there's a lot of complexity, there are areas of potential risk, there are things that you've identified as higher risk. Then there's actual risk, actual harm when something really goes wrong, and I think the last slide you have, or one of the last slides about, we want free flow of safety information. I interpret that to mean something is seriously going wrong and that needs to be surfaced and addressed. I mean, that's how I interpret that. And my question for you and for FDA, because you're sort of saying, we want the federal agencies to make sure there's free flow of information, or at least to promote free flow information, what does that mean? How do we know if something is seriously going wrong – how would we – do we have some level of assurance that that will be surfaced? In your discussion, what are the implications of that? And I am interested in any thoughts that the FDA colleagues have about that one.

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

Sure. So there are – so one example is the Australian Safety Database which basically aggregates safety issues from all over Australia and one actual example is, with one ventilator, people began to report a specific issue going wrong. And when they looked in the Database, it turned out that there were 20-some incidents like that. So, it was very clear that this one – that this particular vendor had an issue with – that was a recurrent theme. So that's an example of how this sort of thing might work, and the notion would be that there would be some database like that, which would probably be publicly accessible.

Joshua Sharfstein, MD – Secretary, Department of Health & Mental Hygiene – State of Maryland

How does stuff get into the database? Is that a required, an option?

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

It's through spontaneous reporting, which I think would be the way that this would have to work. But other comments from FDA?

Jeffrey Shuren, MD, JD – Director, Center for Devices and Radiological Health – Food and Drug Administration

On the FDA side, first of all, I won't presage anything we might do within this space, because again, we're hearing from the working group and we've yet to work out what a framework looks like. But just talking about medical device per se, currently we received information regarding a real or potential safety

problems through a variety of mechanisms. We receive medical device reports, essentially adverse event reports from near misses, and we put that information in a publically accessible database. We have a sort of, if you will, a hospital network, our MedSun system that reports to us or that we query. We are involved in registries for which we may have targeted search for particular problems and we have some pilots underway for actually identifying safety concerns that may be detected through electronic health information.

Where we're going in the future though is towards what we're calling a National Medical Device Surveillance System that starts with a premise that this isn't an FDA system, it is a collaborative system between involved stakeholders, so FDA, the provider community, the patient community, industry and others. And that you have a signal escalation process, you actually have rules of the road that say, when we see "X," we do "A," we see "Y," we do "B." And here are the things though that don't rise to the level of reporting out to the public. So there are rules for the road of how you address particular kinds of signals and our framework starts to be based much more on registries and electronic health information.

And our hope too, with the issuance of a final rule for a Unique Device Identifier, we'll finally be in a position where we can truly link the use of a medical device with a patient's experience with that medical device and move much more into a more rapid system for identification of problems. And hopefully with the system that we have in place, one in which there are very clear expectations for what merits reporting to the public and what we would do about it in that circumstance, and also one that's handled not by FDA per se, but in this very collaborative fashion with other stakeholders.

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

Farzad, did you have a comment?

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

Yeah. I think part of what I want to make sure folks understand is the regulatory – avoiding regulatory duplication part of this, is something that we've, in the Department, have taken to heart. And we've worked with FDA very closely on the draft, Mobile Medical App Guidance. They've worked very closely with us our Health IT Safety Plan. And we each have, in this space, broadly defined, we've each done our activities according to, as you point out, somewhat different approaches, both of which can be improved, as you point out, and both of which we can learn from, in some ways. The – take away from this is there are strengths to either approach, which can be used in some ways, to improve the process that we have. And one of the goals, I think, of Congress in asking for this analysis, is to say well, what else is there? There may be – okay, certified electronic health records, got it, right. We have a surveillance and action plan, there's reporting and surveillance and builds on authorities with patient safety organizations and CMS and JHACO and so forth. The administrations, the department's plan, right, for surveilling electronic health records, we have the FDA devices they've regulated and work on that. But there may be kind of gray areas, and looking toward the future, there are likely to be more gray areas. Can we now, before things get really crazy, can we start to define how to approach those gray areas and then also how do we strengthen the surveillance that we already have for reporting of safety events, each in our own domain. I think that's been the kind of – one of the expectations I have David, of the FDASIA Workgroup is to provide us with that sort of analysis. Do you think the taxonomy group that you've worked with will help give us that sort of kind of delineation of the gray areas? What haven't we already discussed kind of thing.

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

Right. We'll have to talk about it some more, yeah. I don't know if the taxonomy group is necessarily going to do that.

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

So that may be something that we and FDA and FCC have to do during this – period.

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

Good. Gayle?

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

Thank you so very much and I think Josh really addressed a lot of the issues that I was very concerned about when he talked about reporting. And I have a great deal of concern that we establish some mechanisms for that reporting and we don't have duplication and that this is an extremely important issue that we have the cooperation and coordination between the Departments. You have FDA, you have ONC, you have various Departments looking at things and there's got to be some mechanism, some formal mechanism that when reporting happens at one level, it also happens across the board. And that there's coordination, whether it's through JCAHO or however, that you have someone ultimately responsible. And when you have various agencies, you get siloed thinking at times and you may know it over here, but you don't know it over there. So I think as you look forward to how you're setting things up in the recommendations, make sure there's coordination between the different agencies.

Also, the incentives for reporting, certainly regulation can require reporting, but we've learned so much through the FAA on voluntary reporting and really in-depth discussion on near misses and what can happen with that. And so much of liability limits, when you have concerns about ultimate lawsuits and liability, you wind up perhaps not hearing the whole story on things. So, I don't know if you've looked at those kinds of issues as far as kinds of exemptions from liability and really how internal discussions can be really addressed to get to root causes on things. And there can be some negative aspects in prohibiting that from happening. So as your discussion goes forward, I'm just very amazed at the depth of this and what you've really looked at. But those are the two issues that I would really think that need to be addressed, coordination between agencies and also the liability issues.

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

So thank you Gayle. We definitely agree in terms of coordination between agencies and we stopped short of recommending how that might work, because there are so many options we felt that it was best for the agencies themselves to work that out. But it definitely – there's great potential for duplication if things are not coordinated. And I also agree with you about the importance of voluntary reporting, we did not in this discussion, focus very much on exemptions from liability, but I think that there are ways to set things up so that that would happen and we can talk more about it.

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

Question on the phone.

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

Who is that, is that Charles?

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

Yes.

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

So Charles, you're up after Judy.

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

Okay.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

First of all David, thank you that as really an excellent presentation. On slide 39, you talked about higher risk software and I think that is really an interesting thing to approach, because what is really a high-risk piece of software? You have computer aided diagnosis and in some ways, the electronic health record, much of it is computer aided diagnosis, because it's helping present to the physician the patient's history, the current review of systems of the patient, etcetera. So patient aided diagnosis should – computer aided diagnosis should probably be computer autonomous diagnosis if it really becomes a device in that same way.

A lot of other things, what is the definition of being dangerous? A scheduling system that messes up appointments can be dangerous much like a CPOE system failure is dangerous. A claim that's incorrect and comes back to an ACO with indication that a test was done and paid for, may have a doctor make a decision on the patient, and also results in harm. So many things, and even the one that you mentioned in Pittsburgh where they didn't allow orders on not-admitted patients by policy, might not be the same thing as a – it may cause harm in different ways. The other thing I think – so that's one, what is really high-risk software?

Another thing was if certification and Meaningful Use dollars matters only if you get Medicaid money, then are we going to encourage people to opt out of those key areas at even greater – in even greater numbers, and I think that's something that we're going to have to look at here. The next thing I think that was really was innovation and I worry about innovation – you talked about goals but letting organizations – letting vendors reach the goals in their own ways rather than specifying how they reach those goals. But unless those goals are very, very general, by even stating the goal, we're going to be limiting the innovation of a vendor. And an example I might give is that yes, there are lots of things that meaningful use prescribes as goals, but there are thousands more that come in from the users. The everyday users, to the vendors that don't get listed in meaningful use, some of them being much more innovative than what is in meaningful use, and yet the vendors being so busy with meaningful use, won't have time to get to them. And the last thing I wanted to mention is to be careful that a spontaneous collection of anecdotes does not become seen as reliable data.

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

So, all good points and I think your point about computer aided diagnosis is a fair one there. We were referring to a fairly specific thing that the FDA is focused on, but it could easily be construed differently and I agree with you. Around your point about innovation, I would hope that for example with healthcare reform we could set up some fairly broad goals like reduced costs, improved quality, improved safety. And healthcare reform will start to push people in ways that will then make the vendors want to inno – help with innovating ways that will take us where we want to go. When the goals are very proximate, I agree with you, that can cause problems, and we've seen some of that already, in fact, with meaningful use, right?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

Thank you.

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

Did you a comment on this?

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

I have a question for David. The idea of having the local approach to implementation providing flexibility at the local level, and then having kind of outcomes based accountability was intriguing, slide 45. And it ties in, I think, with the concept that for certain kinds of Health IT, it's difficult to separate it, its performance, its safety, its contribution to safety or its lack of expected contribution to safety, which was something you brought up as embedded within the configuration, the training, the implementation, the culture, right, all the different embedded issues within that context. So I'm wondering is this part of the – is this approach, and I guess the way I'll characterize it is, it's not about the device per se, it's about the full range of implementation issues, then does it make more sense to include that – is that a taxonomy issue as well, I guess, is one of the questions I'm wondering about. And whether it leads us to a different set of approaches so the JHACO approach that you talked about, or looking at outcomes around safety or looking at this not as an isolated issue, but hospital safety reporting in general. Does it tilt – do some kinds of potentially regulated Health IT fall more in one camp or the other camp, depending on characteristics of how they're used?

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

So I think it's not just a taxonomy issue and this is a hard problem to address. When you look at the problems that have occurred around healthcare IT, a lot of them relate to people implementing in ways that were just – just did not follow good implementation practices. And how to decrease the likelihood of that I think is a challenge. It's not the sort of thing that has typically been regulated and yet, there are enough examples of things going seriously wrong with it.

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

But I guess what I thought you were saying was, it is regulated, it's regulated as part of hospital safety more generally. So hospitals are regulated entities and hospital safety is regulated and we should use those mechanisms if we can.

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

That's what we were suggesting. I mean, it would be desirable not to introduce some additional mechanisms. It hasn't really been a focus of the Joint Commission, for example, historically.

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

Charles?

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

Yes. Two questions, first, if you look back on slide 11 where you were defining product types and what is in scope and out of scope. You define claim processing and health benefit eligibility as out of scope, which I couldn't agree more with. However, I'd like to make a comment around the use of claim data in clinical setting. I think you may want to consider – that as in scope...vendors use claim data for clinical purposes and on occasion not sufficiently indicating where that information came from. I think that can have pretty dramatic impacts on clinical care. Just to give you two quick examples. For instance, diabetes, if you see diabetes in claims data, the agreement with the clinical data can be quite high, 80-90+%. But if you look at other clinical conditions like unstable angina, the agreement could be as low as 10% and I think with that kind of variability, and the fact that I'm seeing more and more people attempt to use claim data in clinical settings, that might be an area worthy of consideration.

Second comment I'd like to offer is around FDA as a regulatory entity labels drug products and those labels include indications for use. These indications for use can directly impact medical malpractice cases in terms of whether a physician acted negligibly or not. So, the second question is, did you consider the potential medical malpractice implications in your recommendation?

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

Both good questions. I agree with you on the first point, there are multiple instances in which there have been problems like that. For example, ePatient Dave's story, which many people are probably familiar with, I think is illustrative in this regard. And from the second point, good question, it's not something that we discussed at length, but it's something that we can discuss over the next month.

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

Great. Thank you.

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

Are people with cards up, is this another question Paul?

Paul Egerman – Businessman/Software Entrepreneur

Yes, it's not a question, it's a couple of observations. I look at your last slide and you mention vendors, and I just first would make the observation that not all HIT software comes from vendors. There is self-developed software and there is also open-source software, and you can have a complete certified system in operation without using any vendor at all, and either by developing it yourself or using open source software. I'd also make the observation that this is an interesting series of recommendations and discussions, especially when you start using the word device when you talk about software, but there are other discussions about software relating to patent policy. And there are a lot of people who claim the software should not be patented because it really represents business processes and a business process should not be patent. So even some of the things that Judy talked about, how one makes diagnoses, people would say, well that's actually simply a business process as to how those diagnoses are made, that's not really a device. And so, I just – it's just again an observation, it would be very interesting to broaden the discussion to include some of these same concepts as what is happening in the entire patent discussion. Because it certainly seems to me if the FDA eventually will regulate HIT software, then it ought to be able – one ought to be able to patent it. But if the decision eventually is that you can't patent it, it doesn't seem to make sense that you could still call it a device.

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

So, good points. With respect to your first point, we did discuss that issue, that is to say that not all software comes from vendors, and also talked a bit about how should we address issues around that, particularly when software like that starts to spread. And, it's complicated. Fortunately most Health IT software does come from a vendor, at least today.

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

Scott?

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

Two quick comments. Farzad made the comment that we should talk about how we approach the gray areas. I would just offer that we should also ask what makes those areas gray. Because I think there's been some purposeful ambiguity in this space, not in the sort of sinister way, just because it's so new that the definition and the boundaries are very unclear. And I just offer up in the consideration of, as we sort of map out what a regulatory framework would look like here, we also consider perhaps a need for legislation. And I shudder to suggest legislation, I know all the implications of that, but there is a lot of ambiguity and I don't know that we're going to be able to resolve it with a set of recommendations.

And one other comment, when we talk about the creation of a regulatory framework, either a certification process or some process where companies have to submit some kind of specifications or a full-blown pre-market review process by FDA. I think we also need to consider then what would qualify for having to file supplements, to go back through that process or some process if you made modifications to the component. Because a lot of the burden and the impediment to innovation isn't just perhaps in the initial process that lets you get market entry, but maybe more meaningfully in a process that would inhibit you from being able to adapt your software tool in sort of a real-time fashion. So we might want to delineate that as well, because you could think of a perfectly plausible FDA process that might regulate the component up front, but have a very light regulatory component for any modification that's made to allow sort of adaptations easily.

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

Good points.

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

Okay, any other questions or comments? Deven?

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

– my card up at the end, because I didn't have a substantive question or an issue with anything you've put forth, I just wanted to reiterate the comments that Farzad made at the very beginning about what an incredible amount of thoughtful work this is. When I looked at the size of your workgroup, David, gasped. I mean it's important to have all those perspectives reflected, but the fact that you have been able as a group, under your leadership, to come up with some really thoughtful recommendations in such a quick time is just – it's really quite amazing, and to be applauded. And I would say as you continue to sort of wrap this up into sort of an official report, it would be nice to sort of hear what the next steps are. I think it's really important that this work be both thorough and proceed along even those aggressive timelines that were outlined, because there is a lot of innovation out there waiting for more guidance on this. And I know that the agency appreciates that, too. So, all the more reason to sort of applaud all the effort that's gone into being so thoughtful about this, even given the pressures to sort of get some of this resolved quickly.

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

Thank you. Maybe I'll just comment about next steps before we move on, which are, we'll take into account all the comments and suggestions that were made today. There were a number of additional refinements and additions that came in very late last night and we'll be working those in. We're going to be producing some additional textual information. The group is continuing to meet and then we'll be coming back with the final recommendations in September.

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

Good. Thank you very much, it's been very helpful, informative and thoughtful. And Farzad has another word.

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

Just tasking you, as if you didn't have enough to do. So in addition to some of what we heard about kind of being clear about scope and maybe a little more work for the taxonomy group in terms of thinking about which – what are the characteristics of devices that might lend themselves better to one sort of regulatory scheme versus another, right. In addition to how to improve each of those distinct regulatory schemes and the issues of liability that were addressed. I think particularly in this context, reporting through patient safety organizations obviously provides some protections for providers, but it – there are concerns on the part of vendors on that scope.

But one of the things that was really interesting in listening to your discussions was the times when the group broke out of the one axis of protection versus innovation where ideas were identified that could increase safety and the public's health and improve innovation. And one of the two that I'll highlight. One you have here which was interoperability, that if there is a better foundation for interoperability, for systems to be able to work with each other. And it – we've evol – thinking about things like APIs and systems that call each other and it's not a master-slave relationship, but those kinds of – strengthening those kind of interfaces obviously improves safety and obviously improves innovation. So, getting even a little more into detail or depth about what that – what do we need to do on that score? And I heard the point, and Jeff and I will talk about the idea of interoperability and where it lies in between the two agencies.

And the second was around trialability. So being able to bring something forward, to test it in a small-scale before it's rolled out broadly and we heard from the regulatory group that there are already FDA provisions that allow this to be done in kind of an investigational way. But if there's – in the Health IT realm, if there are innovations that come up that could be tested in a protected environment in a way a studied environment that could prompt innovation and also lower the regulatory barrier to entry, before being launched. Because we know that of the thousands of whatever, of new Health IT ideas that come in, often times you only need to try it out on 50 people before you realize, this isn't going anywhere. But to get you to that place where you can try it in a clinical setting without having to go through huge hoops would be really helpful.

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

Well thank you, good points.

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

Okay, well thank you very much David and thank you very much for all the participants on the workgroup for a wonderful report. All right, next we are going to the Privacy & Security Tiger Team for an update on the non-targeted query and the security risk assessment. And it's the Deven McGraw and Paul Egerman show.

Paul Egerman – Businessman/Software Entrepreneur

Good morning, I'm the – of the two of us, I'm the one that's Paul Egerman and we are here today to give our Tiger Team report and to make some recommendations. First, these are the members of the Tiger Team, so these are the tigers, I guess. And this is a very dedicated, hard-working group of people that has been meeting through the summer, through July and August and talking about – having some very spirited discussions on important topics, including a hearing. And our agenda today was, we really have two topics that we are going to be asking for approval of our recommendation. The first is called non – is on the topic of non-targeted query, which we've presented before. I says on the slide, final recommendations, we're hoping these will be our final recommendations, we're hoping that we can tie a bow on these recommendations. And the second topic is Meaningful Use Attestation for Security, which is really a very separate topic, it's not at least directly related to the first. It's just that we've completed our work on that issue also.

So to explain these, first to give you some background, in order to make progress on this whole concept of information exchange and queries, we created a definition of three different scenarios. So the first scenario is something that we called targeted query, and that's really the ability for one healthcare organization to get information from another. And it's something that actually happens all the time already. People will in effect call the HIM Department, the Medical Record Department of another organization, saying something like, I'm seeing your patient this morning, can you fax me the most recent lab results? And people will do that, they will fax the lab results, and so this exists a lot already. And it exists also already in computer systems, usually when both healthcare organizations have the same vendor, but it also exists.

The second scenario is targeted queries that occur when there's some other law that requires patient consent or authorization before the query can occur, it's usually a state law. And the third scenario is what we're here to talk about in this morning's discussion, it's called the non-targeted query and that's basically a situation where a healthcare provider has a name of the patient, and asks like we call it an aggregator, some other entity, possibly an HIE organization, to get the information to them. Either the aggregator has the information or is perhaps a record locator service so it gets the information to them or directs them to where that information should go. We tried to draw a diagram of what that would look like, we found ourselves spending all of our time arguing over the arrows and so we skipped the diagram and we have this discussion about this concept of an – and we call it an aggregator. We also had a discussion whether or not that was the right word, it's probably not the right word, but that was the word we chose, that finds the data.

So these are the three scenarios. Here is the basic background on what has happened so far. In April, we had a series of recommendations on the first two scenarios, which you approved. We also came before you and said, on that third scenario, the non-targeted, basically that's a situation that should involve meaningful choice. A patient should be able to choose how they would be – or whether or not they'll be listed by this aggregator and furthermore, meaningful choice means they have to be somehow informed about the aggregator. So those recommendations were approved. Then in May we came back to you with a recommendation on the non-targeted, in which we basically said, we were reiterating our targeted recommendations and basically what you followed up with was, you asked us to have – to consider it in more detail, to have a thoughtful discussion about the non-targeted.

And so we did do that. In a few minutes Deven will talk about the additional discussions that we had on non-targeted. We had a really excellent hearing where we had I think it was eight different organizations, HIE organizations, these groups that we call aggregators, come and present what they were doing. And basically after hearing those recommenda – that hearing, we are coming back to you and we are reaffirming our previous conclusion. We did learn some things that were new, and we will be describing those, but those new areas usually, like the areas were involving the aggregator or the queries beyond what I would call the treatment relationship. I mean, what we are limiting ourselves to is when somebody asks for information related to treatment of a patient. And so there are other issues that were not included in the scope of what we were working on that arose. So that's the basic background and I don't know if you want to add anything before we dive into it.

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

No, I don't think so Paul that was excellent description. So what I'm going to do is just to remind everyone about the recommendations that the Policy Committee have already adopted. I don't – I won't bore you by exhaustingly going through these. But since our ultimate conclusion is that these recommendations, which we initially came to in looking through the lens of targeted query, also apply equally to non-targeted query and essentially provide the basis for us reaching the conclusion that we don't think for non-targeted query that any additional policies are needed at this time.

So, in order to sort of set the stage and hopefully relieve everyone's potential anxiety about the non-targeted query scenarios, we really wanted to take the opportunity to remind folks that we're not naked on policy in this regard. We actually did come up with a really good set of recommendations involving query that apply in the non-targeted query circumstance as well. So this slide just reminds folks that we have existing legal obligations frankly, on sort of both ends of the query spectrum. But really with respect to the data holders in terms of when they are permitted to disclose information about a patient, even in the context of treatment. In the HIPAA context, patient consent may not be required, but there may be additional laws that apply in other circumstances. So clearly the data holders going to need to know that the person on the other end of the query is who they say they are, some reasonable assurance that there's a treatment relationship and then the data holder is one who makes a decision about whether to release the data consistent with their legal and ethical obligations. And then of course if they're responding, they need to send the data back about the right patient. The entity who's querying needs to present sufficient information to essentially satisfy the needs of the data holder to be able to legally release the information.

And so our recommendations really tried to address sort of each of those sort of existing obligations and essentially we said a data holder needs to be reasonably assured of the identity on the other end of the query. But there are sort of multiple mechanisms for providing that level of assurance, and we defined some of them. The data holder needs to be reasonably assured that there's a treatment relationship with the patient, and we outlined a number of ways that that kind of assurance could be provided. There's not one way to accomplish this, there are multiple ways, because ultimately it's the data holder who needs to be satisfied that in fact, this disclosure that's being requested is both legally and ethically permitted.

Automation. Data holders can make a decision to automate the response and essentially should adopt policies to govern when an automatic response is appropriate. We defined some recommendations along this aspect, too. Most of the details of this are in the backup slides. Again, we're not trying to re-bring before you and rediscuss all those recommendations, but just to demonstrate to you that we had really laid a very strong foundation from a policy and best practices standpoint for queries generally, that holds up very well and helps us in the non-targeted query circumstances.

Well, we talked about the circumstance when automation would trigger the need to get some consent from patients for their information to be disclosed in that manner. And there is a recommendation in that regard that's consistent with previous recommendations that we've made on meaningful choice. We also talked about the issue of patient matching and how much information needs to be disclosed in order to ensure that the right patient's record is released. We also had something to say about responding to que – that a response to a query, you have to say something in response to a query. You don't necessarily have to disclose the patient's record, but to at least acknowledge that you received the response and to provide some response if the record is not going to be disclosed for some reason. But we had a lot of lengthy discussion about how ideally the data should follow the patient and that there are certain – and that assuming that the other existing legal obligations are reasonably satisfied in terms of identity and attestation of treatment relationship, that the records should be disclosed. And ultimately data holders do need to respond to queries in ways that are consistent with their professional and legal obligations.

We talked about how that both the query and the response ought to be logged, so that patient – and patients should be able to get a copy of such a log if they request it. We also had recommendations with respect to sensitive data and the need for technical capabilities to accommodate both the need – identify areas where patient consent is needed to release the record and to be able to communicate that need and then to be able to communicate the consent and ideally store the consent, that's really a technical issue. And then as Paul mentioned, with respect to the non-targeted query issue, we had already brought to you and had approval of a recommendation that when you are talking about a situation where a patients record is being requested based on patient demographics and you're using some type of aggregator or other service in order to find the location of where the patient's records are, the patient should have some meaningful choice about whether or not they are listed in a service like that.

So that's where we landed. We again, as Paul mentioned, we initially came to you and said we don't think that there are additional policies needed for the non-targeted query scenario, but you – a lot of questions were asked how this was currently done in the marketplace and we wanted to get some more information. So, as Paul mentioned, we had a virtual hearing and it was a terrific hearing. We had eight existing non-targeted query models speak to us about their experience and implementing it and what they were doing. There is a transcript available about this hearing, but I'll just – in these slides we sort of have a summary of our top line findings. Access to each of these networks is controlled and limited to members who have executed some sort of binding participation agreement. These agreements are executed with the data holders themselves, as well as those who would query. And in some instances, those agreements get executed with EHR vendors, again, depending on the model. Each network provided patients with some choice. Most of them were opt out, but some were opt in. Many of them had a model where the data was held by the network, but was accessible only for those patients who have either opted in or have not opted out. There was one network whose model was that the data was not moved into the HIE without opt in consent.

In the context of sensitive data, most of the networks who provided testimony to us were dependent on the data partner to withhold the data that required additional consent. There was one network who made substance-abuse treatment data, which is subject to rules called part two, which are more stringent and require patient authorization, they did make this data available in the HIE, but only to providers who specifically requested it and subject to a second consent, a second opt in from the patient and subject to a second attestation of a treatment relationship. And a reminder upon release of that data was provided that the information was subject to redisclosure limits. In many networks, patients who had concerns about access to sensitive data in the HIE were counseled to opt out, or not to opt in at all, depending again on whether the model was opt in or opt out.

Many of the networks have role-based access levels for their participants. All of them did audits of access and disclosures, only some of them made them directly available to patients. The ones that did not make them directly available to patients saw their role as a business associate and said that they would be willing to make them available to their covered entity participants, if in fact the patients requested them but that the patient relationship was with the covered entity and not necessarily with the network. So it wasn't as though they were saying, we won't make it available, it was as though they were respond – I mean essentially they said it's not our role to provide that directly to patients unless our participants ask us to do so. None did an override of patient consent. Some had an emergency break the glass policy that would apply in a circumstance where the patient had said nothing, either didn't expressly opt in yet or had not expressly opted out, where they just didn't have any indication from the patient about what their choice was, then in an emergency circumstance, the provider could ask for the records.

All of the networks limited the access to certain purposes – and treatment – access for treatment purposes was common for all of them. Many others also allowed for operations and public health reporting services and some allowed for payer or payment access. We have testimony on sort of the circumstances of payment access, but payment was not one of the issues that we deeply explored in the hearing and as you'll see in our sort of post-recommendation sort of list of potential additional issues, payer access was one of them upon which there were some concerns expressed.

Most of the entities that we heard from either had inherent or express geographic limits. So an inherent geographic limit would be a state HIE handles the exchange for residents and providers within that state, so it's not sort of a nationwide exchange. There is the possibility to do sort of nationwide exchange, again using query, we're focused on query here, but now that seems to be only happening with limited data sets. Testifies expressed some concern about the potential for federal policy, such as what we might recommend, potentially disrupting the arrangements that they had very carefully implemented working with stakeholders in their communities. But most also expressed a desire for some guidance or common agreement terms that might help facilitate network to network exchange and some additional guidance on how to handle sensitive data.

So given all of what we learned, here are our recommendations. The previous recommendations, which we had initially considered the context of targeted query, also are very important to apply to non-targeted query as well. In terms of whether there are additional policies needed and based on what we heard in the hearing, we think that these networks are currently taking great care and effort in crafting their policies and operations and figuring out something that works for their particular participants in their particular communities. And based on those results, we are reaffirming our previous statement that the existing recommendations on meaningful choice and the various elements that we had initially considered in the context of targeted query are sufficient to address non-targeted queries and that no additional policy is really needed at this time. But as is always the case, we should continue to keep an eye on this marketplace and what is happening and to be able to revisit these recommendations in light of changes in circumstances in the future.

Some of the additional thoughts that we had were that, and these are sort of outside the context of our recommendations, but depending on sort of input from the Policy Committee could be something that we could explore more detail. The hearing really highlighted the state of the trust framework upon which current health information exchange really occurs. And the framework is built in many ways, upon numerous trust agreements with data holders either that exist at the vendor level or that exist at the HIE level, and some of them do cross state lines, but many of them are very state and geographically specific.

There also was a concern expressed, as I alluded to earlier, that some record holders may – given that they have the discretion to respond with data to a query. And that is the case under the law, that people would withhold data for business reasons and there might be a multitude of business reasons for withholding data I think we can imagine, and that ultimately the data should go where the patient goes and needed to maximize patient care. And that's really the sort of underlying foundation of the recommendation that providers are expected to use both their ethical and abide by legal and ethical obligations in making decisions to disclose. And that ultimately the need for the data to follow the patient has to be taken into consideration.

Some of the other issues that caused some discomfort among members, but again, since it wasn't our initial focus on the hearing, folks were not prepared to sort of change our recommendations at all, and that involved access to data through query by payers. Some expect a concern about public health access and issues involving sort of overarching governance and whether the existing framework, especially for the HIE to HIE transactions is sufficient, both from a privacy and security standpoint, but also from a sort of encouraging the exchange of data when in fact we really should be exchanging data.

So with that – I mean, those are our recommendations on the query issue. We have additional – as Paul mentioned, we have some additional recommendations that would apply to the third stage of Meaningful Use, which we were finished with and so we're prepared to present and we have slides on those. But I defer to you, Paul, whether we want to sort of stop and consider the recommendations a query and then moved to the other recommendations or have the whole presentation proceed and then have a dialogue about all of them.

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

Why don't you finish the presentation and then we will divide the discussion into two parts.

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

Okay. So the second set of materials that we have involves what we would suggest for Meaningful Use Stage 3. And we initially considered whether there would be additional security aspects of the HIPAA Security Rule that we would seek to sort of shine the spotlight on, using the meaningful use objectives, keeping in mind that that's been our approach to using meaningful use in the privacy and security category previously. We started with the requirement to either do a review, a security risk analysis and corrects deficiencies, that's Stage 1. And there was additional requirement added in Stage 2 to attest to having addressed the encryption of data at rest.

For Stage – again, for Stage 3 we thought well is there something else in the Security Rule that we need to emphasize. And ultimately we heard from the Office for Civil Rights with respect to what they were learning in their audits of entities for compliance with the Security Rule and getting a little bit of information about what CMS is learning in their audits of meaningful use attestations. And we came to the conclusion that the security risk analysis still doesn't have a sufficient spotlight on it, isn't really being done in far too many organizations or done correctly. And that there are significant deficiencies there that we wanted – and so, instead of picking something else, we wanted to strengthen beyond mere attestation the way we emphasize the need to do a security risk analysis to document that analysis and what you learned and to correct the deficiencies that you identified in that analysis, consistent with the HIPAA Security Rule.

So along those lines, here are our recommendations for strengthening the existing requirement in meaningful use to do or review a security risk assessment. Again, designed to make this something more than a check the box at the end of the process and to make sure people understand that this is a serious and important obligation. For Stage 3, CMS should emphasize that when an entity attests to having conducted a review, the security risk analysis, with respect to its certified EHR technology, that entity is essentially attesting to complying with the HIPAA Security Rule with respect to such analysis, linking those two. It's not any security risk analysis, it's the one that you are already required to do under the HIPAA Security Rule, which then should ideally direct you to a matrix of the things that you need to look for in doing this analysis in the first place. And achieving compliance with this objective means conducting or reviewing the security risk analysis and documenting the results of that analysis, including the actions taken, or a schedule for action planned to be taken in order to correct deficiencies that get identified in that analysis and review.

We also thought about adding an accountability measure, which would involve identifying one or more, as appropriate, individuals who are responsible for conducting and documenting the risk assessment. And the idea here is not to throw somebody under the bus, but instead to sort of require some thought. Again, it's not just a check the box. Did you do this? Who was responsible for doing this in your organization?

And then another recommendation we had would be to rather than leaving it at the bottom of a check the box, would be to link the attestation to specific meaningful use objectives that involve additional functionalities for which a security risk analysis ought to be done. For example, adding view, download and transmit to the functionalities of your certified technology, that an attestation that you've done the security risk assessment associated with that makes – in many ways sort of demonstrates to meaningful users that this is what the risk analysis is about, right.

It's not just, oh yeah, CIO you did this, right? No, it's security by design, right, taking into account the new functionalities that you are adding. And I have to give credit to a chief information security officer who gave me this idea in part because he had been left out of meetings on how to deploy the view, download and transmit capability within his institution. And essentially the response was, well when we get to that part of meaningful use, that last category, we'll let you know and then you'll tell us whether it's all been done, as opposed to having an understanding that this kind of conversation is part and parcel of how you implement something.

And then our last recommendation involves CMS providing some additional information to meaningful users, such as FAQs, on the expectations and importance of both conducting and documenting the security risk analysis. Because one of the things that these audit programs did reveal was that while people attested to having completed the risk assessment, when they were asked where the documentation was, it didn't exist. And that's really part of the obligation is the documentation of both the risk analysis as well as the correction of deficiencies. And some of the FAQs – some examples of some FAQs that the Tigers thought would be helpful would be discussing availability, use and benefit of third party assessment tools and services, particularly those that the regulators have developed. Expanding the FAQs to clarify that a component of the risk analysis includes a requirement to correct any deficiencies that impact security rule compliance. And then also highlighting the potential value of having auditors leverage the audit program guidance that OCR has been using to review what's been going on. Because it's certainly great information on sort of where – what the Office for Civil Rights is focusing on with respect to security rule compliance. That's it.

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

Okay. Thank you very much. So we'll divide the discussion into the two parts, one having to do with the non-targeted query and the other having to do with the Stage 3 security risk assessment. I could open up on the non-targeted queries. So a question that – I have a couple of questions. One has to do with reconciling the summary that says we need no further regulations with the requesting from the panelists, but there could be this federal – there could be federal help on – between organization kind of exchanges.

So I think, so I listened to the podcast but for whatever reason was cut off towards the end. I think most of your testifiers were within an organization, they can be large organizations, but basically talking about creating new trust relationships amongst the members in some defined organization. And you spoke of that and part of what you said is, well, they didn't want anything to interfere with this hard-earned trust; so that all makes a lot of sense. The non-targeted query I think that where there were questions is, what happens when you sort of blindly go everywhere, potentially nationwide, saying, hey, I have this person does anybody know anything about it and would you share that, that crossed all of the pre-existing trust relationships that were so hard to earn and maintain and you have rules for. Because that creates the cross the heterogeneity of the policies and the practices and so we don't yet have interoperable policy. So once you cross that boundary where you've established the rules of the road for this particular group into another group, there are different rules of the roads and how do you deal with those conflicts. One example is opt in/opt out. So when you cross from an opt in organization to a opt out organization, how do you deal with that?

A related thing would be the sensitive data question and you explain how some organizations describe all of the extra steps they took to get it in to the repository and be accessible. But the risk comes when you transfer it and then how do you manage the re-disclosure? And you said, some people said, well we told our members that if you have some of that data, just don't participate, either don't opt in or explicitly opt out. That sort of reveals that people do have this concern and if they don't do that, for example, don't ask people to not opt in, then what does happen when it gets disclosed once and to protect the re-disclosure? It seems like it's a hard problem still. So those two issues, the crossing organization boundaries, however those are defined with the heterogeneity of policies and practices and the sensitive data handling seems like that's where they were even asking for federal guidance and potentially even rulemaking. How do you reconcile that with nothing else is needed?

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

So, the landscape today is that the possibility to do a nationwide query for your patient's data, regardless of which vendor systems it might be held in, doesn't exist. It doesn't exist, you can't do it, right, so in some ways what you can query is already limited by the fact that you have capability to query, for example, in a vendor provided network. You have the capability to query for patient records as part of that HIE for which you are member, but a sort of random query to the world, you can't do yet. So notwithstanding that we might want build that capability in, it's not a – there's not a sort of set of issue – clear issues to necessarily resolve. Having said that, it is the case that the HIEs, I mean so Surescripts is a nationwide query model, but it's for a specific purpose involving specific databases in order to complete the prescription exchange transaction including the formulary checks, right. So it's not the kind of thing where you – I'm looking from my patient's records, you can query Surescripts database, at least not as of yet.

But certainly a sort of scenario where you have no idea where the patient has been, you want to find the patient's records and you can actually find the patient's record reliably, regardless of where they've been in many ways doesn't exist yet. And so we're asking – that's why we said, look, there's not – we do our best work when we know that there is a very well defined problem to resolve. And here there are existing query models that are working and for which there are ongoing efforts to explore how to do, sort of HIE to HIE exchange. But given that the vast majority of patients receive care within a fairly well defined geographic area versus flitting – I mean, where there's a lot of really well-traveled people here in this room today, but in terms of sort of patient migration patterns, they're relatively consistent in areas.

And so it's not that we couldn't in the future sort of work on sort of cross HIE to cross HIE exchange or the ability to have some sort of aggregator that would link all the aggregators so that you could find a patient. But we don't have it and doing policy around a desired endpoint, but without are really clear use case and not sort of resulting in a sort of innovation limiting set of policies, given that we already have policies about when people can disclose data and the circumstances under which they can, seemed really not necessary.

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

Well can I give an example of a cross na – a broadcast non-targeted query?

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

So Paul – let me let Paul –

Paul Egerman – Businessman/Software Entrepreneur

Yeah, I'd just say – I'm actually interested in hearing your sample, but my view is, even in those situations our recommendations work. I mean the fundamental issue is, the recommendation that we put before you that you approved was patients have to be given meaningful choice before being included in an aggregator, being listed in an aggregator. So if there is an aggregator that is national in scope or aggregates things across multiple states and multiple HIEs, patients still have to be informed of that and they have to be given a choice as to whether or not they want to be listed, to be participants in it.

This issue of whether not they opt in or opt out is one of these discussions that you can like go on forever with, but the fundamental issue is once the patient has made whatever the mechanism of that choice is, it doesn't really impact at all the rest of our discussion. In other words, the discussion still is, what are the responsibilities of the data holder and data requester when the request is being made for treatment. And so it's really important to keep in mind, this is for treatment. And so when the patient – when the request is being made for treatment, I think our recommendations still work.

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

Yeah. And keeping in mind, again, that the data holders have – already have existing obligations to consider whether they should release data, right, and if they're getting a query in where they don't recognize any of the information on the other end of that query, they don't respond, right? So, keeping in mind that we've already sort of layered in a lot of – there's both existing law as well as sort of a set of best practices we've identified that you can be reasonable – try to create some reasonable assurance, but at the end of the day, I think Paul's right, our policies address what is possible to address today.

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

Deven, maybe this might be a helpful analogy. This sounds a lot like conversations about standards –

Paul Egerman – Businessman/Software Entrepreneur

That's right.

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

– where this is essentially the policy standard and what you're saying is, it's kind of like some of the standards we had before where there are lots of different – same standard, HL7 2.5.1, whatever, for immunizations, right? It's the same standard but multiple – so that your principles are the standard, multiple people are implementing it slightly differently.

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

Right.

Farzad Mostashari, MD, ScM – Health and Human Services –Office of the National Coordinator for Health Information Technology

And in local markets, that's fine because the people you do a lot of training with, you'll fix those interfaces, there are only a few interfaces to the people in your local market. But once you start to go outside your local market, those standards implemented slightly differently don't work with each other and then you have to get into deeper levels of specificity, removing optionality, meaningful choice isn't enough, you got to tell us how to do meaningful choice, exactly how, right, if you want it to be truly transferable across that. So –

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

Curly braces problem –

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

It's the curly brackets problem. So, it's – I think it's the same evolution that you start with the broad framework, then you get down to more detailed standards that help you reduce, but not eliminate, the need for rework at the edges. And eventually you get down to the point where you have a crystal-clear, not only do you have the implementation guide, but you also have validation, you have testing tools, you have a certification process, and then you get closer to plug and play. But what you're saying now is, we don't have plug and play policy, Paul, and it may be a while before we get there.

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

The example I'd raise would be a vendor administrated – it's basically a vendor administered HIE, where these certainly cross state boundaries, so you automatically by in different poli – different laws, let alone policies, and it's not clear, maybe – you may be very correct that the meaningful choice invoking that is a way to solve the problem. I think it's just like your security assessment where you had to go again in Stage 3, which we already did in Stage 1, because people don't understand it, are not implementing the policies you think should be applicable. So in this case, I don't think all the patients that are seeing their local doc understand the implications of whether they are opting in or have been opted in to exchanging data nationwide, in the case of a vendor HIE.

Paul Egerman – Businessman/Software Entrepreneur

And that's a good point, but that's not – that's not the issue that we were addressing. I mean whether or not patients understood it is a good point, and it's also a very good point as to whether or not our recommendations are getting implemented. But these are still our recommendations, the whole concept of meaningful choice is the patient should understand it. I also wanted to quickly mention here a second issue, which is the issue of re-disclosure of the data. That's a very interesting and complicated issue, especially since the recipient, the receiver of the data, could possibly be getting conflicting data from two different sources. And that's a fascinating issue, but it was just not an issue that we addressed, we viewed that as outside the scope. We really very narrowly focused on non-targeted query, asking the question, getting the answer.

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

Okay let me go to Gayle and then Alicia.

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

Thank you Paul. One of the things I think you are addressing Paul, and I have the same concerns you do, really is when you're talking about trust between organizations and HIEs. That comes down to somewhat of a different topic when you're talking about governance and what's the structure and what are the requirements of the HIE, so I can trust my HIE can trust your HIE. And that's in a little different framework and that really needs to be addressed from a governance point of view, and we've really not done much of that, and that's really kind of somewhat outside the purview of the Tiger Team. And there was a Governance Workgroup, which I think is disbanded at this point, but I think that's truly where that whole conversation absolutely needs to happen. And I would like to see that workgroup really come to some recommendations for us.

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

Gayle, just to point out, and maybe we can bookmark this, it moved out of workgroup but it didn't move out of work stream and we actually have activities going on on governance that we can brief the committee on. Because I think it's exactly – you're exactly right, that's where it gets picked up.

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

That I truly believe is where needs to pick up, and that is an issue I have and would down to what the data holder's responsibility is and basically what our Tiger Team has recommended is the data holder has a lot of responsibility in making decisions, but you can facilitate decision-making through governance. And if you have a governance structure that gives confidence and public trust in HIEs, then you have the seamlessness that is truly going to be required in order for the patient to have confidence and the public have confidence.

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

Alicia?

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

My question was just going back to the opt in/opt out. And I understand that your work was very constrained to certain parameters, but – so perhaps my question might have been addressed in a different meeting, I'm not sure. But the whole opt in/opt out policy, is there ever going to be any standardization of the way that these networks interact, that everything's opt in or everything is opt out, so you're not dealing with one systems opt in, another one over here is opt out?

Paul Egerman – Businessman/Software Entrepreneur

That was an issue actually that the Tiger Team addressed a while back, I can't tell you how long ago, it feels like 10-20 years –

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

August 2010.

Paul Egerman – Businessman/Software Entrepreneur

August 20 – two years ago and the way in which – and the actual issue Alicia, to bring you up, and the way we addressed it is, we came up with this concept of meaningful choice –

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

– which we thought was actually better than opt in or opt out, where patients have to understand and be explained in a way that patients understand what is meaningful to them, and also left a lot of flexibility on the part of the provider –

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

Um hmm.

Paul Egerman – Businessman/Software Entrepreneur

– to make that choice. And I think our hearing sort of showed some value in that, in that as these different people were presenting, they would reflect on what I would call the privacy culture that existed in their state. And so the reasons they each – it was really interesting to learn why they addressed some of these issues differently, and different states would have – the culture which would ultimately be reflected in some state laws that was much more oriented toward privacy protection than others .

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

And I guess just a follow-up then to that. The idea that – and you spoke of the data follows the patient, so does this opt in/opt out, meaningful choice option follow me wherever I go or am I – every time a new data holder is entered into this equation, am I sort of reassessing or reasserting my choice?

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

So keeping in mind that we were very specific about when we thought additional choice ought to be layered on, beyond what the law already requires. Because we know under HIPAA, which is sort of controlling law for data exchange unless there is additional law on sensitive data that requires additional authorization, the data can be shared without necessarily needing to get the consent of the patient in order to treat the patient. Now where we said that patients ought to have some meaningful choice is in circumstances where the provider who they typically trust to make decisions over when their records get disclosed no longer is in the judgment seat anymore, right? That they have sort of disgorged their data, for example, to a centralized database where the data is then easily accessible. Or there's an aggregator, again using – I have to use the term, it's not the best term in the world, but it's the one we used, where there's sort of your name is listed on the list for people looking for your records. Versus a judgment call where a request comes directly in to your provider to I'm also treating Alicia and I need her data or a provider says, well, I know you're going to see this provider tomorrow, and we go send it.

Choice applies in circumstances where there is an exchange that you might not expect, or your data is accessible in an environment that might be – that's somewhat new and that you might not expect. And we said meaningful choice, meaning you have an opportunity to make it in advance, but at the end of the day, if the default – if you say nothing, is you're in or you're out, that's sort of where opt in or opt out doesn't make as much of a difference. You have some opportunity to choose whether you're in these arrangements are not. So choice is limited to certain types of exchange arrangements or where existing law requires it. So in a normal sort of treatment flow of data, with known providers, you don't need to opt – you don't necessarily need to opt in to that.

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

Okay.

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

And so we were trying to sort of issue spot the areas where we don't want the patient to be surprised and we want them to have an understanding of where their data is. And ideally in circumstances where the sort of proxy for making decisions that patients typically trust, their doctor, isn't in the driver seat anymore.

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

So will there ever be any mechanism for me as a patient to be able to see who has requested my data? Or that wants to see my data? I mean the way you go – like if you pull up your credit report you can see that oh somebody –

Paul Egerman – Businessman/Software Entrepreneur

Great question. That's a great question and that's what we will be addressing next.

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

Oh, that's –

Paul Egerman – Businessman/Software Entrepreneur

If this is – unless you want us to address this some more, but that's the plan. Again, we were very focused on simply when there's a non-targeted query, what are the responsibilities of the data holder, what are the responsibilities of the requester. Beyond what already exists, what other things should be asked of the patient?

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

All right. Thanks.

Paul Egerman – Businessman/Software Entrepreneur

But that question you asked about the disclosures, is an exciting question that I look forward to addressing.

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

Thank you very much.

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

Then I saw Christine, Joy and then Farzad.

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

I'm going to go to the meaningful use stuff, so if you have on this, do you want to go first?

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

Could you talk about this scenario that you have heard about or has been testimony around, data holders not having discretion over record release policies? So what are some of the different flavors of that scenario?

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

We didn't get testimony on that Farzad because that was a recommendation that we had previously –

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

Why did we come up with – what were we – what was the use case that we were thinking about?

Paul Egerman – Businessman/Software Entrepreneur

What we were looking at was again, what exists currently and what existed before the EHR systems, where one organization would contact another and ask the Medical Records Department, HIM Department, fax me the lab results on this patient because I'm seeing him this morning. The idea being presumably the record holders have policies as to how to respond to those issues. And so the situations where they may not have policies would be a situation where there was an aggregator involved. Where somebody else is making those decisions as to whether or not data could be released and we just said that would trigger meaningful choice. So that was just –

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

How about –

Paul Egerman – Businessman/Software Entrepreneur

– it wasn't to try to suggest anything bad was happening, we were just sort of saying, when – you don't need meaningful choice if there's direct – if there's targeted queries and the organizations are just doing whatever their policies are to respond.

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

And I understand. I mean in a way you're saying if the provider doesn't have meaningful choice, then the patient needs to get meaningful choice.

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

Right. That's right.

Paul Egerman – Businessman/Software Entrepreneur

That's correct.

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

And I guess what I'm thinking about is, I can imagine – I don't know how often this happens in the real world, but I think maybe it's something that we should think about. There may be policy or contractual or business relationships that essentially enforce, like, if you want to work here, right, then you sign up for the HIE or you join the HIE and they – you know what I'm saying. So, there may not be simply an architecture of where the data flows issues, but a provider may de facto need to – may not have discretion over record release policies. Do you see what I'm saying?

Paul Egerman – Businessman/Software Entrepreneur

I understand it, I mean as I recall, one of the criteria for meaningful choice is that the choice should not be coerced, in other words, the patient should legitimately have the choice.

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

This is the patient – this is the provider I'm talking about.

Paul Egerman – Businessman/Software Entrepreneur

If I recall correctly, our recommendations on that was that providers should have the choice, so that was on an organizational basis not on an individual clinician basis.

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

Yeah –

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

I just – I guess what I'm suggesting is that I agree with this principle, but it needs to be a little broader than simply is there a – does there exist a policy or not. I think the spirit of this really goes to, can providers – if providers cannot really exercise choice, then we should default down to patient exercising meaningful choice. Does that make sense?

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

Yeah, I mean I think that's in essence what our sort of policies all taken together, including the ones from August, as well of these, which is to say we have previously existed in an environment where patients relied on their doctors and the hospitals to make wise decisions about when to share data. And that – and played almost a gatekeeper role. And that in sort of exchange arrangements where those decision-making capabilities are more remote, that could result in disclosures that would potentially surprise the patient and that we ought to give them some meaningful choice before their involved in that.

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

And my point is that this principle, which I agree with, extends not only to an architecture where the patient's data has left the doctor's office and it now can be queried by anyone without going back to the provider. It can also be a factor when the provider does not have meaningful choice about the policies of the organization, the health information exchange that's kind of baked in. Yeah, I buy this product, I have to use their health information exchange or not – or else, right. I can see that developing and I think we should make clear that this policy extends in the situations. Does that make sense?

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

Um hmm. Yup.

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

Joy –

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator

Yes it does and I think that the group – I think that we're so close to it that there is an assumption that that was the case. Right?

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

Yeah.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator

I did want to just very briefly address one of Paul's questions about educating the consumer. We have – we ONC have an eConsent pilot that's been going on, we're going to releasing the results of that pilot shortly, in the next few months, a month or so. And there are a lot of educational materials that will be included with that, so we've heard this and we are taking steps to try to address it so that individuals – providing a number of different ways that providers can work with individuals to make this really something that they understand. It's a very – it's a challenging area because it's very technical yet you need to explain the ins and outs of it, but in plain language. But we'll – stay tuned.

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

Great, thanks. So maybe to pick up a little bit on what Farzad said, it would be helpful – I know that the – I think the mix of the policy – the principle he just enumerated, and your meaningful choice together address the issue. But maybe an explicit examples of here are some of the non-meaningful – the examples where providers don't have meaningful choice and it's implication to giving patient's meaningful choice would be helpful, so we don't have to second-guess what you meant. Because I think what you said covers it, it's just there's some specific examples that could be explicated.

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

Okay.

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

Are we ready to – do you want to vote on this recommendation?

Paul Egerman – Businessman/Software Entrepreneur

We'd like to vote on this one, and then we'll have to vote on the next one.

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

So we're ready to vote on this one, which is the motion to accept with, I think, with some of the clarifications that are requested, accept the recommendation for non-targeted queries. All in favor?

Numerous speakers

Aye

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

Any opposed? Or abstain? Thank you. So now if we could move to the Stage 3 securities.

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

I thought Christine had a question.

Paul Egerman – Businessman/Software Entrepreneur

Christine had a question.

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

Thanks. So this is really helpful. I just want to make sure I get the recommendation about linking attestation to specific MU objectives. I don't think you mean all new ones, but I also don't think that you mean the ones that focused wildly on exchange, interoperability and consumer engagement, because you could make the argument that providing patient education materials in a non-English-language is consumer engagement, right? So, I'm just trying to figure out how do we – it makes sense when you talk about view, download, transmit, I don't know if it makes sense for family health history, patient-generated health data – so it would be helpful to get that level of feedback if you have it.

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

Yeah. So we definitely did not mean to imply that every meaningful use objective, or even every new meaningful use objective would have a corresponding requirement to do a security risk analysis associated with it. We were essentially suggesting to CMS that there could be an exploration of objectives that intro – that where there – that introduced sort of new potential security risks, where you would be clear that the assessment should address those issues, and maybe even in the attestation form, have a way to attest that it was done to address that. We didn't do the work of sort of going through all of the objectives and saying well we think it's this one, this one, this one and this one, in part because this is aimed at Stage 3, where those are not completely done yet. But we can at least clarify that we're talking about the subset of the objectives that raise additional – that potentially raise additional security risk and not the universe of meaningful use objectives.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, so linking it to one or possibly more than one specific meaningful use objective, but it's not to all them. And it's choosing one or possibly more than one to sort of like shine the spotlight on.

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

So my follow up question is, in that case do you – would the whole objective change, so whereas you could – so in your first I think couple of recommendations, they assume that the security risk analysis is happening at large period, right? So now we're saying but it also should be a different one that's applied to specific objectives, is it the same, how do they interact with each other?

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

It's a good question. I think we saw it as additive, like there would be a requirement at the end to attest that you had done the security risk assessment. And if you all agree, identifying who was responsible for it and with more guidance about what that means when you attest to it. But this would be an added way to sort of emphasize that the security risk assessment needs to address, in addition new functionalities that need to be adopted in order to comply with objectives that might introduce greater risk. It's an effort to sort of not have it be just a end of the list check the box, without a sort of thinking through what it means for new functionalities and trying to emphasize that in some way.

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

Which I really support the concept of and I think what I'm trying to think through is, how would it change the current requirement. And would it make – if it is a requirement to do a security risk analysis regularly, independent of meaningful use, if that is on the books already, then would it make more sense to say okay, we're not going require the same thing that's required by the law under meaningful use, but instead we're going to require this. Which is, here are three objectives you absolutely need to do a security risk assessment on, VDT, whatever, whatever, whatever, or some number, because the legal requirement still stands.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator

Yeah, so I think that the goal here is – it's become completely clear that the security risk analysis actually has to be done across the board.

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

Right.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator

And this is not designed to change that requirement that you do it across the board. What it's designed to do is by having – calling out specific areas that you would need to specifically attest to, get it out of the, oh we did it, oh – to focus people on yes, we have to do this across the board. So it's somewhat indirect, but –

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

What I'm suggest – I totally get it –

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

No, Christine, I know what you are suggesting, subst – because we already have the legal obligation to do the overall, focus meaningful choice on those specific things. And I'm pretty certain the response of the Tiger Team, having heard the results of the security audits, would be no. That we can't possibly shine too bright of a spotlight on this thing, and that there would still be a meaningful use need to emphasize the need to do the security risk assessment overall. And also to emphasize those areas where, don't leave your CISO out of the room when you're talking about how to deploy this new functionality, because that's part of what you ought to be doing. It's –

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

That's helpful, thank you.

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

I had a question just to clarify the intent here. Say there's a 90-day reporting period for someone in their first year, they must – your intent is that they do the security assessment during that period or could it be something that they did in the beginning of the year?

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

So I don't think they have to do it during – so they have to – we're just trying to shine the spotlight on an existing security rule obligation. So if they, in fact, have already done a security risk assessment, either before the 90-days of attestation or after the 90-days of attestation. As long as they are directing it at the risks that are introduced by the use of the certified EHR technology, and they're willing to sort of document that assessment, I don't know that the 90-days necessarily is the relevant part.

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

– .Stage 2 is a one-year reporting period –

Paul Egerman – Businessman/Software Entrepreneur

I would answer that differently. I would answer it differently. I'd simply say they had to have completed it by the end of the 90-day period. I wouldn't be concerned about when it had happened, but it had to have been completed by the end of the – so that's how I would respond to it. But again, I know this is a little bit confusing, but we're simply, this concept of shining the spotlight, is what this is all about. And it's very interesting the discussion we had with the people at OCR, and the Tiger Team members involved, this was a very passionate discussion. I mean, people really felt strongly that this is very important. And it was so – and I have to confess to being somewhat surprised by the strength of the emotion that came out on this issue, but it is something that's important. And I think it's great that people feel so strongly about it, and we're not really creating any new policy at all, we're simply trying to use this as leverage.

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

So Paul. You mentioned that certification actually, and auditing of payments similarly requires very acid tests. So, it does come down to a very quantifiable test of, if it's from three years ago, is it okay? If it's from 10 years ago, if it's from a year ago, right? And there – what I liked about what you're proposing here is that it says something has changed, you've implemented new functionality, it changes the environment, it merits a re-examination of your policy. I thought that was actually quite helpful in providing a justification, but you may want to just give our CMS colleagues a little bit of –

Paul Egerman – Businessman/Software Entrepreneur

That's helpful.

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

– additional information.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, that's helpful. Because among the passionate statements that were made about security risk analysis is it should be dynamic, it's not something you did once three years ago and now you don't have to do it again. And it's – it should happen continuously as things change and so, that's an excellent observation.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator

The requirement right now is that you either conduct or review. And so this recommendation is very consistent with that, that if you did something two years ago, but you have now put in place new functionality, then you have to review what you have done in the past in light of the new risk that you might have entered into your system.

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

Okay, any further questions or discussion? Okay, we're ready to vote on whether we accept the recommendations for the Stage 3 security risk assessment. All in favor ?

Multiple speakers

Aye.

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

And opposed?

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

Aye.

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

Was that an aye opposed?

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

That was an aye, I agree.

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

Okay, thank you. Next question. Who are you?

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

I'm not telling. It's Marc.

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

So, you have approval for both of these. Thank you very much.

W

Stay tuned for transparency to patients, accounting of disclosures, coming up.

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

Exactly. Okay, we are ready for the morning session 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 for public comment? While we wait for the operator to open the lines, if there's anyone in the room, and it looks like there is, who would like to make a comment, please come up to the table. Also as a reminder, there's a limit of 3 minutes per comment and the committee is just listening to comments, they don't need to be responding to them. Thank you.

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

And if you'd 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 telephone, you may press *1 at this time to be entered into the queue .

Richard M. Eaton, JD – Director, Industry Programs – Medical Imaging & Technology Alliance

Good afternoon, my name is Richard Eaton. I'm Director of Industry Programs at the Medical Imaging & Technology Alliance, known as MITA, in Arlington, Virginia. As many of you know, MITA represents manufacturers of diagnostic imaging equipment, radiation therapy equipment and radiopharmaceuticals. I wanted just to say a few words about the FDASIA Workgroup process. I think it's been fairly evident from David's presentation this morning that this process has been marked by very dedicated, intense and thoughtful analysis. And I congratulate the FDASIA Workgroup and David Bates and all the people who participated in it. These are heroic efforts that they have done in a very short period of time.

The strength of this process, I believe, has been the product of the collaboration between so many different stakeholders, industry, regulators, providers, communications companies, consumers and patients, and any success I believe that this FDASIA group has achieved to date has to be attributed to this collaborative process of all these stakeholders. I don't think I can over-emphasize that it is very, very critically important that these important efforts continue. This effort should not cease with the submission of this report to Congress in January 2014. And there are a number of good reasons for this.

Number one, the HIT environment is extremely dynamic, it's constantly changing. It is extremely complex, there are many moving parts and just some of the pieces that are very complicated that are going to require all our efforts of concentration include interoperability, adverse event reporting, post-market surveillance, and I'm sure there are many other examples. A balance needs to be struck in terms of considering all of these pieces and all the other areas that we've considered in order to satisfy multiple goals, protection of the public health, ensuring avoidance of onerous or duplicative regulation and allowing for continuous innovation so that the benefits of HIT can be brought to patients.

This is not a cheap, quick fix and it would be a mistake to think otherwise. So again, I would put in a plea that this process be continued and that there be continued interaction between and amongst stakeholders and regulators in order to make sure that we do our best for the American public. And that we ensure that HIT innovation will continue to flourish. In closing, I would like to say that MITA has been proud to support this effort and we are ready, willing and able to continue to participate in it. And thank you.

Mark Savage, JD – Director of Health Information & Technology Policy & Programs – National Partnership for Women & Families

Good afternoon, Mark Savage with the National Partnership for Women & Families. I just wanted to note that yesterday the Consumer Partnership for eHealth, a coalition of patient, consumer and labor organizations across the nation submitted to the HIT Policy Committee a disparities action plan for your consideration and action. And as we mentioned when we submitted it, we did bring hard copies this morning and Michelle placed them at each of your places. I just note that we prepared it in a spirit of teamwork, bringing the consumer partnerships considerable expertise in health disparities. And we also prepared it recognizing the need that the current Stage 3 criteria need to do more to reduce health disparities in accordance with the HITECH Act. We hope that you find it valuable, we hope that it warrants your consideration and action. Thank you very much.

Chantal Worzala – American Hospital Association

Good afternoon, my name is Chantal Worzala from the American Hospital Association. Really appreciate, as always, the thoughtful work of this Committee in digging into some of these really challenging future issues like the work from the FDASIA Workgroup. I believe however, that there's a pressing immediate issue that also deserves your attention and that would be the looming 2014 time crunch that is really facing vendors and providers. The tight regulatory timelines for meaningful use do require that all 500,000+ eligible physicians and hospitals change their EHR systems to the 2014 edition, as well as meeting a raised bar for meaningful use in very short order. And that includes providers that just implemented their EHR this year, as well as those who have yet to come on board, which are often providers that serve the disadvantaged.

We are now 55 days away from October 1, 55 days, that's the start of fiscal year 2014, which is when hospitals should be able to start their meaningful use reporting period. However, as of today, we have only nine 2014 edition certified complete EHRs for hospitals available from six vendor companies. By comparison, there are 313 complete certified EHRs under the 2011 edition certification. Hospitals are reporting long vendor queues and delays in implementation. They're also facing very significant competing priorities, most notably the transition to ICD-10, which is also an HHS mandate. The compressed timelines force providers to rush implementations in ways that are absolutely preventing them from optimizing use of their EHRs. Unfortunately these time pressures could also inadvertently pose risk to patient safety. We also believe that this rushed implementation will widen the digital divide because it is the providers with the least market pull that will be most likely to be left behind.

The AHA together with the American Medical Association did lay out these concerns in a July 23 letter to Secretary Sebelius. I want to reiterate that our shared objective is a safe and orderly transition to Stage 2, that leaves no one behind, no provider and no patients served by those providers. Our letter includes some recommendations on ways allow Stage 2 to start in 2014, but to stretch out the timelines to relieve some of the building pressures and to provide some additional flexibility in Stage 2. I'd be happy to share it with you if you'd like. I do encourage this Committee to address these issues and I believe your July 22 hearing surfaced many of them.

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

Chantal, I'm sorry, your time is up.

Chantal Worzala – American Hospital Association

As I mentioned at the start, we are 55 days away from October 1. Thank you.

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

Operator, is there anyone on the line?

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

We have no comments at this time.

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

Thank you.

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

Okay, thank you. Thanks for the public comment. So we'll adjourn – we'll break for lunch and resume our afternoon schedule at 1:30 p.m. 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 soon. Paul, are we ready?

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

Yes we are, thank you.

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

The lines are open.

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

Okay. Well welcome back everyone, we're almost on time. And we still have a full agenda this afternoon. We're going to have a data update from CMS and ONC. We'll have a meaty discussion with the Meaningful Use Workgroup as we progress in our next version, penultimate version before presenting to you in September for Stage 3, and an update from the Information Exchange Workgroup that we asked for last time. So let's begin with the data update from Rob and Jennifer please. Thanks.

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

Good afternoon. So I will run quickly through what we have on the – these will be mostly June figures, although we do have a July estimate. So we'll run through registration and payment data and then we will, at the very end, take a look at some of what we have, looking at both exclusions and deferrals thus far, when we take a look at attestations. The larger attestation information, the overall averages that we generally present have not changed significantly over time, so we don't actually include them here, but if anybody is interested, if you go to our website in the data and reports, there's a fuller slide deck that does contain that.

So at this point in time, we have about 405,000 active registrations for the program, this is out of a denominator of roughly 533,000 providers, so we have a significant number of people who are actually registered. I've been highlighting lately this Medicaid total per month because I like to highlight the Meaningful Use Program to date so that we can see that there are actual conversions happening from adoption implement upgrade payments to Medicaid providers who are actually becoming meaningful users. And as you can see, up above, we have a little over 18,000 meaningful users at this point in time, which puts us somewhere around 12% of the total Medicaid population have actually become meaningful users now. So as of the end of June, we have about 15.5 billion dollars paid in incentives and almost 310,000 providers who have received payments under the program.

So we are at pretty close to 90% of eligible hospitals having been registered for the program and a little over 80% of eligible hospitals actually having received a payment, now that's both Medicare and Medicaid or in many cases, obviously both. Similarly we have a significant number, a little over 75% of eligible professionals who are registered for the program. And we are closing that gap on payment. Previously when we had looked from this registered slide to the paid slide, there was more of a gap, but we're starting to see that close. We have, at this point, exactly 58% of all eligible professionals have received a payment through the EHR Incentive Program, so 6 out of 10, 3 out of 5, however we want to write that down. This is an indication by specialty and we haven't really seen a change in this percentage lately, but we are looking at, on the Medicare side 61% of all of the eligible professionals who are meaningful users are non-primary care. And this is a breakdown of the specialties, just to remind you, that other category is an aggregation of different specialties.

So at this point in time, we're actually a little over that 79, we're at 80% of hospitals that have received a payment, about 1 out of every 2 Medicare eligible professionals is a meaningful user, actually, a little over that, 55%. About 68% of all Medicaid EPs have received an EHR incentive payment and 12% of those are actually meaningful users, which puts us, as I said, at 3 out of 5 EPs having made a financial commitment to an EHR. July is shaping up to be a slightly smaller month than previous months have been. We're looking at a little over 7400 providers paid, that includes both eligible professionals and hospitals. It is a little bit of a drop, but you can see historically that July has always been sort of the dipping point for us, the low point in the payment graph. And we of course begin to pick up at the end of the year, and we expect to see the same type of January-March spike in 2014, which would be most of the people returning for the 2013 program year.

So as I said, we didn't go into detail with the attestation data in this presentation, but I did want to highlight what we've been looking at as far as where exclusions are happening and where with menu objectives, both deferrals and exclusions are happening. We've been looking at this as time has progressed to see, especially in areas like electronic copy of health information where we were seeing very high exclusion rates at the beginning of the program. And there were some questions that we had addressed with the Policy Committee early on about whether that was people not asking for it because they didn't know that they had access to it, or what the circumstances might be. And as you can see, the blue here represents people who are actually achieving this objective, it is not the performance level, it is actually the percentage of EPs who are attesting under Medicare, who are actually achieving meaningful use on these particular objectives. The red area represents the percentage of EPs attesting who are actually claiming exclusion to these different objectives. So you can see a large number of eligible professionals are now fulfilling the electronic copy of health information, so we're seeing more people come in and ask for that information. As you would expect, the CPOE and electronic prescribing exclusions are identical because the exclusion for those are for professionals who write fewer than a hundred prescriptions during the reporting period.

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

What's the delta then between the blue and the hundred percent if they're core measures?

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

I'm sorry, what's the delta –

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

So what's the remainder ?

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

Oh, there isn't a remainder. For the core exclusions, there's – you're either meeting that objective or you're claiming the exclusion. These are for people who have actually attested. The only way you could successfully pass meaningful use is you either met the objective or you claimed the exclusion.

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

I guess I don't understand, like smoking status says it's a smidge below 90%. What's the other 10%?

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

Well that's an excellent question. I'm not sure why that doesn't come up to 100%. I will have to get back to you on that. There does seem to be a little bit of a top out on that, we'll have to take a look at it.

Similarly we're seeing with hospitals, initially we had both electronic copy of discharge and electronic copy of health information, we had very high exclusion rates at the beginning of the program, and as you can see, they have dwindled to a very small number now, as more and more patients are actually asking for electronic copies of that information. And we have the same problem here with smoking status, I'll find out what the delta is there, why there's a gap. .

We've also been taking a look at the menu performance, this may initially look a little bit complicated, but the green here is our EPs who are actually meeting meaningful use on those particular objectives. The reds are those who are claiming exclusion to those objectives and the blue represents, and I know this is a little bit of a difficult concept, but the deferred objectives, so essentially when EPs have not chosen a particular objective. So in effect, the greens will represent the percentage of attesting eligible professionals who are actually selecting and then meeting that objective. Now we're looking at particular areas like transitions of care, electronic access, where we're seeing pretty high deferral rates, and obviously as we move to Stage 2, those are at the core of what we're doing with Stage 2. The good news, of course, is that as we look at those percentage factors, the people who do choose that perform very high on them.

Hospitals, we obviously have a much higher number of people who are actually meeting these various objectives. Still the deferral rates are pretty high on both transitions of care, and then again on something like medication reconciliation. There are always going to be somewhat high deferral rates in the categories on the right, both for eligible professionals, as you can see, and also for hospitals because those are the public health objectives. And those deferrals are going to be based on their selecting one of the other objectives or the inability of a local registry to actually be able to accept information. You will see that some of these menu objectives for hospitals, there are no exclusion information, but that is because there are not exclusions for hospitals for much of the – for many of these menu objectives. So, it's really only in area such as public health agency that – and advanced directives that they don't have information. So again, if anybody's interested in more of the fuller percentage data, it is available on our website through this link, and you can get percentages for each of the objectives as we normally provide them.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Okay, great. So I'm going to present little more data, sort of round out what Rob presented, by taking a look at overall progress towards meaningful use, looking at the Medicaid and Medicare Incentive Programs combined with the Regional Extension Center Program, and also looking at some of the most recent trends in progress with meaningful use by provider characteristics. So first starting off with hospitals. At this point, over – about two thirds of hospitals have attested to meaningful use, 64% of all eligible hospitals. An additional 17% have received an AIU payment, but not yet attested. And when you take into account registration with the Incentive Programs and engagement with the Regional Extension Center Program, over nine in ten hospitals are engaged on the path to meaningful use in some way through those programs.

When we look at this in terms of the overall percent of beds in the US, over seven in ten beds in the US are at hospitals that have already attested to meaningful use. When we take a look at how this distribution looks over the course of the programs, you can see since the beginning of the programs, pretty strong progress in eating away that gray part of the graph here, which is the percent of hospitals that have not yet engaged with either the REC or the Medicare and Medicaid Incentive Programs. And pretty steady growth in the dark blue section there of the graph, which is the percent of hospitals that have attested to meaningful use. If we look at the most recent period of time, as expected, as Rob pointed out, this is sort of the slow period of the calendar year. But in the past six months, the percent of hospitals that have been engaged with the program has increased by about five percentage points, and the percent of hospitals that have attested has increased by about ten percentage points.

So we take a look at these trends by hospital type. First looking at that gray section of the graph, so the percent of hospitals that have not yet engaged with either the Regional Extension Center Program or the Medicaid and Medicare Incentive Programs, we see the strong decline and getting pretty darn close to zero for most types of hospitals. So critical access hospitals, small rural hospitals, large and medium sized hospitals are all about 5% or less are not yet engaged with the programs. And the one exception here is the small urban hospitals where about 16% at this point are not engaged with the Programs. They do continue to make progress downwards though, so, in the past six months, about a eight percentage point growth in engagement in the programs, and you can see a little bit of a tick of faster growth in this past month.

So now if we take a look at the dark blue section of that previous graph, so the percent of hospitals that have attested to meaningful use over time, we can see some of the same patterns that we saw a couple of months ago, the last time we presented this type of data. So we see sort of the leading group here is the large and medium hospitals and the small rural hospitals, where about seven in ten of those hospitals have attested to meaningful use as of June, 2013. Critical access hospitals are a little bit behind that with about six in ten having attested and small urban are a little bit below with 53% having attested. But still, the majority of all types of hospitals have attested at this point. And if we look at sort of the most recent time trend here, you can see that towards the end of the fiscal year of 2012, critical access hospitals made a pretty good surge and closed the gap between them and the small rural hospitals and larger hospitals. But in the most recent six months, their progress has been slower towards attestation. So in the previous graph we saw that critical access hospitals actually have a really high rate of engagement with the programs. So that's some indication that we will hopefully see another spike at the end of this fiscal year, where they might begin to close the gap again, but something to monitor over the coming months.

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

Jennifer – no, maybe I should – I’ll – we’ll wait to the end for the questions.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Okay. So shifting to take a look at this progress for the eligible professionals. Here’s a snapshot of overall progress towards meaningful use among eligible professionals in the US, looking at both the Medicare and Medicaid Incentive Programs, and the REC Program. As Rob pointed out, about 44% of all eligible professionals have attested to meaningful use and about six in ten have either attested or received payment for AIU. And when you take into account registration with the Incentive Programs and REC enrollment, you see a pretty high engagement with the programs.

Again, taking a look at how this distribution has evolved over the course of the program. We see the strong spike in both attestation and engagement towards the end of the attestation period for 2012. But again, the most recent months have been somewhat slower in growth. So you take a look at these trends by provider characteristic. We take a look at patterns among physicians as compared to all ambulatory physicians in the country. So just a note, that this might slightly understate the actual rates of performance among physicians who are eligible for the programs because the denominator includes some physicians who won’t meet the eligibility requirements. But this just provides us a way to look at sort of trends by provider characteristic.

So we look at the gray section of the graph here, the rate of engagement with the programs by specialty and by urban rural location among physicians. So you can see that in the early stages of the program, by specialty, primary care providers had pretty quick rates of engagement with the programs, and this is likely largely due to the Regional Extension Center Program, which focuses on primary care providers. But in the most recent six months, the rate of engagement has been fairly similar between primary care physicians and specialists. And then on the urban rural location, you can see pretty much overlapping lines over the course of the program, so really close alignment in terms of the percent of physicians who are engaged with programs in both urban and rural areas with very similar rates over the most recent time period.

And then finally taking at progress towards attestation, so that dark blue section of the graph, percent of physicians who have attested to meaningful use. You can see that, while Rob pointed out that in terms of absolute number, there’s a larger number of specialists who have attested at this point, as a percent of all physicians, primary care physicians are slightly more likely to have attested. And we see that their rate of attestation in the six most recent months is just a little bit faster than that among specialist physicians, but nothing dramatic there. And on the urban rural location breakout, we can see again, really close alignment, so virtually no gap between urban and rural physicians in terms of the percent that have attested to meaningful use, and very consistent patterns over the most recent six months.

So I’ll stop there with the data updates, but just to sort of recap, we’re seeing pretty broad engagement across the Programs when you look at the Medicare and Medicaid and REC Programs combined. Again, this month we’ve seen sort of modest month to month growth, as we would expect, in the most recent calendar months. And some small differences in those trends by provider characteristics, but nothing dramatic enough to change the overall patterns that we saw last time in the – a couple of months ago in the data update.

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

Thanks Jen. So if you go back to the hospitals trends that shows the small urban hospitals really separating out. The – I think the difference there is the Regional Extension Centers as well. Because the Regional Extension Centers are contractually required to engage with critical access and rural hospitals, but not with small urban hospitals, I believe.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yeah.

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

So – and then on the next slide you show, right, so where the critical access and the small urban probably are quite similar, except for the fact that the critical access are getting help from the Extension Centers and the small urban are not. Interestingly, actually a few slides further, you see that signature that you pointed out, of the primary care providers quickly – right there, yeah – the primary care providers kind of dropping and then it flattening out in terms of engagements, and you see almost the same pattern in the rural locations. Which again, I think – maybe I'm reading too much into it, but I think it's clearly suggestive that the rural gap would have been there, had it not been for the Regional Extension Center outreach, I think is pretty fair. We have, I think, 60% of all rural primary care providers, over half of all them engaged now.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yeah, I would agree with those points. The REC engagement is definitely a key component of these trends.

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

I think last time you said you were 2.3 times as likely if you had REC engagement to –

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

We didn't say that, the GAO said that.

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

Okay. All right, Gayle?

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

Thank you. Yeah, I do have some concern about those urban hospitals, that's something that I don't know that all of us were attuned to before. And I think these figures, it's the first time we've had it broken out like that where you really see where small urban hospitals are the ones that are falling behind in engagement and in attesting. And have you really looked at that to define, other than not being part of the REC Program, have you gotten any indicators from them or reached out to them to see what the problems are? Are these in inner cities? Where are they located? What's the size of them? Are they mostly non-profit hospitals in deep inner city areas? Or what are some of their characteristics and what – I don't know if we have – if the ONC has the ability to expand the REC engagement with them or to what degree that it's possible to do, under the legislation. But it seems obvious that they are not where other folks are going. Can you give us a little bit better indicator on who they are and perhaps why?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yeah, so those are all really good things that we can definitely look at. I don't have answers to those questions right now, but some of those characteristics that you suggested are things that we can definitely take a look at and get a better sort of fuller picture of who these urban hospitals are. One of the things you mentioned was the for-profit status, we do see on average that not-for-profit hospitals actually have higher attestation rates than the for-profit status hospitals. We haven't looked at that specifically within the small urban group, but on average, the not-for-profit hospitals are doing better than average. So, that's one indication there, but definitely really good things that we can look at and present in the future.

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

Thanks, Terri? Oh –

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

In answer to the part of your question about whether the Extension Centers could, I think they could if there were resources, but we don't have any new resources for the Extension Centers to be working with those.

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

Great. Terry?

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

Rob, my question is for you and it's on slide 18 and 19 and have you guys done any evaluation of the transitions of care? So when I look, and I look at what's deferred, transitions of care is the highest on those, and one could argue, probably one of the most important things we need to get done.

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

So, yes and yes, and we are continuing to do some more qualitative research into this. We regularly interview different practice types to try and get a sense of what the pain points are or the challenge are. The thing that comes up, I think, out of what we have seen is that it's a big lift for practices, especially as they were doing Stage 1. And remember, most of what we're seeing here are people who are in their first year of practicing, because that's – or the first year of meaningful use, rather. Because that's where the bulk of people came in, in 2012. We did have some folks in 2011, but the bulk of people came in in 2012, and they represent most of the people who will have deferred this overall.

I will say that deferral rate has gone down over time, as we've looked at it, although it still maintains a pretty steady high. And it is a question of, in the beginning at least, the information that we had was that it was a question of who they were going to exchange information with and how. Now I think it is more of a making that a regular part of workflow.

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

So just to continue, so it hasn't been an issue of not knowing what information needs to be exchanged or the ability to aggregate that information, it's how to actually do the exchange? Would that be accurate?

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

Yeah, keep in mind, in Stage 1, the elements for this objective or actually the minimum elements are fairly small, I mean it's a problem list, med list, medication allergy list. So the required elements in Stage 1 is a fairly low bar, it's in Stage 2 that I think we're probably going to have to do a little bit more education about, and in fact, we're working on a resource to do exactly that. To tell people the list of what all those elements are, the standards that they go in, what happens when certain information may not be available in a system. I think Stage 2's transition of care objective is certainly a more complex beast, and because of that, a more robust beast. But in Stage 1, that's not really the feedback we've been getting, it's been more of a workflow issue.

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

Okay.

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

I don't know Terry if you saw the paper in Health Affairs that came out this week about health information exchange capability in hospitals. So that's the – we can share that with the Committee members, but the – kind of the high points were, there has been a substantial 48% increase in actual information sharing with outside hospitals – outside of hospitals, but it's still at relatively low levels. The factors that contribute to hospitals having higher propensity to be able to do that include having an electronic health record, so this is on the path, and having a health information organization available, which is also increasing. There were some other attributes, characteristics that also were associated with that, but I think it points both to progress and there is progress in terms of where we've been. But also a need for continued availability of tools in institutions and business cases, which was the RFI for Interoperability that we did with CMS to say what more can we do to make it profitable for hospitals to share information with their competitors, rather than to have no business motive to engage in or invest in those tools.

Robert Anthony – Health Insurance Specialist, Centers for Medicare & Medicaid

And I would also reiterate that even now, in Stage 1 we've seen some of that progress. When we first started with this, we had an incredibly high deferral rate on this objective, I think that that's sort of what prompted some of the initial questions. We had a high 90% deferral rate on this objective and even though we have a still in 80% range, and that's large, we're seeing a move on that. I think, as we move forward, we're obviously going to see more of a move.

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

Okay. Well thanks again Rob and Jennifer for your updates. We're now going to move on to the meaningful use discussion, and I'll switch chairs.

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

I was assuming the chair, when you had the out of 50 meetings, you had the temerity to take one meeting off last time, so I ran the whole meeting, you know. Now I get –

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

And now you're resign –

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

Now I get to do it again. That's right, I couldn't take it Paul. Please, go ahead.

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

Thank you, thanks Farzad. So we're going to cover with you our latest iteration of the Meaningful Use Stage 3 draft recommendations that we're going to come back in September to present to you for approval. So this is, what we've done in the meantime is after you gave us feedback a few months ago, we've gone through all the public feedback and we've tried to reconcile that all together into what you're going to see. In your packets, you have a fuller – a more complete set, because we wanted to have that available to you. What we're going to go over are only the ones that have changed since our last presentation to you. So there's a difference between what you're going to see on the screen versus what you received in your packet. Let's see if this works, otherwise we could use the Privacy & Security method of putting things in the addendum. But at any rate, you have the full packet in order and we're going to cover the deltas.

So this is the hard-working group that's been with you for four years, slugging along and really with all good intent, people are in good faith trying to do whatever is right. They come from different perspectives, but we're trying to do the right thing for the public good. You'll recall this diagram, we're finally there at Stage 3, we're working on measuring and improving outcomes, building on the progress that was just talked about in this last group of Stage 1 and Stage 2. The original principles still stand, we're not measuring and supporting what we used to do in the past, we're working with new models of care. We assume it's team-based, it's much more outcomes oriented and it has a lot of population management involved. The National Health Priorities are not set by us, they're set by the Secretary. You know them as the National Quality Strategy, focused on prevention, the partnership for patients, a number of things. That's who determines the National Health Priorities. We try to serve those priorities by supplying the tools, or at least spec'ing some of the tools that help providers reach those – their goals.

It is a broad – we do have a responsibility to have it broadly applicable, and we do the best we can. Meaningful use is a floor, not a ceiling. The comment made about vendors having to work on – not being able to work on more than meaningful use, it's – yes, meaningful use does take a bit of time, but it's a floor there because the majority of vendors don't supply some of these necessary tools. We do try to address all specialties, we try to consider the different patient health needs in areas of the country, as we just spoke about before. This is not a program that's trying to set the objectives for the comprehensive EHR, things that are already driven by market forces, power to the market. We're trying to cover areas where there's a high priority, like care coordination, and the market hasn't provided those solutions yet.

And yet we don't want to go past – too much past mature standards, otherwise people can't do it, especially address interoperability. So those are some of the original principles that have been guiding us all along and they're still true today.

Lessons from Stage 1; there's been a substantial increase in adoption, the floor creates – allows network effects to take place. We find that the thresholds are consistently exceeded. Use occurs. there's consistent use and accomplishments whether you're the early adopter or now the early majority coming in and we find that reporting requirements turn out to be more costly than doing the action itself. So whether you're a provider doing the action, making the use, sometimes is easier, or at least documenting that you did do it, turns out to be harder than actually using the functionality. And I had a comment from a vendor this week, and it turns out to be true for them as well. Providing the functions in their program is actually easier than proving that it was so. So that's one of the things we're trying to address in Stage 3. And then finally, trying to switch over from this forced march to going to the pull side, using the markets pull and the new models of care to pull through people making effective use of this technology.

So the implications are, we have a critical mass, the tide is rising and we're trying – we're assuming then the gains from Stage 1 and Stage 2, and that's been worn out, will persist. So let's assume they have the functions, let's assume they're using the functions and let's try to reduce the burden of the prove that you did so, and then introduce this new thing that we'll talk about at the end of this conversation, about deeming, or rewarding good behavior, which was the endgame from the very start. The additional goals we have for Stage 3, one is, you've already heard some of the emphases that we're focusing on in Stage 3 which is information exchange, get it to move around to where the patients are, the patient engagement and reducing disparities. So these are three special key gaps that we want to focus on in Stage 3. The other is the simplification addressing the burden that we talked about just a moment ago, and the alternative pathway as you move towards rewarding good behavior, rewarding good performance. So first George is going to talk about the simplification and consolidation work.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

Thanks Paul. Good afternoon. The work formerly known as consolidation, as previously presented to you, now called simplification because as I'll discuss in a minute or two, we realized some of our consolidation's not a form of consolidation, but rather reduction, and I think that's a good thing. Our criteria – our framework originally was if something was advanced within the – if a particular objective was advanced in the concept of another objective, we could combine them, some concepts were actually duplicative. And for some concepts, we had demonstrated use and could trust that it would continue, so it had topped out and we could remove it.

Now I'm going to modify that in a moment, but just with that initial framework, we ended up with these results which is of 43 original objectives, we simplified it to 27, three of which are in future stages, so it really gets us down to 24 objectives. While we were going through this, we focused on advanced uses, in other words, let's keep the objectives that really push the envelope forward and number two, giving credit to clinicians for objectives that should be standard practice after Stages 1 and 2. In other words, if you're doing it and you should be doing it and we're pretty sure you're going to be doing it, then let's give you credit for that and not actually keep counting that. And then this figure is my favorite figure on this topic because it really shows you visually, the green are the ones we kept, the gray are the ones that got simplified and the ones in whatever color we would call that, orangey-gray, are the ones that are for future stages, so I would count them differently. This figure we had shown to you last time we presented, there are minor changes depending on what we did, which will come in the following slides.

A recent conversation kind of had us thinking again about this. And the assertion from the vendors was, sometimes when you consolidate you make it harder for us because if you take something we've already programed once, and now you combine it with something else, I have to reprogram it, and that may be more work than just leaving it alone or getting rid of it. So you may be adding work to vendors, although it may seem like you're simplifying in some other way. So we realized we changed our framework a little bit, that first one, removal is removal for the pur – because it's topped out. So there may be an objective that we believe after you've done the first two stages, you're not going to go back and stop collecting demographics or something like that.

The second form of simplification is implication. In other words, it hasn't topped out yet, we haven't reached 95% compliance in the community, but we're pretty sure that because of some other objective being achieved, that in order to achieve that, or a quality measure perhaps, you're going to be achieved – well, I don't want to get into a different topic. But let's say another objective, you're pretty sure you're going to have to achieve it, so by implication you're going to do this one and we're sure that's going to top out also and therefore, we may move that in there, but we're not going to re-measure it. And then the third one is true consolidation where we put two objectives together and actually measure both, and that's the one we want to be careful of, and that's the one we'll be reviewing also over the next month. But let me – again, our goal is primarily to simplify and reduce reporting requirements for clinicians while not impinging unreasonably on our vendors, that's kind of how we went into this.

So now going into subgroup one. Again, as Paul emphasized, looking specifically at the ones that have changed since you last looked at this in our last presentation. Clinical decision support, our overriding goal here was to combine like items. If there are things that we're doing that looked identical but in different sections of our meaningful use areas, we put those together into clinical decision support. So for example, we moved the immunization recommendation here from subgroup four, and that's under, let me see – find that, number five under certification criteria, a little hard to read on that slide. Furthermore, we moved problem – the maintenance of problems, meds and allergies into the certification, that's item number six under certification with an addition as the last item – last new item under use, for problem list. So you have to maintain problem list using CDS, and you have to have – the product has to be certified to be able to do it for problem list, meds and allergies. And that's what we changed there. We also added some information about the CDS trigger due to public comment, but that's a minor point.

Next, reminders. We altered the wording based on public comment, actually kind of clarified, so, clinically relevant we were asked, what does that mean? We said clinical, social or family history information beyond demographics. And then in addition, as part of consol – our simplification process, we moved patient preferences for how they receive information into the objectives that take them. And so the bottom two red sections in those slides contain the patient preference section.

Electronic medication administration record. What we did is we increased the threshold from 30% to 50%. I mean, there was some feeling that we're on this ramp, we started at 10 and we should go slowly. There was other feeling that this is critically important, we should be at 100% and so we felt – we compromised basically and said 50%, which is not appreciably different for the ones who thought 30%, but once you're at 50%, if it's worthwhile you're going to go 80% and 95% and beyond. And we also clarified what a mismatch is when a provider dispenses a medication that is not intended or dosing that's not intended.

Imaging. We altered the metric to a simple use case to avoid the reporting burden of the denominators. So we didn't know how to count, how many images you didn't do this way, so we changed it to 10 imaging study encounters that you've incorporated the imaging – access to imaging results. But what we're really saying, as you can see towards the right is, we're reviewing our threshold after Stage 2 experience. So it was pressure to make this easier to report, we put that in the objective but we're saying that depending on how Stage 2 goes, we'll set Stage 3 according to that. We also added the certification criteria, once you change the measurement to count how many things you do, you need to know that they didn't just start it at the beginning of the reporting period, count that many and shut it off. And so you see in the certification criterion that you have to be able to display along – I'm sorry, did I just confuse that with the other one that we did. There's a second one we did count – .maybe we need a certification criteria here for that, because I was thinking of the second one. We did add the certification criteria, here we moved in – so I'm going to come back to that point in a moment. We did radiation exposure – we moved it into imaging. We had to decide where to put that, and it was originally in VDT and we decided it made more sense to put it into the imaging.

Next one. Family history. This underwent a lot of discussion and controversy. Remember that at our last presentation, we had moved it to consolidation, I believe, to certification. And there was a feeling that it was important, we had to pull it in, then we tried to narrow it by picking the three diseases that you needed to report on in family history which were cardiovascular disease, breast cancer and the third one, which I'm blanking on –

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

Colon cancer.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

– colon cancer. That was felt to be too limiting in the fact that family history is useful for specialists and they're not on those three diseases, then we're kind of limiting ourselves in another way. So then there was a feeling, well, we had to do family history more broadly and it should be structured to be useful. Then we had concerns about the standards that are available to do this, because in fact I know there's a process in place to do the standards, but that they are not mature yet. So our end result at this point in time was to make it a menu objective so it's not required, but go back to the thing that we had originally presented to you, before the last meeting, which is 20% of unique patients would have a family history recorded. And we're leaving it up to the provider to decide what aspect of the family history is relevant to this patient. So that's the – do you want to do a population health, kind of get all the family history on breast cancer, or do you want to support the specialists and make sure they're doing the family history that they need to know. So that was the – and we ended up with this one for now.

Electronic notes was simply – we made it four calendar days that you needed to write your note by and we clarified it because there was some confusion reading it whether it was 30% of notes or 30% of visits, so we clarified it 30% of visits have to have a note that's written within four days. So that was a trivial change.

Hospital labs. The public comment asked us to put in a reference to LOINC, so we did. Normally we don't name standards in our objectives, but we were asked to, so we put it in. We lowered the threshold to 50%, because we don't really know how the hospitals give labs out to these practices in rural environments, but we'll see how Stage 2 experience is to set the final objective.

Order tracking. There's a lot of red there, but it's actually simpler than it looks. We changed from test tracking, which is what we presented last time to order tracking, allowing us to incorporate consult requests, that is referrals, into here. In other words, we're closing the loop not just on tests, but on referrals and felt that it fit most comfortably in this part. I know it's part of patient engagement, so that's the choice, but we made the choice to put it in here, into the tracking of various kinds of orders, including consult requests.

We added a new objective on unique device identifier. And what this objective basically – because we've gotten – we've actually gotten testimony for a long time, a number of years on needing to include this and we felt that it was mature enough now that we could include it. And David Bates was a strong proponent, he was actually the chair of this section, the fourth – the first area. And so that the EPs and EHs should record the FDA unique device identifier any time they insert a device in a patient, 80%...and the measurement – and the threshold is 80%. Because we felt that that's something that's important and doable and I can't imagine why you wouldn't be doing, can't think of many exceptions to recording the unique identifier, so we went straight to 80% in this proposed objective.

Demographics. We probably didn't have to show – the only change to demographics, which is certification only as we agreed last time. But we put in the patient preferences here as part of our consolidation. So it's still certification only, but patient preferences are explicitly listed, and that's what those two red areas are about. And that's it.

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

Okay. Now we'll move on to subgroup two, which is engaging patients and family, and this was led by Christine Bechtel. Just highlighting the changes. In the VDT, view, download and transmit, what we've done is added an optional family history, a lot for the reasons that George cited, the lack of standards makes this a little bit challenging, but family history is important, so we want to move this along. The other thing we did is certification criteria is to support ABBI, the Automated Blue Button Initiative. We want – it's an active project within ONC. It has good functionality. The workflow is pretty – it was pretty unsettled right now so we did not make it a use requirement, so that we wanted the functionality to be there.

The other thing we did is to support – now that people are having more access to what's in the record, we need to give them convenient access and ability to submit proposed amendments, and that's what we've asked for in this objective. Patient-generated health data; it's been a dream of ours since 2009, and we even put it as a placeholder for Stage 3 thinking surely by four years from now, or actually, I guess it's now six years from then, we would have a market where we could have a lot of these home devices upload data electronically to the EHR. We were chastised by the HIT Standards Committee to say, no, actually it doesn't exist, the standards aren't complete and almost nobody's adopted them. So we want to do everything possible, and that's some of the request to the Standards Committee and creating some certification encouragement to get standards in place and used, and potentially it could be changed by the time Stage 3 rolls around. But that's where we are now. What we've done then is to make an objective to have patient entered data in the form of structured or semi-structured questionnaires. Still very potent, pre-visit questionnaires, patient reported outcomes, lots of reasons that this would contribute to the record, it would be the patient's voice and we wanted to encourage that.

Clinical summary. The main – in a sense, some of this correction is really to correct some of the myths that have occurred around this topic. One is, the notion that you had to put a printout in every patient's hand, that's just simply not true, it never was true from Stage 1 and we're reemphasizing that. We are also asking for it to be in the format that the patient request – they could have it requested and printed for them, they could request it online, but that's the only way you'd have to provide it.

The second concern we heard is that people were – we turned this useful document, which was a one or two page summary of what happened to you and what do you need to know next into this eight page thing that nobody could make any sense out of. And the reason that happened is some either groups or vendors by default printed out the entire summary of the record rather than a very visit-specific indicator of – actionable summary. And so we tried to clarify that in this language. It's really to be useful after you've been in the hospital or after you've had a visit with your provider, what do you do need to know, what's changed, what do you need to do next? So we've emphasized that in the text.

Next is patient education. This begins to address the language disparity, and remember, disparity is one of the things we're trying to focus on, reducing them at least in this stage. So this is to provide patient specific educational information in the language of their preference. And that – so we're trying to get the wording right, we resorted back to, and this is part of the Burden Reduction Act that we're under, is by counting. So if you've delivered at least one patient specific educational material to one patient fulfilling – in their preferred language, then that means you've got the function turned on. And we get away from the denominator and the numerator, which causes so much burden, when really we find that once people get it right, get it implemented and turn it on, then the value persists.

Secure messaging. We did a couple of things. One is, we recognized that's actually one of the harder, more challenging measures in Stage 2. It may not sound like much 5%, and it isn't really that much for primary care providers, specialists have more difficulty in terms of meeting that in a natural way. And what we don't want to do is create workarounds. So we've left it at 5% and we built in some certification requirements to help providers measure what they do, in particular the turnaround time. Are these things being turned around, are they being answered? Well one of the consequences of trying to measure turnaround time is sometimes the patients telling you something, they don't want a response back. So, we built in certification requirement for the patient to be able to indicate that no response is needed. As you can see, we're trying to build in tools so that providers can do the necessary communication when that's advantageous to the patients electronically.

Just mention that communication preference. This is – we're beginning to accelerate access to try – wait a minute, okay, I – my notes wrong. So this is clinical trial query. We're trying to start giving both providers and patients the ability to access trials that are available to them, for which they qualify. And the hesitation here in terms of putting it into use requirement is it just isn't ready yet, but we want to move the functions along for EHR systems to be able to talk to clinical trials management systems. And on the advice of HIT Standards Committee, the standards are starting to be there, but the use is not quite there, so that's why we made it certification criteria only.

The next category we're going to talk about is in care coordination, and this subgroup was led by Charlene Underwood. First in reconciliation, we came to you last time and said, we want to move on med reconciliation to problems and med allergies. It's a good and noble cause, but found that one, the standards aren't there and two, it's hard to do this or med rec to be honest, in other than a check off way. And we didn't want to keep going on check off things, we wanted to find ways that the tool makes it possible for you to do a good job of reconciliation. So in a sense, that's where we stayed with, we did have – you recall George talked about clinical decision support, so we're asking clinical decision support rules, so the system can help you, as a provider, make sure that you haven't omitted something from the problem list or still have some time-limited medication on your medication history list. So those things can contribute to maintaining accurate and complete lists. But we didn't want to force a checkbox kind of activity of reconciliation on to these problems, and med allergies and create unintended consequences. That's the thinking we had there.

Care summary. As you heard, it's one of the things that's the least used, at least in Stage 1. And we want to make it more and more useful, but we also want to make it part of core, eventually. So here's – and you probably can only see it on your printouts, but Michelle has a nice table here showing what we're trying to require and make optional. So first, care summary goes from provider to provider to help coordinate the care. What you'd like to know, as a provider, either the requesting or the recipient is, and in a referral case for example is, why is this person here? And then tell me what did you do and what happened and what do you want me to do? So that kind of transfer of information occurs in three gross buckets. One is when you're transferring site of care, another is when you're requesting the advice of someone else and the third is when you're receiving back that advice from somewhere else.

So in this table, you see those columns are those three kinds of buckets and there are four things we're asking, but not equally of all those use cases. So one is, just tell us in concise free-text if necessary, why you're sending this patient, what do you want to have happen? And what did you find? So that's required for all use cases, transfer of care, requesting a consult, getting a consult request back. So the EHR system we're saying should have a place where you can write a concise, why you're seeing the patient, what did you do back. The second is the contact information, that's pretty obvious, of who's on this person's team, particularly, of course, who's referring or who's the PCP. That should be across the board as well. Everybody should have access to that information.

The third one is, does – is there another family caregiver who's playing a critical role in this patient's care? And right now that's just a does that person exist, and that is required – is there such a per – another involved member, and that's required across all three – no, that's required for two, so they changed that, for two and not required of let's say the dermatologist referring back the patient providing the consult request result. The fourth one has to do with – and I can't read this page – is the overarching patient goals. So that's something that's clearly important as you're transitioning care, transitioning site of care, not as – at least today, it's – these are all desirable things, but is the market, is the are the professionals ready to agree on what does a goal even mean. So that's why we made it more optional. And finally, the patient instructions for the next 48 hours. Again, when you're transitit – having a transition of care, that's really important. The consult request, the referral result we felt that its important, but we wouldn't make it mandatory.

So hopefully that was a description of we're trying to be more precise with the care summary, we're trying to get information that's important communicated as we coordinate this patient's care. We left the 50% and 10% the same, we had originally proposed a higher, but there are still legitimate reasons why, let's say in a rural setting you may not have the ability to have 10% of your – more than 10% of your trans – summary of care documents going electronically.

Care plan. Another one of those noble causes that we tried to put up the flagpole and in a sense, there's one, lack of standards and more importantly perhaps is not agreement in the professional space, healthcare professionals, we would like to have an interdisciplinary universal care plan. We don't have the teaching and the professional guidance at this point and time to even know what that looks like. And so that's why we backed down on it being in Stage 3, we'd like to talk a lot about it, because we want to encourage its development, probably a lot in the professional circles, in the medical schools, in the nursing schools. How do we get together an interdisciplinary goal and plan for – that can be used by patients and their caregivers? That's the direction we'd like to go, didn't think we could make it there by Stage 3, so we laid it out as a future stage. Same thing with the problem list.

Med adherence. PDMP, we heard about this and it's something that can be very useful, it's – particularly in managing controlled substances. We just heard back from the Standard Committee, it's just not full – it's not widely adopted enough to make it a requirement in Stage 3 is where we ended up on that one, so that's a future stage. Now we'll complete the categories with category four.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

Okay, thank you Paul. Art Davidson led this group. Immunization registry, 401-A. Remember this one, we're sending data – immunization data to the registry, this objective was about getting information back from the registry that its putting into action to help people. And what we revised here is we revised the threshold. Here's where we also used the concept of 10 counts of getting things back, and why? Because of the logistics of the burden on the health department and the feeling that if we could do 10, then it would prove it was useful. Here is where we put it in the certification criteria and which probably should be in all of these count-based measures, that the ability to generate a report that the functionality was enabled during the entire reporting period. In other words, to say that it wasn't just done ten times then shut off.

Case reports was moved to certification only, so I think that was accidentally put forward. Okay, so then we had three registry related objectives, there was the mandated registry that was required, there was the voluntary registry, the second one, and the healthcare associated infections, was basically a third form of registry. So what we did is we put them – those three together into really one objective for eligible professionals and one for hospitals. And so if you read through here, it basically contains the logic of the previous registry objectives, but put into one. And then what differs between the EPs and EHs, is only what examples we used, because we used examples relevant to the EP or the EH in that section. Is Art here or on the phone? No, okay. I'm looking for the measure, it's attestation submission for at least 10% of the patients who meet registry inclusion criteria during the EHR reporting period. So basically what we're asking for is 10% of the patients who are eligible get reported into two registries which could be mandated or voluntary, any two. And I think the exclusion criteria there is actually misstated, so we'll have to fix that later on, just to note that Michelle. So that's the EP version. The EH version is identical except that the examples are more relevant to hospitals, for example, the healthcare associated infection.

Adverse reports was unchanged, so we didn't mean to include that one, and that's it.

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

Okay, so we'll finish up with the deeming option, which is an alternative pathway. The assumptions underlying this program or the proposal for this program is one, providers have already met functional objectives in Stage 1 and Stage 2. Two, that in most cases, you cannot achieve high performance without effective use of HIT. We want to promote innovation, you heard a discussion in the FDASIA Work report out and there's this line to walk between requiring things and allowing innovative ways of solving a problem. We want to go more towards achieving an outcome and letting innovation cause people to achieve that in different ways.

At the same time we want to reduce the burden and we want to reward good behavior. So we're trying to create an optional pathway that would allow people to relieve some of their reporting burden on some of these functional objectives by achieving good outcomes, which was the goal of the entire program anyway. Now an interesting part is – and that would all be well and good if we had a great way of measuring good outcomes. I think people – we've talked about this before, we currently don't have a great set of measures that would measure outcomes for most of us. And so part of this is predicated toward getting there, and so part of what we want to do by proposing this program is to stimulate more of those measures that would measure outcomes that we're striving for so that we can truly understand who are providers that produce good outcomes, not just processes.

This may mean that if adopted, this program would require – would ask let's say CMS in this case, to contract for more measures of the kind that would be worthy of deeming. So, I just want to put that out front. So what we're going to present, it's a review of what we showed you before with a tweak, is an example framework. So I put not QMs meaning don't concentrate on the quality measures that are listed here as examples, they happen to be dealing with what we have, not what we want, or perhaps even what we need for this program. But it's a little bit of a chicken and egg, if we don't provide the incentive for why would we need this measure, we won't get the measure. So, that's the spirit in which this is proposed.

So one is to recognize high or improved performance; high, we've raised the ante here to the top quartile instead of top 30 percentile. And performance, we have this closing the gap kind of definition where you'd close the gap between you and high performance by 20%. So you have two ways of achieving this deeming program. What we did add, was very important, as we mentioned one of the priorities we have for this Stage is to reduce healthcare disparities. We talked a lot about it from the beginning, we're trying to put some action – some meat behind that – some teeth behind that. So we have two – so you would – the theory would be that you'd pick two measures from two categories, and we've outlined let's say a prevention category and a control of health condition category. As I say, these are example measures, but we'd prefer, honestly, better measures.

Then we've added the requirement that for one of those four measures, that you reduce the disparity, that is you reduce the gap between the performance in some disparity population and your mean. So we're assuming that for some disparity there is a gap and we're asking to reduce that for one of the four measures. The reason it's one in four is because like four in four would be really, really hard and we want to make it possible to achieve this and yet point people in the right direction. Similar thing for hospitals, pick a couple of measures out of these buckets, patient safety, care coordination, and still have the reduction in healthcare disparities. So, we tried to think of one of the things that you would have to use if you were going to be a high performer or a high improver, and that we put on the left side. So almost – you'd almost certainly need clinical decision support, you'd have to be reaching out to patients with patient reminders, you have to be taking notes and tracking tests. Are they being completed? So there are a number of things that we thought you would have to be using of your EHR in order to be a high performer.

And so that's what we've listed on the left side. There isn't a 1 to 1 mapping between the QMs that used to deem, it's basically if you – if we can come up with good outcome measures, and you're performing against those, then chances are you're – a good chance you're using the EHR successfully. Additional considerations, well what to you compare to. We originally proposed six months, CMS said that would be logistically hard, so we've gone to a 12-month – the 12 months prior. One of the implications is that you have to choose your measures carefully for the previous stage, because you're going to be compared to it in future stages.

The second piece is that specialists just by the nature of the quality measures, does not address what specialists do as well, so it's possible that a given specialty may not be able to find four performance measures suitable for them, they wouldn't be eligible, this is an optional pathway. And we'd like to see better alignment between this program and other CMS programs like ACO, PCMH, eRx, etcetera. So we even think of it as bidirectional. It's possible that if you satisfy – if you're deemed a high performer in the Meaningful Use Program, you'd also qualify for PQRS or vice versa or both. It's just – and I know CMS wants to do this as well. The more we can have harmony between these programs, and the less reporting burden, everybody's a winner and they're spending their money wisely.

Next steps, feedback from you. We're going to pull back and discuss that and revise these proposed draft recommendations before bringing it back to you in September 4. We're also going to take up timing of Stage 3, not Stage 2. We understand that the concerns are around both, but Stage 2 is a final rule, the administration is listening to and dealing with feedback about Stage 2 timing. We're making recommendations on Stage 3, there are probably implications based on the same things we hear about Stage 2 and Stage 3 and we're going to take that up in discussion this month and get back to you with our recommendations in September as well.

To deal with some of the quality measurement challenges that I spoke to you about, there is a Tiger Team that's made up with members from the Quality Measures Workgroup and the ACO Workgroup that is trying to look at what are the kinds of quality measures of the future. In particular if you look at small ACO, these different kinds of models, of accountable models, there's just got to be better ways to measure your performance than process measures. So what do we have either in the works or things from the concepts we've proposed to you probably over a year ago from the Quality Measures Workgroup that could be at least put into the recommendation hopper for further work by CMS. And that team will bring back its recommendations in October.

So in short, the trajectory's been good. You heard the numbers just before this section. We're on the way to really getting this stuff out there. We are leveraging the work of functionalities from Stages 1 and 2, that we want to focus more on the tools that providers can use to measure and improve outcomes; that we want to reduce and simplify the functional objectives and provide alternative ways for rewarding good behavior, because of effective use of HIT. So Mr. Chair, that's our report.

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

You know each of the stages on that – on our swoosh that talks about the progression of meaningful use has had a main message or theme. And in Stage 1 it's going digital and incorporating into – collecting the data and beginning to just dip a toe into population health management and other uses of the data. Stage 2, the message was clear, it was about interoperability and exchange taking a big step forward and sharing of data between providers and with patients. What I'm – what we had always hoped for and want there to be a strong signal on for Stage 3 is outcomes and improvement. And I sometimes think that the way regulations are written, have to be written, and the way that Committee takes a huge amount of work and divides it up and puts it back together and reports out, obscures, sometimes, the connection between the individual requirements and the end goals.

And I hear, too often, I hear people say, this is a list of – it's a laundry list of stuff and it's not clear to folks how it relates to their ability to become a successful accountable care organization. And so I wonder if we could take another look at how we present the information, and that may have implications actually for our simplification work, our deeming work and so forth, and to literally turn it around to starting with the outcomes in population health, in care coordination, in safety. And really organizing it – our thinking again, and making it explicit that this – the goal is reduce readmissions. In order to do that, we need – what are the causes, right? When people bounce back, it's not having the notification that the person left, it's not having the medications reconciled in the long term – when the person goes to long-term care or goes home. What are the causes of safety events that we have in hospitals and what are the tools we need then to be successful in those?

I worry that the – for people who are not deeply engaged in the process, and maybe even for some who are, despite the best of the workgroups efforts to focus more on measuring and improving outcomes, reducing – functional objectives, providing the deeming pathway, all the right goals. I still worry Paul and George, that the workgroup product as it is now, doesn't sufficiently signal the goals.

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

I think you are right that when you deliver the product it doesn't show how you got to the –

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

The why – starting with the why and working backwards from the outcomes.

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

In parts – so there's a couple of comments. One is, I think the group itself does look at it from a how you would improve, and then from its experience says, well, you need to know what you're doing. Oh, that's reporting, oh, you need reminders, oh, that's clinical decision support. And so we've essentially extracted from working backwards, because there's experience there. And the other piece is this problem with the extant quality measures, is right now, you wouldn't want to go chase how often have you done this test versus are you – is the patient having less pain or more functional or breathing better or living longer. So we're missing, and actually asking as we presented, we're asking for better measures to help drive – you can't drive to somewhere if you don't know how you're performing currently and no one actually does.

So an orthopedic surgeon actually doesn't know what percent of their patients walk again, and we don't have a measure, we don't report on it and you can go through a whole career not knowing. And same for a lot of other things. And so it's a little hard to drive the system without the measure. So we're trying to set up the framework and the incentive for having those measures. And we see that having good measures would percolate, and actually the irony is, I think that would activate the intrinsic reward system that would drive improvement, because that always does, not external forces.

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

Paul, in your concert for deeming, would the measures that could be used for deeming have to come from the EHR itself or could, for example a readmission measure based on claims data be used to deem for some of the care transitions?

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

Yeah, I don't think it's limited to the EHR, but this readmission you bring up is an interesting example. As you know, probably – terms of health have more of an influence on readmission, and a lot of other things, than what's given credit for and we're not measuring those and how would we? It raises almost a whole – we need to change the medical model of how we deal with health and disease. So some of this is beyond the scope of what we're doing in this HIT adoption program, but I think it's within scope to have – measure things that matter to patients, providers and their caregivers. And that's the cry we are trying to spread, by setting up the framework for what you would do with those, if you have those measures.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

I don't want to cut my own legs off, I mean what I imagine – so typically the Committee hears this and says, okay, that's easy, make a matrix, all the objectives, columns are the three population health, safety and can't even remember – care coordination, right. And then you check off the ones, or put a one, two, three there and it doesn't really add anything, it's just a make work exercise. I'm thinking that what I would do next is take the objectives that actually have measures, that is the green ones in that colorful slide and create a narrative of one page that explains why we did this. When you have a narrative and

It's 50 pages, what you want to do is go to a matrix so you can understand it better. When you've been working matrices for four years, sometimes it's good to go to a narrative, and not the letter that we give to ONC, which is a matrix in narrative form, but actually just explain why the green ones are green in this little slide. I mean, I think that would be better than going to a matrix and trying to explain it. That's my instinct is that I would like to sit and think.

Remember Farzad and I had a conversation about a year ago on what we needed to focus on, care coordination and patient engagement and you made me throw in quality, because I thought quality was going to be done by CMS anyway. And it's kind of like taking that conversation, going one step further and just explain that someone could read and say, okay, I understand what their thought process is behind this. In addition in doing that I think we might say, I can't figure out where to put this objective in this narrative of one page and maybe there's a reason.

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

Another comment is, we're trying to put the t – we're trying to do something to help specify the tools that go help drive – facilitate the model. And I think what you're asking for is, how do we have this new model achieve these new outcomes? And can we actually map the tool functions to the new outcomes. We're taking this intermediary step in the sense of, we're doing what toolmakers can relate to, but we see that as connected to the outcomes we want to achieve with this new model of care. In a sense we're doing that mapping implicitly, but we are mapping down to the tools.

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

Other committee member's reactions? Let's do Paul, Christine, Judy.

Paul Egerman – Businessman/Software Entrepreneur

I agree with what Farzad just said. I mean, I looked at this, at the initial slides where we talk about outcomes, then you had like something else on the slide where it said, also to fill the gaps on everything else. And I felt what people are using to fill the gaps is the vehicle to put in absolutely everything here and it felt like this shopping basket. So it would be helpful to see how it relates to outcomes. And in particular I look, I think it was on slide 46 where we talk about enrolling – automatically enrolling people in clinical trials and I just don't see how that relates to outcomes. I mean, I think that's a – it's a nice thing to do, but I just don't see how it relates to what the focus is and to me it's much better if we stayed focused on outcomes.

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

Well, let me at least clarify. So it was not an automatic enrollment, the goal was – about the – there's two issues, one is to generate new science and the other is to translate it into practice. And what we're trying to do is put features into the EHR that help with both. So in this case it's the generate new science, one of the rate limiting steps and an expensive rate limiting step is finding people that actually engage in the trial, even though they could either potentially benefit from it if they only knew. So that was the logic behind giving the capabilities of connecting dots between people who want to advance the science and people who would even want to participate in that. So that's au – so it's not an automatic – it's only a certification criteria right now.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

That's why it ended up in the list, and then why is it a certification only criterion, not just lack of standards but a feeling of the same feeling you just had is that we had and that's why it wouldn't have been green and wouldn't have ended up in my one page summary.

Paul Egerman – Businessman/Software Entrepreneur

You make it certification only which means the vendors still have to program something –

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

Yes, I know, we understand that.

Paul Egerman – Businessman/Software Entrepreneur

– and we just had this hearing on usability where people talked about one of the challenges with usability is these products have too much stuff in it. And there's the whole concept of what's called bloat ware, where you put in so many features that the product is expensive to maintain and difficult to use, and I still don't understand how that specific feature, for example, relates to outcomes. I mean, I'm not trying to argue that it's not a good thing to do, I'm just saying that the focus here is on outcomes, why is that in this – why is this here?

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University

So stepping back, another thing to do is look at our certification only criteria and wonder how many of those should be future stage instead of certification criteria.

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

Or optional for people who want to serve a particular market, if you want to serve the academic medical center research market, then that could be a certification criteria – something you want to market on the basis of, so you have optional certification criteria, but not make every vendor do it, potentially. Christine and then Judy.

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

So on the sort of framework and why does this matter component, I like George's idea of a one-page narrative. I like the idea of CMS and their – all of their tip sheets and all of their implementation guides carrying that message through in those ways as well. But on the other hand, I spent a number of years doing polling work for AARP and what the researchers would always tell me was look, a public education campaign never changes anybody's mind, it just doesn't work. The stuff that is going to work is the stuff that has a real material impact, and for this community, I think that's payment, I think that's probably participation in these – some of these public programs around readmission, etcetera and feeling those penalties. And I also think it's consumer expectations, right, so the experience they have – the experience that consumers have today going into their doc office or the hospital is markedly different than it was several years ago and it is becoming an expectation to have an electronic health record. And as more people implement reminders, for example, we will come to expect those and ask them and it will become a market driver, I think, over time. So I do like the idea, but I think we have to be aware that there's a limited amount that we can do, I think, in the current or that education alone, anyway, will do. I have a series of smaller comments on the slides, do you want me to do those now or hold that for when we're done, big picture stuff?

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

Big picture.

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

Great.

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

Judy ?

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

Okay I have a number of things to – first, sometimes being here reminds me of reading all about the history of people who tried to change the ecology of islands. And they brought in one organism to compete with another but that ran amok, so they brought in a second one to compete with the first one that they had brought in, and that ran amok. And I think we have the job of being very careful we don't get into running amok. And so some of the things I wanted to mention is, what I'm hearing, this is just one thing, the 5% secure message that providers have to have from their patients.

We have heard specialists saying two things. One is, that they will omit critical things to their patients so their patients have to contact them. The second thing we have heard is that they will have monthly raffles for those who have messaged those, to give them an award to get to the 5%. And so that's some of the stuff that we're beginning to hear that I think we have to pay a lot of attention to, what are the unanticipated consequences of this, and go slowly and carefully enough so that we get it right. I would say that providers who see a lot of patients, say providers who are above the 50% mark in seeing patients in their specialty, should be reviewing this carefully to say, how is it going to affect them? Will it work okay?

Similarly, I think we have to have developers look at it. I heard one group of developers saying that if you put this together with the deeming stuff, it will break the backs of developers. And therefore I think you need to – or we should be getting developers from different vendors and saying, is this really stuff that it's reasonable for us to be doing. I have two examples here I wanted to mention. The one example is SGRP 113, page what is it, 113, is clinical decision support. If you look at that, there are a lot of new things added, even though it's one measure. It's a new data element to collect, the reason for overriding, it's the requirement to connect to external decision support systems, it's to build an immunization recommendations, it's to build in immunization rules. It's to add the capability of prompting to add problems, it's to add the capability of prompting to edit problems. And adding the capability of prompting to delete problems. They're different things, some of them are very large and although they may be written in a small, short sentence, it doesn't necessarily make them simple to do.

The other thing I wanted to mention, and I have it right here, hold a second is order tracking and that's 122. Going to what's specific versus what's generally a goal, if you look at that it says, able to assist with follow up on orders to improve the management of results. But what it has in it is getting back to the provider and alerting the provider when things aren't followed up appropriately. There could be better ways to do this, maybe the system can be alerting the patients and getting back to patients, for example, and not adding to basically the in-basket of the provider, which can be a big problem. So I'm thinking that this stuff needs a lot of care and review before we release it because the effect it will have both on the vendors and on the users. And we don't have yet the results for Meaningful Use 2, that would be important to get back and see how that affects people.

Another thing I'm worried about is it does say that, I think we said that we're going to approve this next month, in September and given that we get these – the information kind of late. There's not really a lot of time to go through it, make really careful judgments on something that's going to be very expensive, not just for the vendors to do, but for our healthcare organizations to install, and for the providers to use, if it really slows them down. And to do that in a rushed way is, I don't think wise. And the next thing is, it's not a meeting, I think, that we're going to have in person, is it? And it's harder to do that on the phone. So, those are some of my concerns.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University
– well the timing one –

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yeah, just on the timing issue. We've said that we're not going to do rulemaking in this year.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems
Oh, okay – there was something that said that, we're going to vote next month –

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Yeah, I understand. So I'm saying is that this is the Policy Committee and the Meaningful Use Workgroup of the Policy Committee. When I said we, I meant the Department of Health and Human Services. The Policy Committee does not do rulemaking, the Policy Committee gives recommendations.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems
Oh, okay. Well, it's hard to give the recommendations –

Farzad Mostashari, MD, ScM – National Coordinator – Office of the National Coordinator
Judy, if I could just keep going on this train. So, we're not doing rulemaking in 2013. So one thing we could do, and I think this coincides with your, Paul, recommendation that the Meaningful Use Workgroup take a look at the timing issue, is we could kind of take a step back. In terms of having kind of the drive to get us kind of – for the workgroup to feel that they're under the gun to give final recommendations, when, as Judy points out, there's more analysis to be done potentially. And maybe we can take another look at the one-pager, the kind of backward planning on outcomes and seeing if there are some more things we can do here. So I guess, if it would be helpful Paul, and I think more time is always appreciated in this workgroup, for us to take a little step back and see what we can do in terms of re-factoring, if that's the right word, what we have so far from the Meaningful Use Workgroup.

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

Well, that would be appreciated. You just say the word.

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

So let's take that – and we'll discuss that with CMS colleagues in terms of timing and giving the Meaningful Use Workgroup a little more time and seeing if we can't get a little bit closer to the vision that I think we all share around outcomes and improvement being the focus for Stage 3 and communicating that clearly.

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

Can I answer a few of Judy's com –

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

Oh sure.

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

One is, it sounds like we could be more – perhaps more precise in what we suggest, let's say you picked on the clinical decision support. I mean, I happen to know your products, they do all this and maybe – and so it's clear that you don't recognize that what our intent was actually is not very onerous, it's giving us tools that exist in many EHRs now. They don't exist in all of the EHRs, which is the floor problem. So we want everybody to have the tools to be able to pick up that, oh, diabetes – there's lots of evidence to present diabetes is not in the problem list. You can use your existing tools right now to do that, so potentially we're thinking more basic than you're interpreting it.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

Well I happen to have a hat on that's not just our products, so –

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

Pardon me? So, anyway it's more basic and maybe we can be more precise on what we mean, because we are talking about a floor.

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

Okay, Gayle.

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

Thank you. I appreciate that. I am a little overwhelmed and I know the providers out there are very overwhelmed, and I spent the summer talking to many, many of them at various medical groups around the country. And I can tell you they're still reeling on Stage 2 and when we – and very concerned that the products are not going to be out there. The vendors are not going to have products for them, that they're not going to be able to implement in time, and they are – when this whole discussion on where we are on recommendations for Stage 3 and the complexity of this is huge. And I can tell you, there's a lot of frustration out there and people are truly feeling that they are being pushed to the wall on things, both with ICD 10, Stage 2 coming up, the lack of interoperability, the demands on things, it's huge.

I am – as I look at this and read this, and it's going to take some time to really digest this and just getting it this morning is not adequate time, but as we go through over this next month I will do that. But I can tell you I'm very concerned. If we really want to improve outcomes and we have some mechanisms out there the duplication and the burden of doing PQRS, for instance and Meaningful Use Stage 3, and ACO requirements and everything else, we need to look at the whole picture. And maybe taking a little time out and looking at the big picture might be worthwhile, and seeing what kinds of coordination in real measurement and what are improved outcomes and how can you integrate some of this so that you're not – so our providers can actually reach Stage 3 of Meaningful Use and not be so burdened.

Also, I want to say in looking at this, I don't – I question how it's going to be – how we're going to really raise the bar and improve outcomes for specialists. Again, we're so geared to primary care and I don't find the kinds of measures, the kinds of things that we need to really raise the bar and improve outcomes for specialists out there. So, as you perhaps – I really thinks this needs more time, more discussion and we don't need to be in such a hurry to do this, really.

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

Just a – maybe explain part of the challenge here is that we want to provide early signaling and in the past, right, that the Meaningful Use Workgroup has been a place where you discuss things far in advance of rulemaking, when the final rule comes out. And yet, where we are right now, as Gayle says, people are just finishing Stage 1, they're trying to gear up to Stage 2, and I think even the discussions about Stage 3, regardless that it may be years and years and years in the future, right, when it may take effect, are, I think, overwhelming for folks. And so perhaps our desire for the greatest transparency possible and the greatest signaling and so forth, are maybe having an undesired effect.

And all that to say, the Meaningful Use Workgroup working under very tight pressures, has done, I think, an extremely thorough, professional, hard-working, incredible job, as always. But it is, I think, appropriate for us to make sure that we get, we nail Stage 2 and that we get the attention on, appropriately, on taking that step up to Stage 2 on time, moving forward, getting interoperability in place in Stage 2. And I think we do have, for your workgroup, a little more time and maybe not flooding the attention of folks with the thoughts about what might be in Stage 3.

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

I'd like to jump on that again and say yes, I totally agree Farzad that that's part of the problem. But also I think we need to learn some lessons, and sometimes it takes a little bit of a breather before you even start making signals and start sending smoke signals up is that evaluation is necessary. An in-depth look at where we – what is actually happening out there and what those improvements in outcomes – how the measures that we're putting in place are actually impacting improvement in outcomes and how you can measure that better. How you can coordinate better with existing programs that are pushing outcome improvement? So evaluation of Stage 1, moving on and seeing Stage 2 implemented before we totally get into such an overwhelming discussion on Stage 3. And yes, you need lead time, and yes we need rulemaking time, but a thoughtful approach and thoughtful discussion before you really come down to matrices is perhaps a little bit of a conversation we need to have more of.

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

Let's do Charles Kennedy, who's been waiting on the phone, and then Terry.

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

Okay, thanks very much. My comments are going to revolve around Meaningful Use 3 alternative paths and the deeming model as it relates to an ACO. I think many of you know what we do is we form relationships with delivery systems and form a collaboration to help them go down to the path of an ACO and one of the things that we do early on is to create something we call our efficiency and effectiveness model. It's a series – kind of to Farzad's point, of outcomes measures and financial measures. And the reason that's so important is that it paints a picture as to what the ACO must do to be viable, both viable financially and viable clinically. These analyses are almost exclusively claims-based and yet tend to be the most important component in helping a delivery system shape its overall strategy to becoming an ACO.

What I have found is that much of this work is non-technical in nature, or non-HIT in nature and that the role of technology is more as an enabler to achieve some of the outcomes and measures that we have put in place that tie to the strategy and critical success factors of the organization. What we have frequently found though is that many of quality measures and requirements of the Meaningful Use Program tend to be treated as things you must do to get paid rather than an inherent component of driving the business strategy. The biggest role we've found for technology, HIT, is mainly in the data and reporting area. And yes, much of that is clinical, but I'd like to highlight that most of the ACOs out there find the financial or claims-based analytics to be as important or sometimes more important than the clinical component.

So kind of what does that all net down to? I think that when we looked at deeming strategy, if you think about an organization that's trying to become an ACO. If they can articulate their business strategy, identify their critical success factors and then identify technology's role in achieving that, I think a deeming approach that ties to that kind of a process will probably make much better use of the taxpayer's money than one where we are kind of setting what the quality measures should or should not be. So I guess I'm arguing for even greater flexibility in the alternative pathway.

And then the only other comment I would offer is, I did look at the quality measures here. They do seem to align with the quality measures in the ACO program, the four domain measures, but they are different. And I would just encourage us to even more so align the quality measures for simplicity and ease of reporting than what I see here.

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

Thank you, Charles. As Paul pointed out, those were somewhat illustrative, but I think the other point to mention is that this is – there's a need for harmonization, not merely mirroring. And I know that CMS colleagues are interested in truly harmonizing the two parts so that we do create de novo measures that matter, that make use of information that is not available in the administrative information. And that is more outcomes based and that does matter more and that is longitudinal to the patient, and use those for the ACO and other payment purchasing programs as well. So, point well taken and I think in line with the rest of what we're discussing, but let's not take the current measures as the end of the line, Charles, I'm sure you'd agree.

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

Oh, fair enough. Yes.

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

Terry?

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

First I want to thank you for all of this work. It's really a great product from what you've been able to do. However, I don't want anybody to leave this meeting scared that we've created fear in the hearts and minds of people out there, so I just want to reiterate the fact that we are in dialogue here. That nothing has been stated and to reiterate what Gayle said, I think the complexity of this issue reminds me of my first two years of medical school where I thought I would never understand physiology, I'm not sure I still do. But having said that, I'm really intrigued by the deeming concept because I think the deeming concept puts in front of us the outcomes. It basically says, this is what matters, we believe that these five, ten, eight functions, capabilities need to be embodied in your EHR. And you may not even know they're there, because there are many times in medicine I don't know how I got there, but I got to the right place.

So I think what may be helpful is to – for me at least, to flesh out what you ended up with and start with that. And I think that this echoes what Charles said too, that ability – obviously there's not cost in here, but this ability to say the outcome is where we want to get, we can harmonize. And Farzad I agree with you, we need to harmonize, not only with CMS but also with people who are – the boards for many of our specialties, which are also pushing us to look at how do we improve care, how to we report on that on a yearly basis. But I think the nidus for what needs to happen in Stage 3 is in here and I think some of it's just related for us pushing a little more on the concept of measurement from an outcomes perspective. And, oh, by the way, if you do this – and Paul, I think it went – it goes back to what you said, your system probably already does a lot of this, the issue is, just making that in a sense invisible, because I'm utilizing it to get to the outcome.

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

Christine?

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

Thanks Farzad. So I think to the timing issue, I'd like to ask – I know we are going to talk about it in the Meaningful Use Workgroup it sounds like. I'd like to ask ONC to help us with as much detail as we can get around what the potential policy impact would be of changing or recommending a change to any timing. I also think that we need to think about Stage 3, not Stage 2. Stage 2, I think, was probably the hardest of all three, right. Stage 3, we've already simplified of from 46 down to 23 objectives, the vast majority of those 23 are not new, they were in Stage 2. They're maintaining so the vendors don't have to build those capacities out further, providers may have to make some limited workflow changes. But we need to think not – I mean we keep talking big picture and complexities and I think we need to get real and recognize the hard work we've already done to try to really simplify, condense and consolidate and get very specific to exactly what are the impacts in Stage 3.

In Stage 2, it strikes me that we had this exact same discussion and we got criticized both ways. In Stage 1, we got criticized for taking too long and being too soft – the issue of the criteria, right. Then in Stage 2 we got the opposite feedback. And so sometimes it becomes a little bit difficult to know what's legitimate here. I know that I got telephone calls from providers who were pretty irritated because they had counted on those incentive dollars in their budgets for the coming year and now that Stage wasn't going to be available to them. So I think we have to get very specific and very contextual to this particular point in time. I also think, and I've mentioned this before, it would be helpful to have some input from CMS to look at the active programs they have like CPCI, like ACO, Pioneer, Shared Savings, the Bundled Payment Program, the readmission stuff, and understand our relationship between the timing of those programs and when providers are going to either have an opportunity to claim those incentives or they're going to get hit with those penalties, independent of meaningful use. And what Meaningful Use in Stage 3 has to offer that is wholly different than it was Stage 2 around population health management. I think people aren't connecting the dots and that if we just go, ooh, this is – it looks kind of hard, people have been saying it's hard, so we should delay it, we will do a huge disservice by not making sure the providers have the tools they need to perform. So I'd like some data from CMS about those payment mechanisms and how they line up time wise with Stage 3 and Stage 4.

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

Thank you. And just in terms of, at least interpreting what I'm hearing and suggesting here, it's not so much that – how hard it is. It's are we making clear that Meaningful Use Stage 3 as exactly as you said is what you need to do to succeed as an ACO. And I think that's where we do need those dependencies, not just temporarily but functionally and in terms of capabilities. So that's the work that I think we really need to engage on, we've – it's been what we've meant to do, but I don't think we're quite there yet in terms of making it crystal clear everybody why this is here and why it's necessary for new delivery and payment models. Paul?

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

Probably I'm just going to reinforce what you said. First of all, timing wise Gayle, we were being very responsive to people marching up and saying we want to know more – want more lead time. So that's how – we worked backwards from that and that's how we got July and that's how we got September. We would much appreciate more, if we're granted more time to work on these issues. So, ironically we're trying to do everything we can to give people the lead time, and that puts us in the schedule we have.

Now, I think Farzad hit a nail on the head. In a sense, if you look at this matrix of essentially functional objectives, in a sense, we tried to do the hard work of translating what does it take for a provider to be successful in being accountable for a population of patients? What would that look like in the EHR? And that translate – not many people can do that, that's what we actually set out to do and used as a criteria for this HIT Adoption Program. What Farzad's pointing out is, we didn't make clearer that's what product you ended up with, and that's George's one-pager. So we need to do that and that's sort of the stepping back. But our process has been figure out not so much what does statutory date requirements, but as a provider I know that we need each and every one of these and more to do a good job of what we set out to do.

There are things that we do not have, tools we don't have, to answer basically, what's my population today doing? What do I need to work on today? And they could be there, because the data's there, it's the functions that are missing. So we're trying – the timeline we're up against is how do we be successful in just meeting even the new programs that are being rolled out, that are pointed in the right direction. And in a sense, that's probably the driving function probably for the folks on the workgroup, and I think a lot of people on this Committee, it's not just a statutory – some arbitrary date. So we're pushing, almost pushing ourselves because we find the need, as providers for example, to do the right thing. But I think Farzad's right that we could do a better job explaining what actually we ended up with – what does this represent? It's really the translation of what's needed for providers into functional requirements for an EHR.

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

Judy, then Terry.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

First of all I do want to say that I think you did a good job on this and I would much rather have too much and figure out how to narrow it down than then too little and be stuck with the needs growing. So, I like where it is. What Christine said about its duplicative and it's not going to be hard, it may be. But what I'm trying to say is that I think until the developers really look at it and have the time to evaluate it, that might be a guess. And the same thing with the physicians as Gayle was saying, how do we get the really busy physicians to look at it and give the feedback? One of the things that folks have told me is that, let's take the CDS example. Meaningful use implies that we're going to construct a specified measurement for it and that we have to do it on a per doctor basis. And then they'll want a dashboard so they can see whether they're being in compliance or not. And then we have to save the data to prove to an auditor later on that it was in compliance each of the measurement period. And so where it might be yes, it's done, even for some of the vendors, it might be that there's a lot of work behind the scenes to get it done in a way that's acceptable. And that's why the developers need to look at that and say is it okay, is it not okay, I don't know, but I would rely on them to know.

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

I don't disagree with that Judy at all, but I also assumed that that was the crux of the public comment process that we went through, the developers and clinicians that we got feedback at that time about workload, etcetera, so I think we should always be open to that feedback. But it's hard when it comes from one person here, one person there and then somebody else comes along and says something different and it becomes very anecdotal and it's not data-driven and it's not representative necessarily of an industry –

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

I agree with you and if there is a way to organize it so that we could get groups of doctors and groups of developers from different places to review, that would be great.

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

– the ONC.

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

We do have representatives on the workgroups who bring the perspective, and hopefully the information from the communities and we do have requests for information that perhaps need to be engaged with more by folks. But Judy, the one thing I'll add to your characterization of looking at the developer time needed to do it, the other thing we need to look at is, yes, what's the squeeze? But also what's the juice? What are we getting for it? And if it's really necessary for improvement, if we need to know for improvement whether a decision support tool has a 1% predicted value positive or a 50% response rate, then it's worth doing that work, right? But, if it's not on the critical path towards the outcomes and improvement, then it's just work.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

And then it just may be not this needs to be done, but what's is the timeline for it to be done?

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

I had, if I might take the chair's prerogative. One comment to make which I think isn't too specific, it gets at the observation of what have we learned, Gayle said? And one of the things we've learned is that thresholds don't matter too much. That we spent too much time debating thresholds, 25%, 30%, 35%, 40% it should be 50%, it should be 80%, right? We spent way too much time on that and what we're finding, and we've seen the data for this all now, is there are a very, very small number of providers who

are on that cusp, but that if you can get it to the point where you change a workflow, you change the workflow and it ends up being CPOE for 90%, 95%, 98%, it's not 35%.

The one thing I worry about, though is George the point you brought up, that to say even 10% creates a different mentality than ten. Ten to me says check, I'm done. That's what ten connotes, I think, and that's the kind of behavior that it creates. So, I could be wrong, I don't have science behind me on this George, but my concern is that the goal for us is to create patterns and habits and I worry about the ten imaging, ten immunization, or ten anything really.

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

Gayle?

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

One last comment and I want to kind of jump off what Christine had to say, in that I think that the harmonization of the overall goal and CMS's goal – changing payment model goal, that needs to be really the driving force behind the structure and what's in the package and what's the ultimate Stage 3. So without that harmonization, without having that information as to what exactly is there, what are their timeframes, how do you build those things in so you make this as seamless as possible, as comfortable and easy for hospitals, for physicians, for all providers, so that there's that coordination. And that you don't get that level of frustration that I can tell you is very much out there right now. So stepping back and taking a look, and perhaps pulling in those resources and maybe it's just articulating it as opposed to – maybe the harmonization is there and the coordination is there and everything is working together and we don't know it. Perhaps it's just the articulation of it, but that in itself, I think, would go a long way to alleviating all of the angst that's out there.

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

Okay. Well, I think given that we didn't go through the line by line, we actually can end this session a little early Paul and George? Thank you. Thank you. Let's give them a round. All right, is Micky on the phone?

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

Yes, I am here.

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

You're here.

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

Yes.

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

Would you like to comment on Meaningful Use Micky?

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

No, no. Hi Farzad, what's new? Yes, I'd be happy to. Are the slides up?

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

Yeah.

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

So today, from the IE workgroup, we're going to discuss two things. One is revisiting the provider directory conversation that we had last time, at last month's Policy Committee meeting and then talk about data portability, which we haven't talked about yet. So, if we could jump to slide 4, I'm sorry, I should be on the WebEx so I can see. There we go.

So in terms of the provider directory conversation, you may recall that at the July Policy Committee meeting, the provider directory recommendation was approved. But the Policy Committee asked the workgroup to revisit this principle on authentication, where we had put in as a step in sort of a transaction framework, principles related to what a transaction standard might look like, a step about the requester presenting authentication credentials. And there was some concern that perhaps that would be misaligned with the ongoing S&I framework work, so we had a workgroup conversation, we invited some S&I framework staff to come and talk. And you'll be happy to know that we not only confirmed the initial recommendation, but we doubled down on it and came up with the recommendation that authentication on both ends. So, that's just a little bit of background and I'll describe it for you in a second and I think it isn't opposite to the direction that I think was essential to the Policy Committee last time. I think it's very much aligned.

It turns out that as we discussed with the folks from that S&I framework that in the conversations going on in the S&I framework, they did have and they do have authentication being a part of the work that they're doing. But it's on the other end than we in the IE Workgroup had contemplated, which was the necessity for the provider directory to present authentication credentials, so that the requester knows that

the provider directory is, in fact, a valid provider directory, and you can imagine the issues that might arise if we don't have that kind of protection in place, that someone could spoof a provider directory and then redirect transactions to bad actors or to other destinations.

So we thought that was quite important and so we thought it was important to add then mutual authentication. So the thing that I'd like to stress is that, and I don't think I made this quite as clear as I should have at the last Policy Committee meeting, is that our recommendation is solely focused on certification of the EHR technology and not about use. So this is not a policy requirement that authentication should be utilized in provider directory transactions, it's about saying that the capabilities ought to be in place or in the certified EHR technology, so that those who choose use it are in a position to be able to use it. We believe pretty strongly that it gives maximum flexibility to the market and implementers and policymakers. One is the provider directory market, as we know, is still evolving as are the use cases. And what we're seeing in the market right now is that a lot of provider directory implementations are utilizing authentication, which may or may not be a good trend. But the fact that that is happening suggests that it may be something that we just want to make sure that technologies have in place should, from a policy perspective, those users want to invoke that capability if they'd like to. So let me pause here and see if there are any questions or comments on that.

Okay, let me move to the next slide then. I've just put in the same slides that we saw from last time, just so you have the full set of slides. This was the recommendation that we had from last time, I'll only cover the changes that we put in. Next slide please. This slide again was the same, no changes from the previous version. And then finally I think it's on the next slide that we have the two changes, which are denoted in red, which are to, if we have mutual authentication now you would have the querying system having the ability to validate the authenticating credentials of the provider directory. Again, to make sure that that is a valid provider directory and not one that's being spoofed. And then the provider directory in turn have in the ability to present those authenticating credentials to the requesting entity. And then we already had in place the other side of the authentication transaction.

So again, in taking feedback from the Committee last time, we did deliberate it and we came back again with I guess the two things I would just highlight are a) these are certification requirements, they're not – that they're not suggestions about requirements on using the technology. We believe that this is an important feature of secure technology for those who would like to be able to use this function and to allow that market flexibility to make that to happen. And we believe that it is quite important to be able to enable that technology – or that capability on both ends of the transaction. So from a process perspective, I think the committee did approve this last time and I think this was really more just an information request for us to go back and reconsider and come back and report to you. So I don't know if any further approval or anything is needed. I'll leave that to you, Farzad.

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

That's right, Micky. I think we're good with the previous recommendations that were approved by the Policy Committee then. Thank you so much for taking us back and taking another hard scrub at it, really appreciate it.

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

Sure. So, why don't we then move to data portability, so, next slide please. The background of this is, first off there is a data portability certification requirement in the Stage 2, 2014 edition certification and this would build on that in a couple of different ways that I'll highlight. First, one thing just a note on data portability is there are actually two elements of this that as we started to think through this in the

workgroup wasn't apparent, at least to me as I thought about it. One is that I think the provider-centric use case is one that most people have in mind, which is the provider switching from one EHR vendor system to another.

But as we started talking through this, it became clear that there's a very important and arguably equally important patient-centric use case which is about a patient requesting the migration of their records from one provider to another. And their wanting to be able to have as complete a migration of that information as they can possibly get, not just a clinical summary and not just a multipage PDF printout. So, both of those seemed to be pretty compelling as we think about it and I think as we look at the market, we certainly expect to see rising demand for data portability in general. Just purely as a function of a growing install base, you're going to start to see the need for this growing and then in addition, the market surveys that suggest that there may be a lot of churn in the market in the next couple – coming years.

Currently the data migration in general is a barrier exit, we think, for providers who are switching vendors and certainly a barrier to continuity of care for patients who are switching providers. In part because it's a very ad hoc process, it's highly variable, fraught with potential for errors. It's pretty difficult to include in EHR contracts in a way that's operationally executable when needed, in part because there are no standards around it. So, it's kind of hard to write that language. And it's also difficult because if the vendor isn't cooperative or if the system has been highly customized or if there's a mismatch between the source system and the receiving system, whatever you may have written into that contract may not apply at that point, and it's hard to anticipate what those issues may be. So, next slide please.

There are also some safety concerns and other concerns related to quality. And I'll just reflect on, I was on Facebook a couple of months ago, I do that occasionally. And someone who I went to college with, who is not involved in HIT it turns out, they just posted this on Facebook that they had gone to their physician who had just changed their electronic health record system. And for the previous couple of months there were signs all over the practice about under construction and please forgive any confusion around our change and we're changing systems. And so the first visit that this person had with their primary care physician with the system, they sat down, pulled up the record, the demographics were correct and the medical record was absolutely wrong, it was someone else's clinical information, though the demographics were correct. And it was completely wrong, all the clinical information was wrong, it was clear that it was another record entirely that had been inadvertently matched up with this person's demographics.

So, yeah, obviously, that's just one anecdote, but there are obviously huge safety implications for poor migrations and for the kinds of errors that could happen. Let alone the importance for – as we move to wanting to have greater abilities to measure and greater abilities for people to take that seriously and be able to act on it. And we don't want to have the case where because you switched the system, you're now starting from scratch with respect to CQMs, clinical decision support, what have you. And then finally there's the administrative data, which are typically not necessarily thought of as a part of the data migration, but any kind of disruption in revenue cycle can lead to a lot of frustration and disruption as well.

I will note that one of the things that came out in our deliberations is that a standard for data portability is hard, because it's difficult to completely specify what the requirements ought to be, because they seem to vary locally. And we have a number of clinicians on the workgroup and we have four of five clinicians, and I think we had ten different views, on what's important to include in a data migration. And there also may be varying laws related to record retention, provider, patient preferences, what have you, and certainly provider documentation patterns as well. So that makes it a little bit hard to completely and firmly specify it, so we decided to punt all that over to the Standards Committee. But we did think that setting a floor will certainly inspire greater market dynamism by lowering barriers to exit and by promoting safety of continuity of care by reducing opportunities for error, to the extent that we can.

So, that's kind of the background to this. If you can move to the next slide please. Let me pause here and see if there are any questions on the background.

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

Sorry, question from Paul.

Paul Egerman – Businessman/Software Entrepreneur

Yeah Micky, I'm reading through this, this is the Information Exchange Workgroup, how is changing vendors related to information exchange?

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

Well I think that we're – that this ended up being put on our agenda way back in the process of the RFC, so last fall, I think that data portability was an issue that is a process. The Policy Committee wanted to include in the Request for Comment, and so we were asked to take on data portability for that purpose, and so we've just continued that work. And I think to the extent that it's about import and export information, it seemed, I think that functionally we're dealing with a lot of the same things. And as you'll see, our recommendation is that we build on the approaches that we are using for interoperability in general to facilitate data portability.

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

Thanks, Micky. In terms of the background and the significance of portability, I would just underscore that and just remark that high switching costs are a classic source of market failures. And in a sense, the increased ability of providers to switch products, I think, will be a huge net plus in terms of moving the average usability, safety, efficiency and so forth of the products that are being used upwards and the cost downwards. So, it's an important part of making a market work effectively, as well as for an individual patient, the safety and continuity of care issues you raised. So, important issue that we really do need to make progress on.

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

So the recommendation, as stated here is, and I'll follow the same kind of structure that I followed before, which is to just state the recommendation as cleanly as possible and then talk a little bit about the background, which is sort of the principle behind it and some of the – more detail under the covers. So the statement here is about that EHRs have the ability to electronically export and import medical record and administrative information across systems to enable both the patient-centric as well as the provider-centric use cases that we discussed, without significant or material loss of clinical or administrative data. And we worded it that way obviously because it is difficult to specify exactly what that means, but certainly we want to start with the intent and then try to get our arms around how we can put some meaning to that intent in a way that can push us forward.

Next slide please. So this is again, the same kind of structure. I'll just – I can walk through it pretty quickly. But in terms of some of the various components of it and principles, one, the first principle was about consistency, where we mean having an approach that is consistent with the way we've been thinking about interoperability. So to the extent that we've got a CCDA approach, which is a structured way to be able to take content across systems, we thought it was very appropriate to sort of build on that approach and then further it in ways that would give us the completeness and comprehensiveness that we want to be able to have for data portability. And it may be that perhaps there's a set of CCDA templates or something that are specific to cross system data portability or something like that. That could be the outcome of this or you're able to assemble from the existing set, a comprehensive set that enables it, those would be questions that the Standards Committee might – could engage in.

We thought in terms of content that it should, again, as stated, that all clinically and administratively relevant information. It's hard to pin that down. One of the things that we thought sort of made sense was that it should go beyond what the current requirement is, which is the common MU data set, which we've listed there, but is really sort of a little bit parsimonious. And so we thought that it should certainly go above that, again struggled a little bit about how far above and what do you include there. In terms of other elements of the content, we thought it would be – that it was quite important to retain the structuring of discrete data, where it is already discrete. So for example, discrete lab results, and we've heard in the market lots of stories about migrations resulting in discrete data turning into text BLOBs, which obviously is very disruptive and could have safety implications.

That a migration approach should include and retain the structure and context of notes, so again, these are some of the war stories that you hear about textual notes that are in specific sections of EHR not being appropriately linked up and being put into, again, massive text BLOBs that are difficult to remap. And then finally, allowing the transfer of attached documents and retaining that attachment to the patient. So this would be the scanned PDFs, whatever those may be. For example, scanned documents such as in advanced directives, would be one, I think, important example that we as a policy process have thought is quite important. More often than not, those are attached scanned documents that we want to make sure are part of the migration.

We can read through the administrative data there about claims, scheduling appointment information. One that came up in the discussion that again wasn't obvious to me as we started was the retention of audit log metadata or reports for medical/legal purposes. Again, we're early – very early in the use of EHRs, but as we move forward, we can certainly expect to see these kinds of issues coming up that you switch systems and some kind of legal issue comes up and you want to be able to have some type of tracking of what happened in your prior system.

Next slide please. And then finally, we thought it was very important to add some flexibility to the way that one would be able to configure the type of information that you want to be able to export. So, some of the things that came up are first off, a time horizon, that seems important to have some kind of user configurability for the setting of the time period, again to cover legal medical record retention requirements, as well as to support look-back periods. So in Massachusetts seven years for ambulatory providers, it's different in different states. And then, as we know, different measures, different context have different look-back periods, colonoscopy is 10 years, other things have other time periods.

By encounter was another dimension that the clinicians on our workgroup thought could easily come up. So, you might want to be able to have the ability to just do office visits, for example, that exclude telephone encounters, would be one example of that. And then finally by patient, being able to have the export and import of a single patient in order to facilitate the patients bringing their entire record with them, which is that patient-centric use case, which is another dimension of that configurability that we'd want to be able to enable. So I think that's the last slide, if I'm not mistaken. Yes, I believe that's it.

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

This is Farzad. Micky, how is this being done today? What are the different ways in which the migration is being done today for – and I recognize there's probably a big difference between a one doc office and a hospital, but tell us – give us a little flavor, the Committee and those listening, a little flavor in terms of how those records are being migrated today.

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

Yeah, I mean my experience, and I think what we discussed in the workgroup just trying to get a sense of what the current state of the market is, is that it's the biggest range you could imagine. So down at the small practice level, it's everything from you really don't have much of an option except printing out whatever you can and then – and scanning that into the next set of systems to being able to pull out certain types of demographic and certain types of structured information. Or the ability to do it electronically but it all ends up in essentially one record, one patient, all of it a text BLOB.

To the other end of the spectrum which would be the highly sophisticated systems who have the ability to do what we might think of as more an enterprise kind of transport, where the sending system and the receiving system have the ability to send it at a data level. I would point out that I think in most cases, that unless it's the same system, and often even if it is the same system, because of customization and other issues, you're almost never going to get a perfect migration. You're almost always going to end up with a bunch of structured data on the base case that translates over as structured data, perhaps with some remapping required. But then a bunch of stuff that was structured in your original system and ends up having to be sort of a text BLOB kind of information in the receiving system. And I know of very few instances where you get almost what one would think of as sort of a complete migration, which is probably too high a bar. I think we all have to recognize that this is – we are talking about difficult kinds of things with very complex kinds of information, so, I don't think that it's reasonable to expect the bar of perfect – perfection, but it seems that we can do much better than we're doing today.

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

And the EHR Vendor Association code of conduct mentioned as one of the kind of behaviors that would be considered good, that the vendors would assist their customer in being able to get their own data out for migration purposes. Do the different vendors have a standard approach they use for kind of exporting the data and making it available or is it a case-by-case or even a practice level problem?

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

I think that again, there's a lot of variation and I think that standard – I don't think that there is a standard approach that I have seen across vendor systems. I think that each vendor has a standard way that they do it, but it may be that the results of that vary by practice even within their own installed base because of the customizations and the different documentation patterns that may have happened in that practice. And that's what I meant by the syncing up issue, that they may have a way of exporting it, but the receiving system may not have the ability to consume it in that way. So you end up always at the lowest common denominator in that pair that ends up with your result is always going to be the abilities of the least capable system.

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

I'd love to hear the broader group provide their insights and perspectives.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, so Micky, it's Paul Egerman again. I understand what you're trying to accomplish, I have to say I'm a little uncomfortable with this recommendation because I feel like we're making a recommendation that's like a design criteria in terms of what something should be, and that doesn't seem that's policy work. But I understand what you're saying about consuming the data. And I'd like to sort of suggest an alternative concept for you to consider, which is when you look at information exchange in general, we've have done very little with the receiving system consuming the data that it receives. And so if we started to work on that concept, so receiving system could consume a CCD or could consume a medications list or consume laboratory results or could consume an encounter report, then you would create the building blocks for this kind of data portability. But you would also take information exchange forward significantly. And so my suggestion is to focus on the concept of consumption as part of information exchange and to view the data portability as a byproduct of that process.

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

Yeah, I completely agree with you Paul, I –

Paul Egerman – Businessman/Software Entrepreneur

– consume is that if you request a CCD or you request a medications list, to be able to take that from the other EHR system and bring it into, in some form, into the existing EHR system as discrete data, perhaps somehow segregated from other data until you go through some other process. I don't know all the details, but to actually...in other words, it's not just being able to view it, it's being able to in some sense consume it, import it into the EHR system and then operate against it. That would be a big step forward in information exchange and as I say, would create some of these building blocks that are needed, just laboratory results consumption would be a step forward.

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

I completely agree with you, Paul, and if I didn't communicate as well as I should have, then I apologize. This – but what I meant by the point of consistency was exactly that point. We assume that the interoperability framework is moving forward and the ability to consume this stuff. And what we've focused on are the things that are unique to data portability so specifically, we can move forward on – just as you suggest, the ability to consume this information. But we have EHR vendors on our workgroup and they pointed out that things like being able to set a time horizon, for example or to set the ability to export CCDAs for a particular patient is not something that is present in almost any system. And so they thought that it would be helpful to be able to have that kind of configurability so that you can

build on those CCDA building blocks, which I agree with you, are a part of interoperability. But you still don't have the functions in the systems to get the kind of information – the information cut in a way that you want it to appropriate to data portability, which is different from use cases for information exchange. But it is the same building blocks.

Paul Egerman – Businessman/Software Entrepreneur

And – to say, it is the same building blocks and so that is why I would focus on that. And – because I think that's where you could make significant progress and there's a compelling argument for doing it and you can weave it into our stages of meaningful use. This is very hard to do, to try to do it all in one shot, by itself and runs the risk that you would do it in such a way that was inconsistent with how you might implement information exchange at a future point.

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

Well, that certainly wasn't the sense of the vendors in the entire workgroup and again, this is completely aligned with information exchange. It's just I think that the – that it's not "either" "or" we're talking about both here. And that there are specific requirements related to data portability that would never be a part of an information exchange framework, unless we specifically called them out .

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

Micky, last comment from me, I have to go. But – two-part question. One, is it possible that following a CCDA plus approach is going to represent a step backward in terms of what information would be available with the vendors current process of their own proprietary or whatever, their non-standardized, but their own current approach for assisting that migration, one? And two, how would this approach compare to what our chief technology officer, Bryan Sivak, I'll credit him with this plus or minus, which was to simply say to each vendor, you must publish the – you must export in any machine readable format and publish what your schema is for doing so? So, just want to put that on the table.

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

Right. So, let's see, to the first question I certainly suppose that in certain cases, to the extent that some vendors have the approach of a complete and entire data dump. To the extent that a CCDA or CCDA plus construct is constrained by definition I suppose that in a way you would get less information, now whether it's usable information is a separate question. But I guess, in that sense, to the extent that you are constraining it, putting constraining parameters on it, then you are by definition sort of narrowing the funnel for those vendors who have a big pipe that they just sort of spit the data out in. So I think that's a fair point.

And yeah, I mean I think certainly another path would be, as you suggested, that path, which is the open publishing of schemas. So that would allow each – vendors and as long as it's industry standard, to be able to do that. And I guess it's – like with a lot of the stuff, it's what is our expectation that that will happen and how patient are we willing to be?

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

Okay, Judy.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

I haven't heard too much about vendors not cooperating, what I hear more is that if vendor "A" has to send to vendor "B" and vendor "B" is – has a data field that is coded and vendor "A" is free text, that's pretty hard to do. And I am not sure what the CCDA plus specs would say under those conditions, what happens there. I do think it's important for the CCDA and the CCDA plus to work hand in glove or else there could be big problems.

The other thing I wanted to mention was just to be careful with the administrative stuff, because for scheduling for example, we recommend that that becomes the way that the schedulers learn to use the system, take the remaining schedule enter it in, by the time you're done entering it in, you've learned how to use the scheduling system. And it saves the conversion and it gives an excellent training situation. Billing. Most vendors don't do line item billing, so getting the billing across at a detailed level is probably not the right thing to do. So I think we have to be very careful on what we say comes over and have enough exceptions to deal with different vendors ways of doing it, as long as there are good reasons there.

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

Any comments, Micky?

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

Oh, no. No, I think those are all fair points.

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

Terry?

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

I want to take – follow-up on what Paul said. Just because we're struggling with this, the concept of sharing interoperability integration. The need to consume when and where and how, I think is really critical and I do think it's about health information exchange. And so what I would hope is that the data portability discussion somehow feeds into the overall umbrella of health information exchange, because I think that that really is where it is. And I think there are so many unanswered policy issues, consumption issues, authoritative source issues, integration issues, that we need to spend some time on that, just – the VA right now is really struggling with this. What do we bring in? Where do we stash it? To go to what Judy said, if it's coming in and it's a BLOB, do we consume it or do we say we're not going to consume anything that isn't mapped. I think it's really important and I think that the beginnings of that is in this discussion, it's in this data portability discussion. But I think we probably need a lot more work in this area.

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

And I guess one question in my mind is remembering that we're the Policy Committee, so these are really sort of a just a first policy statement that this type of data portability ought to be a part of certified technology. And the Standards Committee then being the place where they really dig in on a lot of these very detailed issues.

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

So some of the ways that we handle this Micky is, let's say for meaningful use, we pose questions to the HIT Standards Committee, have that as input before we make final policy recommendation. And it's sort of – it's this kind of thing, in fact, you heard us when we talked about meaningful use objectives. Some of the things that we initially proposed just didn't hold up because of the maturity of the standards or unanswered questions. It sounds like that's what we're getting into with this discussion, right. I think everybody is – everybody understands both the problem to solve this data portability and are in support of fleshing this out. It's sort of when and what needs to be done in order to fully specify it so that it can be done so that the whole industry can react to it. Is that fair – first of all, is it fair from the commenters point of view?

Paul Egerman – Businessman/Software Entrepreneur

I mean I think it's fair and it makes sense. I just think that also what is written here from an overall data portability standpoint is impractical and may not be necessary. I mean if you have two large EHR systems and they need to – you have an existing system and you need to switch from one vendor to another, it's not unreasonable that you would have like some specific, like almost negotiation, about how that would occur. It's not necessary that that transition occurred same way every place around the country. This is also an observation. So again, I think about what Judy said about like line item billing. So there are like three or four different ways of doing that, and you don't have to specify one way only of doing that. Yet the information exchange, however, you do need to specify hopefully one way of doing it to do it right. And I still think that's where our focus should be, knowing that that creates the building blocks for what is intended with this concept. I mean the goal is good, but it's sort of like the goal is saying, we want these systems to be usable. Well yeah, we do want them to be usable and we want the data to be portable, but we have to think of some incremental way of getting there.

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

So you're questioning actually the concept of it having to be standardized for data portability –

Paul Egerman – Businessman/Software Entrepreneur

I'm questioning whether it's necessary and whether or not it's doable. Now if the Standards Committee can answer certainly the doable part, but I'm still suggesting an alternative, which is to focus on the consumption piece, that that I think is much more interesting and will accomplish not all of this but as much of it that can be accomplished.

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

And Judy and Terry, what's your – is it more work needs to be done to specify the standard format and whether that's good and capable or that it may not be required or practical?

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

I think for me some of it is I think this consumption part of it needs to really be fleshed out. I am somewhat agnostic about the other part of it, but I don't think we know enough yet to – I don't know whether we were voting. I don't think we know enough yet to vote.

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

So the question is, well, go ahead Judy.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

And I agree with Paul who was agreeing with me that there are many different ways to do it and if we become very specified in how to do it, we could really mess things up a lot. And especially with all the mergers and acquisitions that are going on right now, this is happening a lot and these things are not easy. To be able to do a conversion when there is an acquisition, even if it's the same vendor to the same vendor can take a long time and cost a lot. As Micky had put in the beginning there, that there's so much customization that goes on, it makes things different.

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

So I wanted to know whether the next step is to get more information as part of what Terry was saying or are you actually saying this isn't a good idea, question whether this is a good idea? Oh, okay Judy.

Judy Faulkner, MS – Founder and Chief Executive Officer – EPIC Systems

My feeling is we may be trying to solve maybe more – to solve a problem that doesn't exist except that it's hard and people are trying to work on it and by trying to solve it, we make it harder than easier.

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

Claudia, I'm sure you have something to add here.

Claudia Williams – Director - Office of the National Coordinator for Health Information Technology

Just a couple of questions for you, I guess. What I heard from Micky's presentation was not to try to solve the whole migration problem but to try to enable more coded data to be moving when you are moving the data, so that – the more discrete data. So I guess that's one question is just, I think a lot of different ideas are being presented here, but the hopefulness of being able to have coded data move over when you migrate and whether this is a good model for that, is one of the sticking points. I guess it's one question.

I guess I would – this whole point of migration is something that's in part of the framework from Stage 2 and was also the part of the framework in the RFI. So I guess one thing I'm hearing is questioning – but this isn't a new idea, this is something that's been part of our approach for a while now and just wondering – so the question I think Micky and his group was trying to address is, what more can – should be done right now on that issue? So those are just two questions I would ask you guys to think about just in this discussion.

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

Okay. So one wa – so I guess I'm not hearing a great deal of consensus on moving this forward as presented. I think one way is to invite further ammunition Micky, in terms of feedback from the Standards Committee potentially and more about the needs and whether this is a solvable problem in a universal way. Would that be acceptable?

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

Sure, absolutely.

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

Okay. Alicia?

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

I just had a question, I guess, in terms of the visibility into this process we're talking a lot about, mergers and acquisitions or switching systems, going from one vendor to another, what kind of visibility into this process should the patient have or can the patient have? When your bank goes through merger, you get a sort of before and after snapshot of what your account looks like and you can check your balance and you know that all of the information moved over. But is there an equivalent analogy, I guess, on the healthcare side that if my primary care physician moves from one EHR vendor to another that my relevant information is correctly moved there? Is there some sort of check built into the system that allows for that?

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

– say, if they were both EHR certified systems and they were both meaningful users, then you would have VDT before and in the transposed state, so I would assume that that's one way. And then, we even in Stage 3 were proposing a mechanism for you to request a correction of something.

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

You'd still have to know that there was – that your information needed to be migrated, then you'd have to know to go online and do the download. So, I don't think it's that great solution. although it's technically feasible. But it spreads the burden of, or the problem of the lack of portability on to the patient, which doesn't seem particularly fair. But I do think that Alicia's raising a good point, which is that consumers would have legitimate expectations that their data's going to – if they're still seeing the same doctor, they should still have the medical record.

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

Good. Oh, David?

David Muntz, MBA – Principal Deputy National Coordinator – Office of the National Coordinator

Yeah. I think one of the things that when we try to listen, we try to distinguish what the messages are and so, one of the things that we do is use the same terms kind of interchangeably and migration and transportability or data portability, in my mind are very significantly different. And we have situations where patients want to have portable data, they want to move from Kansas to Michigan. They want to be able to transport their data, they want to be able to take it out in whole and move it the same way they would move paper records. And so that's a pretty easy way to understand transportability.

Then there's the issue of migration, where you want to move from product "A" to product "B," and if you're a large healthcare system, I can tell that you understand the issues much more clearly than a single practitioner would, but the cost and difficulties of doing it are significant. So when a physician moves, it depends on the specialty a lot about how much and how little data gets migrated from one system to another. And so I think exploring those distinctions, where VDT I see works great for transportability, it's not good for migration. And it depends on whether you want to do it, for example, if you were doing accounts receivable in a financial system, whether you want to take the balances forward or you want to take the detailed transactions? And those are decisions that you want people to be able to make based on their own needs, not based on an assumption.

So I think it's worth having a conversation to clarify the vocabulary to ensure that we are going to address a problem that does exist for both the patient and for the practitioner. And to try to segregate those so that transportability is patient-centric and provider-centric is where we're looking at a migration and then deciding whether or not you want to include that. And then I think playing that against what the EHRA has put out in their code of conduct is kind of interesting. It talks about wanting to migrate or keep the barriers, as I interpret it and this is a loose interpretation, that they want to lower the barriers to migration, but then they mention in the explanation underneath, that it's going to be by that CCDA, and so that reminds me more of transportability. And so I think just clarifying for the community what that means so that the single practitioner can make as wise a decision as the eligible hospital.

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

Okay, so –

M

– good idea to work with the EHRA.

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

Let's see, I think Mickey said there are a number of vendors on the workgroup, I mean Judy's proposal is to reach out to the EHRA to get more input. So is it fair to do a bit more homework on this one and bring it back?

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

Sure, happy to.

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

Got considerable feedback. Okay. Well thanks a lot Micky, appreciate it.

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

No, thank you. It was an excellent discussion and really appreciate the feedback. So, thank you.

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

Okay. All right, I think...it's been a long day, I have to say. By the way, September is going to be face-to-face because of the amount of discussion we we're going to have, both the FDASIA and we promised that meaningful use would be engaging. I'll have to ask Farzad about extending our time. Okay, so now we're going to open for public comment please.

Public Comment

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

Operator, can we please open the lines? If there's anyone in the room who would like to make a public comment, please come up to the table. As a reminder, there's only 3 minutes for public comments.

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

And if you'd like to make a public comment and your listing via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via telephone, you may press *1 at this time to be entered into the queue. We do have one comment online. Please go ahead, state your name.

David Tao – Technical Advisor – ICSA Labs

This is David Tao, Technical Advisor to ICSA labs. Thanks for an excellent meeting and the opportunity. I'd like to compliment the stats on Meaningful Use by providing hospitals with some information on the stats of product availability from vendors for MU 2. As of today there are very few vendors certified for 2014 edition, there's only 136 products, only 21 complete EHRs, only 14 complete vendors. And in contrast, 2011 had over 4000 products of which 2000 were complete EHRs. So, thus far we're only at about 1% of the number of product offerings for complete EHRs compared to 2011. Obviously, there's some time to go, but it's already late in the game, so it indicates that there's difficulty that vendors are having meeting the 2014 requirements in time for the start of Stage 2. And I worry that some significant percentage of hospitals and providers will have products that just are not available to be used for attestation at least in most of 2014.

So I suggest there be real careful analysis of these vendor type stats and their trends, and I suggest that the Policy Committee consult with the Accredited Certification Bodies to understand what their experience has been with product certifications, and that could also inform decisions about MU 3 requirements. Thank you.

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

We have no more public comments. Thank you.

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

Thank you very much. Thank you for sticking it out, thanks for the robust discussion. We're going to take all this input back and bring it back to you in revised form. And Judy, we sort of have about in every – about half of them would be virtual is our plan, not necessarily every other. So, we'll try to get you out an advanced notice when – with how the next meeting's going to be, but September will be face-to-face. Thank you. Thanks everyone.

Public Comment Submitted During the Meeting

1. Based on today's CHPL statistics, there are very few certified vendors and products for 2014 Edition: CHPL lists only 136 products (Amb + IP), only 21 "complete" EHRs; and only 14 "complete" EHR vendors (8 amb + 6 IP). In contrast, 2011 edition has [3342 amb+1089 IP=] 4431 products, of which 2023 [1702 Amb+321 IP] are complete EHRs. So 2014 thus far has only about 3% of the # of products, and only 1% of the # of complete EHRs, compared to 2011. This indicates the difficulty vendors have meeting the 2014 bar before the start of Stage 2. What percentage of hospitals and providers, using their current vendors, will be unable to attest 2014? Careful analysis should be given to these stats and their trends. I suggest working w. the ACBs to understand the pipeline for additional product certifications for 2014. These should inform decisions about requirements for MU3.