

**HIT Policy Committee
Final Transcript
August 3, 2011**

Presentation

Operator

Ms. Sparrow, all lines are bridged.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, operator. Good morning, everybody, and welcome to the 26th meeting of the HIT Policy Committee. Just a reminder, this is a Federal Advisory Committee so there will be opportunity at the end of the meeting for the public to make comment, and a transcript will be available on the ONC Website. And a further reminder to members in the room and on the telephone to please identify yourselves when speaking. Let's go around the table and introduce ourselves, starting on my right with Gayle Harrell.

Gayle Harrell – Florida – House of Representatives

Gayle Harrell, state representative from Florida.

Marc Probst – Intermountain Healthcare – CIO

Marc Probst with Intermountain Healthcare.

Judy Faulkner – Epic Systems – Founder

Judy Faulkner with Epic.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Paul Tang, Palo Alto Medical Foundation.

Deven McGraw – Center for Democracy & Technology – Director

Deven McGraw, Center for Democracy & Technology.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Larry Wolf, Kindred Healthcare.

Paul Egerman – Software Entrepreneur

Paul Egerman, Software Entrepreneur.

Christine Bechtel – National Partnership for Women & Families – VP

Christine Bechtel, National Partnership for Women & Families.

Michael Weiner – Military Health

Michael Weiner, Military Health.

Judy Sparrow – Office of the National Coordinator – Executive Director

And on the phone we have Art Davidson.

Art Davidson – Public Health Informatics at Denver Public Health – Director

Yes, here I am. Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning. Connie Delaney?

Connie Delaney – University of Minnesota School of Nursing – Dean

Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, Connie. Linda Fischetti?

Linda Fischetti – VHA – Chief Health Informatics Officer

Good morning, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

And David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO

Yes, good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director

Anybody else on the telephone? All right, with that I'll turn it over to Dr. Tang.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Good, thank you. Thanks, everyone for joining us for our August meeting. In honor of the season we're having an abbreviated agenda. First of all, I want to let you know that Farzad is going to be joining us from Minnesota, so he'll be joining us over the phone around noon-ish.

The agenda items we have for today include Privacy and Security Tiger Team making some recommendations having to do with view and download. This relates to the Meaningful Use Stage 2 recommendations. David Lansky and Tom Tsang are going to be talking to us about the letter they prepared for the national coordinator relating to the quality measures output. We had previously approved their framework and they have a more detailed letter that they'd like us to approve for today to pass on to ONC. We have an update from CMS, which is going to be a regular occurrence in terms of keeping us informed about how the meaningful use attestation is going. And then I'll give an update on some of the plans for the Meaningful Use Workgroup as we move towards Stage 3 and beyond. Farzad will join us at around noon with an update from Minnesota, and then we'll hear from ONC about the Beacon program with Jodi and Craig Brammer. Then we'll conclude, as always, with our public comments.

Any other adjustments to the agenda? I'd like to entertain a motion to approve the minutes from the last meeting. And second?

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Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay. All in favor?

All

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any opposed? Any abstentions? Okay, thank you. We'll begin with the recommendations from the Privacy and Security Tiger Team, so Deven and Paul are going to make their way down this long corridor.

Deven McGraw – Center for Democracy & Technology – Director

Wow, that's a pregnant pause. Thank you all very much, and we look forward to presenting these recommendations on transparency with respect to the view and download functionality today. As always, we always start with a slide that recognizes the members of the Tiger Team because they're a hard working bunch and we thank them very much for all of the work that they've been doing on this and many other issues that have come before us, so recognizing them.

So what the scope of this discussion, again, as Dr. Tang pointed out, we have already as a committee sent to CMS a recommendation that in Stage 2 of meaningful use both hospitals and eligible professionals provide a view and download functionality for patients, and this is actually, here on the slide, an accurate summary of what was in the recommendations on Meaningful Use Stage 2 that were adopted by the Policy Committee. It's been pointed out to us that the letter, we always try to do, again, a draft transmittal letter and some slides, and the letter actually isn't accurate; the slide is accurate. We will make the adjustments to the transmittal letter when we finalize it. So again this is the actual measure, the 10% of patients and families on the hospital side view and have the ability to download information from the record. As well, eligible professionals it's a similar figure, 10% view and have the ability to download. It's not quite right in the transmittal letter. We will fix it.

Now, remember also that that letter had a notation that the Privacy and Security committee, the Tiger Team, would consider whether a privacy and security warning should be part of standards and certification criteria. Warning being letting patients know that they're downloading the information and it's moving from being in the possession of the institution or the provider and into their own hands, which might involve some risk. So what we did was take that on, because you asked us to, and we had actually reserved it as something that we had wanted to do in the future and we moved it up on the agenda and essentially what we have been talking about over the last month, is the transparency implications of giving patients this view and download capability. And the rationale for really addressing this is pretty simple and common sense, and that is, it really is a basic, fair information practice to help people to understand what they are agreeing to and doing. And then consequently downloading information in an Internet age opens people up potentially to new privacy and security risks, so we don't necessarily want to leave patients in the dark about what's going on when they use this functionality.

And thankfully, we actually at the Tiger Team did not have to start from scratch in terms of thinking through some policy recommendations. The Markle Foundation had done some work with both representatives of the VA as well as Medicare and some other stakeholders and they run a multi- stakeholder collaborative called "Connecting for Health" about a little more than a year ago launched this Blue Button initiative, which is about view and download functionality in provider based EHRs. They did a policy brief which sets forth some recommended policies about how you would make this happen, and they addressed the transparency aspect of this in order to help individuals make some informed choices again.

And the areas that they hit in their policy brief were to provide a very clear and concise, really short explanation of the download function and its most fundamental implications for the individual, but then provide links that, for patients who want to get more information about what those risks might be, what is this download functionality anyway, that there be an ability to click on those so that you don't end up with a notice to patients that's pages long that you want them to scroll through before they can download data. You do something simple, but give them the ability to access additional information if they want it, and

then get independent confirmation that in fact, if they want to download data that, yes, we in fact do want to download this information. And so you can see an example of the notice, the actual worded notice that's in their policy brief, very, very short, very concise, and not scary, not warning with a big poison sign on it or something, "Don't go there," but realistically here's what you're about to do. Are you sure that this is what you want to do?

Similarly, on the My Health Vet Blue Button initiative follows a similar script, but it's not exactly the same. But they hit the same areas, and the initial explanation is very concise and short, but they have links to more security tips, which we have another slide that expresses those in some more detail, they make the patient aware that when they download the data it's their responsibility to protect it. (Audio interruption.)

Interesting, I'm not sure what just happened. This is the slide that has some more detail on the security tips that veterans using My Healthy Vet, which is a view and download functionality, can click on to receive, again, it's not scary language, but it's very matter of fact and very informative. Then similarly, with the Medicare Blue Button initiative for Medicare enrollees, again, a similar set of very simple tips, clearly worded, not terribly complicated, links to additional information, following sort of a similar pattern, slightly different wording in each case.

So we considered whether we would want to recommend that the certification criteria for EHRs require a notice of this type, and our concern with sending this through the certification process would be that we would end up really with over specification and inflexibility with respect to what would actually be in that notice. We thought it was really important to allow providers and hospitals to be able to work with vendors to tailor notices to their own patients. There are certainly models that they have that they could use with the VA, with CMS, with the Markle Foundation policy ..., they're not without resources that could help them in this regard but that generally if we were going to send this through the certification process we might end up with a one-size-fits-all, very regimented solution. That's what they do best. When we need an interoperable solution where everybody's doing the same thing, we send it through Standards.

Our members on the Standards Committee who are part of the Tiger Team probably pushed back on this the hardest. You don't want to send this through Standards. You will end up with a result that you might not necessarily like. We want to leave some room for flexibility here. So, instead we opted to provide some best practice guidance for providers who are participating in the Meaningful Use program and then of course the vendors and the software developers who are serving those providers, and Paul is going to go through those best practice recommendations that we were asking for the Policy Committee to endorse today.

Paul Egerman – Software Entrepreneur

Thank you very much, Deven. I'm going to take you through, we actually have four recommendations. These all relate to best practices. As Deven said, for reasons that she said, we did not want it to be inflexible and we wanted providers to be able to customize based upon their own populations. You have these two concepts, view and download. View means view; see what's on the screen. Download means you can get a stream of data where it's actually somehow transferred from the provider's system directly to the patient, so that's what a download is.

People talk about view and download, and we're actually talking about it in the opposite order, we're first talking about the download function. In the download function basically we say that providers as a best practice, as guidance, should offer patients clear and simple guidance regarding the use of the view and download functionality in Stage 2, and then we have these three bullet points, which actually follow very closely the recommendations from the Markle Foundation. So that once a patient or a patient representative has indicated a desire to download data the three bullet points are, number one is to

remind patients that they will be in control of their own medical information once they've downloaded it and that they should take steps to protect their own information. The second includes some sort of a link where they can find out more information. And the third step is to obtain independent confirmation that the patient wants to complete the download of transaction or transactions. Independent confirmation means one of these questions like "Do you want to proceed?" And some of them are "Yes or no," or "Please download," or however you want to write it. When it says download transaction or transactions what we were trying to suggest there is depending on the practice and the environment this could be asked every time a patient downloads data, but it might be done also just one time for the patient. It's really up to, again, the provider to decide those kinds of issues. Again, this is really an effort to make it flexible and not just another thing where you see it and you click "I agree" without reading it and it becomes just a nuisance. That's the concept on downloads.

The next recommendation, number two, relates to the concept of the view. Now, on the view you should read what we say, it says providers should also consider whether to offer clear and simple guidance at the time of viewing the record. This seems a little bit more timid, where the recommendation is that you have to think about it or consider it, and the ... is active and when we came to the view process the members of the team were somewhat divided. There were some members who felt it would really be important to give some warnings to people saying things like well, gee, you've got to be careful to review this at a public terminal, like at an airport or at a hotel or something. While others said I think people already know that stuff, and so the issue there was the suggestion that providers should consider that and they probably, as they consider it they consider their patient population as to whether or not they think that that's necessary. That reflects the views of the Tiger Team.

The third issue is a technical issue. It's a little complicated to explain unless you already understand what it means, but basically in many of these kinds of systems browsers are used to view data, and browsers do something that's sometimes called storing a local cache. In other words, when you do a view, what a browser will frequently do is keep a local copy of the data on the terminal, and it's done for efficiency reasons to make things faster if you flip back and forth between several different screens. So good data processing practice for this kind of a view would be to have, once the event is terminated, in other words once you have finished the viewing process, would be to clean up all those cache copies, to not leave them around.

Again, we put this simply as a best practice. It's sort of suggested in two ways. One is that providers should request that their vendors have this clean up of the local cache function and that ONC should provide that also as a best practice for software developers to do that to clean up the local caches. It's a little bit of a tricky recommendation because not all technology views local caches and there are lots of different modalities where this data might be viewed, for example, on tablet computers or on iPhones. So sometimes this recommendation may not necessarily apply, but where it does apply we thought that this was an important recommendation to make.

And then the fourth recommendation is that providers can review ..., this is really a recommendation to ONC, to suggest that besides making recommendations that there ought to be some specific examples given to providers as to how to do this. So we're suggesting that what the Markle Foundation wrote is a great example and certainly what the My HealthVet Blue Button and Medicare Blue Button has done are also great examples, so that as part of putting forward these best practices we wanted to make sure that there were examples of what to do also if people wanted to copy them.

Those are recommendations. Did you have anything you wanted to add, Deven?

Deven McGraw – Center for Democracy & Technology – Director

We didn't take that issue on because in essence it had already been described through both the meaningful use recommendations and then some direction given to the standards, and they have, as Paul noted, some work to do on that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Marc?

Marc Probst – Intermountain Healthcare – CIO

Thank you. This is really great. Thank you. I really like the approach with best practice guidance. I agree with the concept of fairness that you outlined at the beginning. I really have a question, and maybe a fairly naïve question, but within HIPAA can we actually shift liability or responsibility of this information to the user that's downloading it? Or, is this just a warning that they're still, if you had the right language would you shift the liability and if you don't have the right language, you really haven't shifted that liability of the patient. Does that question make sense?

Deven McGraw – Center for Democracy & Technology – Director

Yes, it does, and whether you do the language or you don't do the language it has no bearing on who has the legal risk for the data. But the fact is that if it's in the possession of the institution then it's the institution's obligation to protect that data under HIPAA. But if the patient knowingly takes a copy of that information, then the patient is actually responsible for it. Now, is there some sort of time in the middle where it's unclear? Probably. But we weren't trying to address that and I do not think, and I'm just putting my lawyer hat on here, that the presence or absence of shifting responsibility language in a notice is terribly, what we call dispositive. It doesn't have a bearing on that. If there's a problem that occurs, like an interception in the transmission, whose fault it is, is unfortunately going to be some sort of facts and circumstances test involving computer forensics and where the error occurred. But patients are covered by HIPAA, so once they have the data in their hands, what they do with it, the hospital, the physician is not responsible for.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

But would there be a best practice, and maybe it's in the examples that we have, you use the term "knowingly," and again, I'm not trying to be critical at all I'm just trying to –

Deven McGraw – Center for Democracy & Technology – Director

I think that the knowing part is actually one of the reasons to do the independent confirmation of the download. Are you really sure you want to do this? Like when I download music, are you sure you want to charge your credit card for this song? Yes. It's an affirmative step that I think makes sense both in terms of making sure the patients are aware of what they're doing, but also quite frankly from a liability standpoint. You knew what you were doing when you pressed the button.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, thanks. Christine? Oh, sorry, Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I guess I have an invisible card this morning. I support this whole approach of putting forth some recommendations rather than passing this on for specific certification criteria, and I thank you for the references to the Markle Foundation material, because it's quite a wonderful report. It raised in my mind a question that I don't see specifically addressed here, so I'd like to know if the committee addressed this or your take on whether it's important to address. The Markle policy brief seems to make a big deal about distinguishing between an individual asking for information and some kind of bot or automated process requesting information and they have several suggestions around how to distinguish those things, but

there's no reference to that here, and given that the way a consumer might choose to get their information would be through some kind of PHR or some kind of tool kit that would help them interpret the information, it seems like that actually might be useful. Also, in terms of protecting the information more broadly, a reminder to providers that if you're putting up a system that's easily hacked by people pretending to be patients, maybe it's worth thinking about some best practice to minimize that likelihood.

Deven McGraw – Center for Democracy & Technology – Director

We didn't specifically address that piece, unless Paul's going to tell me I misspoke an enormous part of the Tiger Team conversation.

Paul Eggerman – Software Entrepreneur

My view of that is we didn't really specifically address this because the thought process, perhaps influenced by the word "view" and "view and download," was that human interaction would be there, however, if you look at the first recommendation where we talk about downloading a transaction or a series of transactions, the environment that I think you're talking about is an environment where a consumer might set something up where they say I somehow set up an arrangement where a PHR system can automatically retrieve information from my provider's EHR, and then once it's automatic I don't have to do anything. It just happens. Basically the way our recommendations are written is this recommendation would apply to that. In other words, it would just be that you would provide some sort of notification to the patient before they initiate that series of transactions. So presumably they have to enter something on the system to authorize it so you still get the series. I think it works in the environment that you described, but it wasn't really specifically addressed by the Tiger Team.

Deven McGraw – Center for Democracy & Technology – Director

Paul is right, and also pointing out that we were addressing the circumstance of the view and download functionality that is going to be tracked and required to be reported on for meaningful use and which will be transparency associated with that. But we did accommodate the possibility of a multi-transaction arrangement being set up between the patient and the provider. But, again, I agree with Paul. I don't think the transparency issues are necessarily any different, although there are probably other functionality issues such as the problem of making sure that the access isn't compromised and you don't have the problem of some individual, I mean, I participated in helping to craft some of those Markle recommendations and they had a recommendation with respect to the use of CAPTCHA or some other mechanisms to make sure that it's really an authorized transaction that's taking place. I think there are a host of other issues that might arise for which it's a little out of the scope of what we were tackling in this round.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Christine?

Christine Bechtel – National Partnership for Women & Families – VP

I agree with everybody. A great set of recommendations, very clear and straightforward. I have a question and potentially a recommendation or a suggestion about the second recommendation, which is about considering whether to offer clear and simple guidance at the time of viewing a record. I'm wondering why we would not just ask them to offer that guidance instead of to consider it in the recommendation. The reason that I'm a little bit worried about it is because really of the last piece, which is failing to properly log out. So that definitely requires, I think, some action on behalf of the patient to do something and not just walk away from your computer or whatever the case may be. I can see a number

of situations where this kind of an alert would be very helpful and I can see where it would be very harmful to not have it, so I'm not sure why we would want to ask them to think about recommending it as opposed to we're saying you really should provide patients this function even on view.

Paul Eggerman – Software Entrepreneur

It's a great point. The reason that it came out this way was there was not a consensus on the Tiger Team that this was important to do. Some people thought it was important, exactly as you said. Other people thought it just wasn't that important, that users would already know these things and that you were just going to annoy them by telling them stuff over and over again that they already knew. So there was not a consensus on that, so that's why we wrote it that way. The Policy Committee can change that. If this group wants to take out the words "consider whether to", take out those three words, that's up to you. I'm just saying this is why we came to this conclusion. Judy, I wonder, since you were one of the people who spoke, do you want to comment on this?

Judy Faulkner – Epic Systems – Founder

I think when you said in the beginning we have to watch that balance between being cautious and reasonable and being overly prescriptive, this could go into the overly prescriptive area if you're not aware of who your own patients are and what help they might need. My thinking here was, first of all, people use e-mail, they get sensitive e-mails, there's not a sign on the e-mail that says be careful when you're viewing this that other people don't see what you're viewing. People use Web sites at all different times, at work, etc., and there's nothing that says on the Web sites don't watch this Web site if anybody else is watching who you might not want to see. I have the sense that in general between e-mail and Web sites people know, if I'm in a public place and I don't want people to see this, I know not to do this.

The other thing that I was paying attention to is paper, so I started looking at the various things I got from my various physician groups and not all of them said, "Don't read this in public." So I get these paper things and they don't have that warning on them, and my greatest concern I think with this is we're going into the future, and as we go into the future this is going to become so commonplace that it's going to be feeling like it's overly prescriptive as we go down the future because everybody's going to know, yes, I shouldn't be reading this stuff if it's private because I know not to. That part I think is fine. Now, the notice to log off I think that that's a different thing. I think there could be, "Be sure to log off to protect your information" notes about that, but not something in the beginning that has to come up in the very beginning to me, but just as I'm in it, it could always have something that's ... there.

W

Judy, these recommendations don't deal with user interface design. They deal with, at some point in the process, however you choose to do it, whether it's burdensome or not you need to say something. So I'm worried, I think, first of all, and my reaction to your comments is I understand what you're saying and I definitely don't think we should be overly prescriptive. On the other hand, all patients are not alike. All patients are not online, they are not using the Internet, and they have different experiences, so most Web sites absolutely have a privacy policy posted. Almost every e-mail I'm getting these days has a humongous paragraph at the bottom with the legal jargon that talks about everything in here is confidential and blah, blah, blah, so I don't think it is a safe assumption to assume that everybody knows. And I think given that this is health information, it probably warrants being extra cautious. Whether or not you focus only on failing to log out or the risk of being in the library and having somebody stand over your shoulder, I just don't think it hurts to give people one sentence like that, that warns them about that. How that sentence is designed, where it comes up in the process I think is totally up to the design, and that's not what we're dealing with here. I think what I am saying in fact now is that I'd like to see this sentence say "Providers should offer clear and simple guidance," and then just leave the sub-bullet as is underneath it.

Deven McGraw – Center for Democracy & Technology – Director

The transmittal letter actually provides a level of detail that we left off of the slide. I'm not sure why we did that, but we did, probably to keep them shorter. And that is, that providers should consider whether their particular patient population would benefit from having clear and simple guidance offered at the time of viewing a record and such guidance, for example, could alert patients to the potential risks of viewing information on a public computer, viewing sensitive information on a screen that might be visible to others, such as in a workplace environment, or failing to properly log out after viewing. So it was about tailoring to the specific population. If you're a geriatrician and your patients are largely elderly and most of them don't have a lot of experience with using the Internet or even e-mail, that that might be a step that you might want to take.

The other thing that I'll point out is that the Medicare example, the VA example and the Markle policy brief all focus on the download risks. Don't spend a lot of time talking about the risks of view, because, quite frankly, they're much less from a privacy standpoint. Having said that, it seems silly to argue about this, in many respects, it's best practice guidance, but I do think because of the difference of the risk of view and download that, again, we don't have actually a lot of guidance in Markle Health or CMS about how you would present a screen for people that would provide some sort of warning about view. I happen to also be one of the people who thought it was overkill absent a decision that you were dealing with a patient population that probably was not familiar.

W

So again, I'll just say, and again we can go vote or whatever, but I think it doesn't necessarily have to be a separate screen. I think it's all in how you design it. You can simply put it underneath the log out button. You can put something on the page where the actual information sits. But again there is no one patient population, so even in a geriatric patient population you have caregivers who are going to be pretty sophisticated, but does every patient have a caregiver; maybe not, maybe so, I don't know. There just is no one patient population. I read that before, but I just didn't love the language of a particular patient population because there's simply too much diversity and experience. Then again, failing to log out actually requires an action that even I might not have thought of, so if there's no harm, no foul, I'd like to see it be a little bit stronger knowing, and maybe we can put some information that says in some sort of easy to understand way so it's not overly burdensome, but I just can't see how it could possibly be overly burdensome to have one sentence somewhere on the document about this.

Judy Faulkner – Epic Systems – Founder

I do think that it's one sentence on there, say it was on one of the beginning screens, so there it is, it may be just like those sentences you said at the end of the e-mail, which there is just a pain. Who reads them.

W

Right, but we're not dealing with usability. We don't have recommendations on usability. If we want to develop one, then that's fine. But to me that goes to usability more than what our responsibility is. We had a huge discussion that in fact I think you started, Judy, about when we first began the idea of view, download and patient online access, well, what are they going to do with it and is it responsible. I don't see how this is anything but responsible to just cover the bases.

Judy Faulkner – Epic Systems – Founder

Yes, the other thing I do want to say, though, is how many years is this going to last? How far into the future will this go? Because if we're saying this is for a few years into the future, I feel one way about it. If we're saying this is ten and twenty years into the future, I feel a different way about it.

W

It's only a best practice, right, so if the best practices evolve, they evolve.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Let me go to Gayle, please.

Gayle Harrell – Florida – House of Representatives

I just wanted to put my two cents in. I was on Christine's side of the argument in the Tiger Team discussion, and I think that in a situation when you're dealing with a diversity of population you really have to err on the side of caution. I would prefer us err on the side of caution and make sure that we inform people there's no harm done, but if you don't do it there is potential harm done. I think it's easier and better for whatever patient population and a physician or a provider may not know every single patient out there and what their capabilities are. I wouldn't doubt that they do, therefore, you want to make sure that you have covered the eventuality in case people don't know, especially the log out function. Even the most computer savvy person out there forgets to log out frequently. And you can leave a lot of information sitting there on a computer in a public place or even in your office, or a private place or whatever, and people can view it. So let's err on the side of caution.

Charles Kennedy – WellPoint – VP for Health IT

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Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Yes, please.

Charles Kennedy – WellPoint – VP for Health IT

Hi, it's Charles Kennedy. The question I have as this was presented is, as we look out at the market and see all of the various new ways that are evolving for patients to download their personal health data, be it from a health plan, WellPoint, Aetna, Cigna, Humana, various Blues, etc., allow you to have a Blue Button like functionality, versus downloading it from an electronic medical record, and again what you'll get as an output there will vary depending on the nature of the deployment, whether ... small group deployment versus larger integrated delivery systems. I'm wondering if as a part of this we need to provide any guidance to the population about the variability of the completeness of the record and the accuracy of the record when they begin to download these records from a variety of sources. I think about our e-Patient Dave... before some time ago.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

That's a very interesting topic, and it's one I think many people would not know, and e-Patient Dave was one of the ones who first raised the visibility through the *Boston Globe* article. Did the workgroup discuss that?

Deven McGraw – Center for Democracy & Technology – Director

No, we didn't. We were narrowly asked a question of whether there ought to be transparency with respect to the view and download functionality that's going to be offered by eligible providers and eligible institutions as part of the meaningful use program, and that's what we confined our recommendations to. It's a good point that Charles raises, but in many respects it was beyond the scope of what we were asked to tackle.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

I think that's fair that it's off the scope of privacy and security, but it raises the bigger question of education, which we've always talked about. There's almost a primer on dealing with electronic information that's distributed, and we'll go back and work with ONC and see if we can come up with a way

to dive into this, unless, Jodi, do you know if there's work going on in this area, just the public education about electronic health information?

Jodi Daniel – ONC – Director Office of Policy & Research

I don't think anything specific enough. We do have a big public education consumer campaign that we're getting ready to launch. If there were some recommendations about specific areas that we could provide some guidance on, I think that would be useful. But I don't know that we have anything that would be directly on point.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Thanks.

W

Your campaign will include a Web site that will have a consumer structure to it, so that might be a good place.

Jodi Daniel – ONC – Director Office of Policy & Research

I think there is a great opportunity on that Web site to have a set of tools for consumers, guidance, best practices, any of that kind of stuff. If there are specific things that would be helpful for us to provide tools or guidance or best practices on, I think there would be an opportunity to try and develop some material. I don't know that we have anything specifically that would address it at this point, but, yes, opportunity to do so.

M

Paul, I would just say that I know this is pushing the bounds of what the workgroup was asked to do, but I do think it is quite a bit beyond just general public education. There's going to be variability on the download by download or source by source basis, and if this isn't the group I think we need to have some policy thinking around making sure that the public understands what they are getting and what they potentially are not getting through some of these channels.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

It's so important. I'll just point out one thing from the e-Patient Dave experience, so he had some diagnoses that weren't true. Some of those diagnoses could have prevented life saving drugs from being administered, so in peptic ulcer disease you would not give thrombolytics. That can save somebody from a stroke or heart attack. It's that kind of education. It's beyond the well, what happens with your information. It is Charles' point, which is sometimes if it's inaccurate it can come back and cause some deleterious effects on your health. It seems like a good topic for us to figure out how to deal with, but I think we owe it to the public on how to deal with the information, and not all information is alike. Good point. Thanks for raising that, Charles.

Art Davidson – Public Health Informatics at Denver Public Health – Director

Paul, another question.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Yes, Art?

Art Davidson – Public Health Informatics at Denver Public Health – Director

Thank you. Thanks, Deven and Paul for the presentation. Speaking about best practices, I wanted to know if the VA and CMS had a best practice about should you be keeping an audit trail of the

confirmation, or in those institutions do they have a time out, getting back to Christine's point, is there a time out so that if someone does not log out that we recommend that there be a time out?

Deven McGraw – Center for Democracy & Technology – Director

That's an interesting question. I'm thinking back, we did a series of recommendations on security related to view and download, and I don't have them at my fingertips and I'm trying to think if we addressed the issue. We certainly did make a specific recommendation that the functionality for view and download have a way to automatically log off if someone was trying to get in using multiple password attempts, like somebody trying to hack in essentially, either as an individual or a machine hack. So we did have some specific recommendations with respect to functionality that would shut it off in the event that that was occurring. But I don't think we said anything specific about having an auto log off function if the view and download function is just left open for some period of time. I think that's a pretty common security practice, but we did not specifically address it in the previous recommendations.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I wonder, in listening to this, which seems to be one of the hot points for the recommendation, I wonder if it's three classes of risk that are being addressed. One are some of the "obvious" Judy mentioned well, if you're reading a piece of paper even you would be aware of the things around you. You certainly get that warning at the ATM about covering your password. The other are things that are not so obvious, meaning it does take some knowledge about computers to understand that some people actually program screen scrapers, or there are ways that what you type, it's not just people around you, but can be stored in other places and used. The third are things in this log out category where I think HIPAA security even requires automatic log out, certainly on the provider side, it probably doesn't go on to the patient side, but you could put this actually with your recommendation three, where you request that software developers clear the cache. It seems like this is almost that important, everyone mentioned it, that they should also have an automatic log out, the timing of which is configured by the organization. But it seems like it's that important and that clear from a security point of view.

The one friendly amendment to this could be to include auto log out with your recommendation three in terms of what the developer provides. Would that address it, Christine and Gayle?

Christine Bechtel – National Partnership for Women & Families – VP

It addresses a significant part of it. Again, though, even if we look only at the first part of the sub-bullet I just don't see the harm in having that sentence in there, and either way, even if this recommendation goes forward, I really do object to considering their particular patient population. And what I'm struggling with is knowing that patients are not all the same even in a defined "population" but also knowing that we've spent a lot of time as a consumer group trying to figure out how to enable providers to have more time to talk to their patients and get to know them, and they don't. We hear from patients over and over again they are tired of being treated like a collection of body parts and diseases, so I don't really feel good about thinking that providers actually know all pieces of their population and oh, by the way, they're not all the same. Even if this goes forward without my suggestion, on the first part of this sentence in the letter I'd really like to remove the "thinking about their particular patient population."

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

What you're asking for, Christine, is that we delete the "consider the patient population."

Christine Bechtel – National Partnership for Women & Families – VP

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I just want to find out, are you okay with the concept from the previous slide of transaction or transactions, so a provider might choose to only warn a patient once the first time they do a view, that they don't necessarily have to do this on every view.

Christine Bechtel – National Partnership for Women & Families – VP

Again, I think it gets to design. So, yes, I'm okay with that. I just think that the best practice is you've got to offer clear and simple guidance even about view and how you do it and how many times and where it shows up on the screen isn't really what we should be trying to manage as a policy. That's a technology, that's a design issue. So I'm okay with that, but I think we just need to say as a best practice you offer some guidance even on view.

Judy Faulkner – Epic Systems – Founder

I think one of the interesting things is, what's the downside? And that gets into software design. If you don't design it well people won't read what's there and you haven't gotten the salient points to them because you've cluttered it up with stuff that they may think is obvious. And for many people it's going to be the potential risk of viewing sensitive information in a public place is going to be obvious, I think to a large number of people, therefore, they're going to stop reading. So there are several things about it. One, you don't want to create systems that people won't read, and two, there's a limited amount of screen and you have to use it well for the folks. So how do we do it to get both? I think the idea of maybe do it once is a good idea. I think the idea of log out should be timed and happen automatically is a good idea. Maybe the advice just should be for log out. But there are certain things on there that if you start reading it, and if I started reading something, of course I've experienced this, but I think a lot of people would read view sensitive information in a public place and they'd think oh, I'm not going to read the rest of the sentence and then go on. So how do we write stuff, we're getting into really software design isn't really something irrelevant. It is very relevant. Why do something that people aren't going to use and take up screen space and time for that.

Christine Bechtel – National Partnership for Women & Families – VP

I agree, Judy, and I'm simply saying I'm not saying it's not relevant. I'm simply saying that we're not covering that here. Now perhaps what you're suggesting is that we would cover that here and simply say alerts and warnings to patients should be designed in a way that vendors believe will be most impactful and useful for patients. But it's not something that's so horrendous they're going to skip over, they're not going to see it 10,000 times So one overarching recommendation around design I think would be fine here.

Judy Faulkner – Epic Systems – Founder

But if we just took off the beginning and said, providers have to offer this at the time of viewing a record, then we've done it, I think, design wise for people the wrong way. We will have –

Christine Bechtel – National Partnership for Women & Families – VP

There's no "have to" in here anywhere. There's no "have to."

Judy Faulkner – Epic Systems – Founder

No, I mean if we did it that way then we wouldn't be doing it –

W

Right.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And making it a best practice and making it a transaction or transactions, I think you create the situation where it can be done one time. It could also potentially be done at the time in which a patient signs up for a service, or as part of the package of how you sign up, and depending on the environment that can work out well, because some people will create, for security reasons, a situation where material is physically mailed to the patient as far as signing up. And so as far as signing up, here are the things you need to know and –

Judy Faulkner – Epic Systems – Founder

Then we would have to change that sentence that says "offer clear and simple guidance at the time of viewing a record," because that, to me, implies every time they view a record, and maybe I'm misreading it, but that's –

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well yeah, that's suggesting it's not just at the time, it's prior to view or a series of views of the record. So that would mean either at the time. It could be the time of application, it could be the first time you do a view, or it could be every time. It depends on the environment and what the provider decides to do.

Marc Probst – Intermountain Healthcare – CIO

This is Marc Probst. I don't know if the wording's perfect the way it is. I do admit that when I read it, "whether their particular patient population," it actually got me thinking about the differing populations as we offer a viewing for our patients. So I like the concept that different people may need a different level of explanation, and I agree with you, Christine, as you were going through it, I think it's just common sense to put that, you should log off, but then I also agree with the design side. I like the wording because it made me think about the different populations and the need that they have and as a best practice, not necessarily those specific words, but the concept of looking at particular populations as useful.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I wonder if there's a way to address this that will ... all these concerns. One way to do it is to keep in all of their words, so say, providers need to consider the populations when they make these decisions and that the best practice would be that prior to a view or series of views of the record, that the patient is notified of the importance of viewing the data in a private setting and logging off so that you try to accomplish both concepts.

M

I can see practically where it comes up on some of these options where it says don't show me this again. I read it. I said don't show it to me again, gone, a done deal. But I got that warning through and then I made the choice of I don't want to see that again.

Christine Bechtel – National Partnership for Women & Families – VP

....

M

Yes.

Christine Bechtel – National Partnership for Women & Families – VP

There's a nuance between what I heard you say, which is I believe everybody needs to know at a basic level. The question is how much they need to know and what the mechanism is. That is something that you should consider all the dimensions of your patient population, but there is a fundamental, you still need to know, and I don't think as a best practice. The best practice is everybody knows. How you tell them and how much you tell them, it does need to be patient centered, not overly burdensome, as Judy was pointing out. I agree with that.

Gayle Harrell – Florida – House of Representatives

I think the Tiger Team maybe, or perhaps just Paul and Deven can go back, having heard this conversation, and wordsmith it. Trying to wordsmith something in a committee like this is an extremely difficult. That's the definition of a horse made by a committee becomes a camel. It –

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, it's a good comment, Gayle –

Gayle Harrell – Florida – House of Representatives

But the wordsmithing certainly can be done. I think the consensus seems to be that there needs to be a little bit more than just, it should also consider –

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Instead of just wordsmithing, I'd like to make sure that we have direction from the committee as to what we're supposed to do. This discussion does show that the Tiger Team had wisdom and did not recommend specific wording because we would never have gotten that through that entire process. But the concept I have is that through all of this providers do have to consider the population and the sense I'm getting from Christine is that there needs to be some information about viewing that informs the patient about things like logging off and accessing in a public environment, but that could be done in advance of the first view or it could be done with each view. There are a number of different ways that that could be done, and that these would all be done as best practices, so it's not like it's required.

Linda Fischetti – VHA – Chief Health Informatics Officer

This is Linda Fischetti.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Hi, Linda. Go ahead.

Linda Fischetti – VHA – Chief Health Informatics Officer

Real quick, this has been a joy and almost like déjà vu to hear this conversation. These are very much the conversations that we had internally at the time that we were launching Blue Button with our colleagues from the DoD and CMS, and, yes, it does actively log off. We do have the ability to lock down the account if there are repeated unsuccessful attempts. It usually catches me because I'm bad at password management. But this has just been a great discussion and I really want to emphasize, as somebody who's already implemented it in this area, the value of this guidance for others who have not yet gone through the implementation, so thank you for your attention and diligence to this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, Linda. Let me give, Christine, a heads up of what I'd like to bring to the floor and then I'll go to Larry; two amendments, one having to do with log off and what we can do and the other is give you a chance to write a language in terms of guidance for. And we'll vote on that as well just so we have official guidance for the workgroup. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

We obviously have a user interface problem here. Back on recommendation number one, you actually addressed some of this, I think, because you talk about use of view and download.

Deven McGraw – Center for Democracy & Technology – Director

Yes, we do, although the problem with most of the text in number one is that even though it says you should provide guidance on view and download, it's mostly about the download, and specifically about the download, which is why you end up with a separate provision on access. But one way to address this is to have recommendation one just clearly say patients should be offered clear and simple guidance regarding the view and download functionality, period. Then with respect to download, here are the three points we suggest you address. With respect to access here are the points we think might need to be brought to people's attention, so that would be my friendly amendment to what we've done here, which is, again, not to make a distinction between "should consider" and "should," it all will say "should," but to have number one be clear and simple guidance because that is really important. The more you chunk into a notice, the less valuable it is. So it's got to be clear and simple with links to more information if people want it. Then we can say with respect to download here's what we suggest you address. With respect to access here are the issues that you should consider dealing with. And then the second piece, the second amendment would be to include the auto log off functionality as a best guidance for vendors.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Judy?

Judy Faulkner – Epic Systems – Founder

I loved Marc's comment that the individual then can select not to see that information again. I think that's one of the –

Deven McGraw – Center for Democracy & Technology – Director

We can add that as something that should be considered.

Judy Faulkner – Epic Systems – Founder

..., yes.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Let me bring a couple of amendments forward to vote on. The one that it seems like there was universal consensus was to include auto log off as part of the recommendations, and it seems like the logical place to move that is to three, because that was also, you had a “should” request. Any further discussion on that point? All in favor of that amendment?

M

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Any opposed? Any abstentions? I’ll indicate that at least Deven voted for that as well.

Deven McGraw – Center for Democracy & Technology – Director

I did. I did. It’s a really good idea, yes.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay, so that’s point one. Christine, would you like to offer the second amendment.

Christine Bechtel – National Partnership for Women & Families – VP

I think what I heard Deven say, and I agree with it, is that, here’s how I would implement it, though, Deven, number two should not be a separate piece. It should be integrated up under number one, because number one deals with view and download functionality. And so it becomes a sub-bullet at the end that says something like “Alert patients to,” it just takes the bullet from the previous piece, “Alert patients to the potential risks of viewing information on a public computer.” And then what I’m hearing Judy say is that we might add another bullet that says something like, “Provide this guidance in ways that are clear, simple, and not overly burdensome for the patient.” Close?

Deven McGraw – Center for Democracy & Technology – Director

I don’t think you need to do that much wordsmithing to this to make those points. So one is, “Providers participating in the meaningful use program should offer patients clear and simple guidance regarding use of the view and download functionality in Stage 2,” period. Sub-part A, “With respect to downloads here is guidance specific to the download functionality which should be offered before a download occurs.” Then B would be “With respect to access here are the potential risks you should alert patients to,” and then it moves on from there. Is that what –

Christine Bechtel – National Partnership for Women & Families – VP

That’s fine.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay. Any further discussion on that point? Adam?

Adam

I hope this isn’t semantics on that, but if we’re going to be doing the view function I think caregivers should be considered to be included with patients, they’re going to be viewing that information with them.

Christine Bechtel – National Partnership for Women & Families – VP

Anybody who views the screen. It’s just on the screen, Adam, so if I’m allowing a caregiver to access my view and download account then they’ll see what I see.

W

Did you want a separate bullet on the ability to click once, I don't want to see this again?

W

Oh, okay.

W

Another best practice, I think we would put that in the vendor and software developer bucket, giving patients an ability to remove the notice, decline receiving the notice after the initial viewing.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It seems like a Any further discussion on that point? Michael?

Michael Weiner – Military Health

... regarding so we have no –

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

No, no, no, this is on this point before we vote and then we still have more. It was on this one or it's a new one.

Michael Weiner – Military Health

... on this topic?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Yes, please.

Michael Weiner – Military Health

So we have no cached copies, auto log offs. The other one I just want to make sure was addressed was the audit trail. The audit trail was part –

Deven McGraw – Center for Democracy & Technology – Director

We did it already, Mike –

Michael Weiner – Military Health

Okay.

Deven McGraw – Center for Democracy & Technology – Director

... in a previous recommendation. Yes, it's a really good point, but thankfully we had that already before ONC and the Standards Committee, yes.

W

That's for meaningful use as well, right?

M

Yes.

Deven McGraw – Center for Democracy & Technology – Director

We already had endorsed as a Policy Committee a set of recommendations on the meaningful use view and download functionality that would require an audit trail functionality to be able to be produced with respect to access to this account and be able to be shared with the patient.

M

Can I ask one question about this software point, because I did hear other people, do you really want to bake that into the best practice?

W

I'm afraid if you don't people will read it in such a way that every vendors going to have to make sure that every single time it's there, otherwise they're not meeting best practice. And that's how I think it should be baked in.

M

It doesn't diminish I think, the recommendation, and it just puts a little more clarity into it. But, yes, I think it is a software ..., for example. I asked the question because I wanted to look at Christine and see if she thought that was okay, and so I think that we'll answer some questions that might show up later.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Any further discussion on the points that were made? All in favor?

W

Aye.

M

Aye.

M

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Any opposed or abstained? Okay, so that's additional guidance for the workgroup.

Judy Faulkner – Epic Systems – Founder

... the amendment to the recommendation

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Do you think it's clear enough that the words will flow from this?

Deven McGraw – Center for Democracy & Technology – Director

I do. We can always distribute by e-mail if folks have a problem with it. Again, I think Gayle's point about wordsmithing by committee is a great one, but the concepts I think we've got agreement on and they're already very good.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

So the workgroup will update the words and then can distribute it and then we'll put a transmittal letter out. Good. The next topic, just a question on this one, on Larry's question to you all, Paul and Deven, sorry this is still on your letter, it's just a question, so the transparency having to do with essentially personal representatives and it had to do with the PHR kind of discussion that Larry raised, your comment was you would want transparency this whole, are you sure you want to do this, the re-confirmation? Now, when a third party's involved the provider may not have control over that transaction. Does that mean that, what's the implication of that for your recommendation?

Deven McGraw – Center for Democracy & Technology – Director

I don't understand what you mean.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

You have a recommendation, for example, here in terms of download and the following three points you'd like to recommend that the provider do. What if a personal representative, i.e. a PHR vendor, comes at the provider, does this transition to that third party these recommendations?

Deven McGraw – Center for Democracy & Technology – Director

In other words that the third party would make that part of what they do –

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

... and the provider no longer has control.

Deven McGraw – Center for Democracy & Technology – Director

No, it does not. Again, we are staying within the purview of who the Office of the National Coordinator advises in terms of their programmatic reach. So again, we were looking at a view and download functionality that is, if our recommendations are accepted by ONC and CMS, going to be made a part of Stage 2 of meaningful use that's implemented by hospitals and providers. So it doesn't cover PHR vendors, for example. This is specifically to provide transparency to what those providers participating in the program ought to be providing to patients when they download data. It's a good set of recommendations, but we don't set policy for personal health records, quite frankly. The issues about patients using, what we wanted to cover is the transfer of data by the patient from a protected environment into their own hands. Now, if a patient wants to set up an auto data flow to a PHR provider, they can certainly do that. And in fact under HIPAA once those regulations are finalized they will have an ability, in the case where they're requesting a copy of the record, to have it directly sent to a PHR, assuming that the connectivity issues are in play.

But I don't know if this would be the right set of guidance that I would suggest, for example, for a personal health record to provide to their patients. It's a different set of issues. IT's not the question we were asked to address, unless I'm misinterpreting what your question is.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Well, let's look at it the other way. I think with the Recovery Act one of the provisions caused the business associates to inherit some of the responsibilities of this.

Deven McGraw – Center for Democracy & Technology – Director

Yes, but that's only if you hire a PHR provider to actually provide your view and download functionality on your behalf. Those business associate provisions do not apply when I, the patient, engage, let's say it's Microsoft Health Vault, because that's one of the common ones that's out there that's available for people to sign up on their own, the mere creation of a conduit between my healthcare provider and Microsoft does not, and we had this advice specifically given to us by OCR on the phone on one of our calls, does not mean that Microsoft Health Vault is suddenly a business associate of my healthcare provider. Business associates, again, if you decide as a healthcare provider that you're going to contract out this view and download functionality, then whoever is contracting should abide by this guidance. If you're providing it on someone's behalf, you should be held to this, because you're standing in the stead of the provider in the case.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

We seem to have stimulated a few more comments. Gayle?

Gayle Harrell – Florida – House of Representatives

I think we need to be very careful when we go down this line. First of all, you have to look at what the statute provided, the original statute under our 2009, as to what our responsibility is. So we want to make sure that we do not, I don't think we have the ability to make those decisions. Also, we want to make sure that, and I think the clarification on who's a business associate is extremely important, and we don't want to put more liability on those providers by extrapolating what our recommendations are. So if we go down this line and we need to be extremely cautious in the recommendations we make that we're not expanding beyond our scope and that we're also by that expansion not putting more responsibility and more liability for those records on to the providers.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Marc?

Marc Probst – Intermountain Healthcare – CIO

I love the simplicity of what we're doing here, so I hope this comment, and maybe in a completely different topic, but what about proxies like for children, or as an adult do you have the same download button capability when I go in as a proxy for my child, or should you or should you not? Is there a recommendation or did you talk about that?

Deven McGraw – Center for Democracy & Technology – Director

Yes, again this is related to Adam's earlier question, if you allow people to designate a caregiver to be able to access an account, or a parent, in the case of a minor, to be able to access an account, the view and transparency piece of this, including the ability to download, is arguably going to flow with that functionality. I do think institutions could, and probably should, make some decisions in terms of offering patients accounts in terms of the age of the patient and what their legal obligations might be with respect to information sharing based on type of information, based on age of the patient. It definitely varies, and there are going to have to be different decisions made by institutions based on what their legal obligations are, which tend to vary by state, but whomever is accessing the account would get this transparency.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Capability.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay. Now – Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Sorry, I guess this is a personal old techie piece. Inside of organizations we tend to be very clear about, you use your account for all of your accesses, and if you're accessing information that's under someone else's control you get some kind of proxy capability that allows you to access that information. You don't use their account. I don't want to blur that in our language here.

Deven McGraw – Center for Democracy & Technology – Director

We're not. We're not changing the language to address that at all.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Good, because as you know, that's a huge topic and not one we should just glance into.

Deven McGraw – Center for Democracy & Technology – Director
Understood.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Great.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So far we've had a couple of amendments to recommendation two and three. I want to see if there are any other comments before we vote on the whole letter. Okay, all in favor of moving the letter forward with those amendments?

M

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any opposed? And abstained? Thank you very much to the Tiger Team. The next topic is the Quality Measures Workgroup, and before, as I mentioned earlier, we had approved the framework that the Quality Measures Workgroup had proposed a couple of times back and now they have the full letter for our review and approval. David or Tom, do you want to introduce this at all?

David Lansky – Pacific Business Group on Health – President & CEO

Sure, I can do it. This is David. I'll be happy to do that. I assume Tom is on the line. I think he's also in Minneapolis. Tom, are you there? Hopefully Tom will join if he's able. Thanks again for the opportunity to present the work of this workgroup to you all. On a couple of previous occasions we have presented the framework, as Paul said, and subsequent to that we had a full draft of the transmittal letter that would go to Farzad on behalf of the full Policy Committee representing the recommendations for both the framework and then a more granular level of recommendations about how the framework would be used and some of the methodology issues that we think should continue to be addressed. Then there's, as you've seen, an appendix which lists a number of the specific measures that at least provide a library from which CMS might work in drafting the rules for Stage 2. We would like to ask today for a discussion and hopefully approval of the full transmittal letter, and then in the context of that I've got a few other things to just catch you up on in terms of the current work plan and activities of the workgroup. So if that's okay let me go to the next slide.

In terms of our activities recently, as I said, we've had a previous discussion of the framework, which you've all approved, and hopefully today we'll have approval of the transition letter. The measure concept recommendations that you've seen going back several months from the Tiger Teams have been accepted by ONC, and ONC has issued a procurement notice with solicitation in conjunction with CMS to have measure development work done with, there are some funds available, I believe through CMS, Tom can clarify that, which will allow them to commission some additional contract work to flesh out the measure concepts that you've all discussed previously and hopefully generate specifications for quality measures that can actually be brought into the rule making process, certainly by Stage 3 and hopefully at least to a modest degree in Stage 2 next summer. There's also a joint hearing with the Clinical Quality Standards Committee on eMeasure standards implementation that we conducted, and I think we summarized for you some of the discussion that occurred at that hearing as well. Go to the next slide, please.

Mine hasn't advanced yet. Do you all have

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

We do, thanks.

David Lansky – Pacific Business Group on Health – President & CEO

I don't. It still hasn't advanced on line.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Is Tom controlling a separate broadcast? No., have we advanced the slide to the donut?

David Lansky – Pacific Business Group on Health – President & CEO

Now we've gone to the donut.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thanks.

David Lansky – Pacific Business Group on Health – President & CEO

So, as you recall, you reviewed and discussed these six categories of the menu and our proposal is that we would invite people applying for the Quality Measures for Meaningful Use to both respond to a core set of measures, which we've slightly expanded in this new proposal, but the expansion includes measure concepts that are not yet fully specified. So that is contingent really on the work that is underway, as I mentioned earlier, that's been commissioned. Then in addition, our recommendation is that CMS ask each of the submitting eligible professionals to provide at least one measure in each of the categories that are depicted in the framework, and that's obviously flexible when they look at the details and what's actually available at the time of rule making might feel comfortable making a different requirement than one from each category, perhaps it can be more than one. Our guess is that's going to be dependent upon the availability of appropriate measures in each of these categories.

I think we regard this framework as something that's hopefully fairly durable over a number of years, but will gradually be improved as the availability of the measures improves to populate it. That will both give professionals more opportunities to choose measures appropriate to them, and give the CMS program and ONC the opportunity to take the concepts that we've all wrestled with in our work and have them realized in the quality measurement field. Next slide, please.

So, in terms of our timeline now, as I mentioned, there is a procurement that's about to be awarded hopefully to develop additional measures that would flesh out the measure concepts we've discussed before. Hopefully that will be evaluated and awarded by the end of September. We're a little farther behind schedule than we once hoped to achieve, given just the complexities of the procurement process, but nonetheless we think the work will be in the field in the next six weeks or so and ideally we would ask the contractor to, as rapidly as possible, generate a small number of relatively low hanging fruit measures that can be put together in an acceptable form in time for next year's Stage 2 rule making process, and then certainly they would probably give most of their attention looking out another year further to developing draft measures for consideration by us for Stage 3. Then late in 2011 we would ask the contractor to give us the preliminary concepts for Stage 2 and by next spring we would try to have some things that we all can review and approve to recommend for inclusion in the Stage 2 rule. Next slide.

In terms of the workgroup itself, we certainly have some things we'd like to take up going forward. We will be working, I know Paul is giving some thought to an October hearing to capture additional input from the Stage 1 experience, and we're also very interested in eavesdropping on that hearing and learning what

we can about the decisions that are being made in the field to supply quality measures under Stage 1, and hopefully that will inform our thinking about how to make additional recommendations on the quality measures for Stage 2 and Stage 3.

Then in the fall we have several issues we'd like to take up as a workgroup. One of the ones that's emerged most interestingly for us has been the question of whether the availability of all the data you need to do quality measurement and the computational work to do all that, the reporting, should exist within the electronic health record at the individual doctor or hospital level, or do we need some intermediate layer of infrastructure, which you can think of as an HIE, it could be a registry, it could be a vendor, a variety of ways of aggregating data across multiple settings or points in time and then doing computations on that data to produce a quality measure. I think this has been provoked because a lot of the policy areas that our committee, this committee has talked about and that are now in this framework will stretch the capacity of a single EHR to do all that.

So some of the measures are longitudinal over time, for example, change in blood pressure from time one to time two, some of them seem to require care coordination, so we want to find out if we've closed the loop on referral or MEDREC, so the transmission of data between providers will raise a number of questions both technical data standards, transition standards, the computational issues that arise, the validity of the data questions that arise, who aggregates that data, or if there are multiple parties contributing to a measure, are they sharing responsibility for producing that measure and being in some way accountable for that performance on that measure. So a lot of issues there, and then there's the raw infrastructure question of what is in the middle between the individual practitioner on the one hand and then the receiving entity, let's say CMS, on the other hand, is there anything between them? Or does CMS directly capture all of this primary data from the individual reporting entity.

So that's a very open question that we don't, by any means, have an answer to but we think it's time to discuss. That may also take up the question of registries and where do registries fit, which I know we have discussed several times over the last couple of years.

There has been a suggestion that we should be working closely with the Clinical Quality Workgroup and Standards Subcommittee on the adoption of ICD-10 and whether there's both appropriate inclusion of SNOMED for clinical transactions and whether we and the vendor community and the provider community have the bandwidth to accommodate the implementation issues around that concurrent with the ICD-10 implementation. So we will talk about whether or not we want to get into that subject matter this fall.

A suggestion Tom has made, and maybe Tom can amplify on it, is that we give a little more formal thought to how the meaningful use requirements for clinical decision support, which I think we've all agreed we would like to enhance over the next couple of stages, how do they link to the measure concepts that we've already discussed in the workgroup, and can we create a tighter link between the functional requirements around clinical decision support and the quality reporting requirements about quality measurement. I think that's a very worthwhile topic for us to consider, closer alignment there.

Lastly, as you know we've had half a dozen methodology questions which have been persistent, and they're mentioned in the transmittal letter, and a couple of them are probably things we'd like to take up within our workgroup, as well as ones we'll forward to other workgroups this fall. One big one is we have an increasing interest in getting data from patients, but there are questions as to whether it's done through EHR by each doctor, or is it done through an independent data collection platform, something similar to what a CAHPS survey research platform might look like, for example. And if it's through an independent platform, how do we make sure it's in the hands of the provider quickly in order to be used for care and then how do we ensure that it's linked to other data in order to transmission as a quality

measure. So there are a lot of questions about patient data capture and use. Then there's an opportunity emerging that a number of the eMeasures that have been retooled recently seem to call for the same data elements, and perhaps it's worth our looking at a basic data dictionary of the data elements that are most germane for quality measurement and trying to encourage publishing and standards around those data elements and make sure we've done a review of that in time for the next meaningful use rule making process. Those are the things we have in mind coming up next. Next slide, please.

So the methodology issues, these are mentioned in the transmittal letter, just to refresh your memory on them, sorting out some of the issues around patient reported data, including transmission standards and then the content standards for those measures, looking at the methodologies for these more complex measures that we would like to use, like ... over time, finding a way to define standards for problem lists that could then be used for quality measurement and for reconciliation among providers, capacity and scalability of EHRs. I think our concern is, and we certainly heard from some of the vendors, that every time we introduce a quality measure it requires some rework and engineering at the vendor site and we'd like to minimize that and have a platform at the EHR level that can generate the data needed for quality measurement without having to be reengineered each time the quality measurement field, or the policy field would like some new information.

Then the attribution question, especially when we have multiple providers on a care team, which of course is something we're working toward in meaningful use, who gets credit, if you like, for the quality measures and how is attribution determined with these more complex quality measures that occur over multiple settings and over time.

Let me see if there any more slides. I think that's the end of the update. And with that, I'd like a discussion of the update and the themes I've mentioned, and hopefully we can turn to considering the transmittal letter for adoption. Thanks, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, David.

David Lansky – Pacific Business Group on Health – President & CEO

Also, let me just see if ..., if he's on, if he has additional comments I may have overlooked.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Tom, are you on? Okay. We have a number of questions in the room, David, starting with Paul Eggerman.

Paul Eggerman – Software Entrepreneur

Thank you, David, and thank you, Tom. This work is really very important and absolutely fascinating work. I wanted to comment on this concept of guidance on EHRs having capacity and scalability and your suggestion, David, that there might be some intermediate organization that somehow accumulates or aggregates this data. It just seems to me that we should be, it's almost like a reflection of our previous discussion, we should continue to be focused solely on the EHR system, that if you start trying to create a whole series of little organizations across the country, that that's going to be problematic. If you look at our HIE or HIO organizations, they have multiple models. Some models have centralization of data, but many of them do not have that capability, so that even when there's HIE organizations in place they don't necessarily have the capability to do this, plus it starts to raise a whole series of other issues, including privacy issues. We're going to be starting to transmit information that is patient identifiable to these other organizations that produce these reports, so I think the guidance should be, we should stay focused on

the EHR system and we should be able to produce whatever it is the EHR system is able to produce. That's my number one issue. Actually, I have a couple of other issues, but maybe I should just stop there.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Why don't we discuss this one? Other comments on this point? Gayle?

Gayle Harrell – Florida – House of Representatives

I would absolutely agree with Paul. Here again comes into what is our purview as a policy committee, what are charged with doing. And we have to be very careful that we don't get mission creep with where we are going and what we are assigned to do. Also, you have to say I think making sure what happens to that information once it is aggregated, are we going to set that policy as well. We need to concentrate on what we are assigned to do. So I would absolutely agree with Paul on that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Patrick, is this on this topic? Okay. Anybody else?

Gayle Harrell – Florida – House of Representatives

I have some other things too, but let's finish Paul's first.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'll chime in as well, speaking as a provider group we do struggle with getting the quality measures out of the systems, but we would like to struggle less with that. And that's the direction where we'd like to go because we want to provide it to ourselves almost on a daily basis. Right now we view the aggregation and provide it quarterly, which is pretty real time in these days, but we'd love to do it on a daily basis so that every day we can be working on how do I reach out to the folks that need this kind of So building it into the EHR system I think would serve that goal. And, Deven, if you didn't hear also supported Paul's point. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I just want to jump in with the scope and agree, but I also want to point out we should not be excluding the ability of organizations to use third parties. And some of the measures we've talked about are actually very helpful and useful measures in general, but are out of scope for what you could do with inside a single record and we shouldn't warp the record to start to accumulate all this information that doesn't really make sense to have in it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Other comments on this point? David, did you want to comment on the comments?

David Lansky – Pacific Business Group on Health – President & CEO

I think they're very valid cautions and I think it's a trade-off we will need to consider as a policy committee the larger goals of the program, which it goes beyond the EHR incentive program, and the reasons I think we've all emphasized some of the policy directions around these quality measures and the meaningful use goals, the policy framework that we've adopted, including things like care coordination and patient engagement are very obviously powerful domains which, almost by definition, address the capacity of any single EHR. I think our responsibilities aren't limited to the EHR incentive program, and I think the concerns you've all raised are completely valid and important and we should have hopefully a robust discussion about how do we balance achieving objectives like care coordination and patient engagement with the realistic limits of our scope and the environment that we're working in.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Paul had his hand up first, and then Christine?

Paul Egerman – Software Entrepreneur

This is Paul Egerman. I was going to respond to what you just said, David. The way I look at it is to me if we're talking about quality measures as part of the meaningful use program then they have to be done by the EHR system. However, if we want to look at other issues you can always say well, there's other public policy levers beyond meaningful use. There are other things that CMS has and other vehicles than those outside the scope of the EHR. But as long as we're talking about meaningful use in that area, then I think it's the EHR system, that's how I would address these other issues you're raising by saying, hey, maybe you need to look at some other policy levers that are different than meaningful use, because sometimes I think we put too much and it's almost like we have this meaningful use like toy and we're putting too much on that toy. And that toy is not intended to change how healthcare is delivered in this country. The toy was intended to simply provide incentives to implement EHR systems. It was not to completely alter and fix everything that's wrong in our healthcare environment.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

I'm sure Paul meant "tool."

Paul Egerman – Software Entrepreneur

Tool, yes.

Christine Bechtel – National Partnership for Women & Families – VP

This is Christine. My thinking is probably not as black and white. I absolutely agree with the fundamental premise that our primary focus is electronic health records. However, HITECH was not about electrifying paper, and that is the current system. And so when I think about HITECH and the goals of HITECH around clinical quality improvement and facilitating care coordination, which are both explicitly mentioned, I think the concept is not limited to just simply an automation of our current system, that that wasn't part of the goals of HITECH. Now we cannot fix everything, as you point out, I agree with you on that.

So I'd like to suggest, I agree with David Lansky that it is a good reminder and a good fundamental starting point to be oriented around electronic health records and what they can do. But when we think about two of the areas that I think have the most potential to make a difference for patients, which is care coordination and patient and family engagement, electronic health records have immediately an enormous limiting factor if we think about them only from the construct of measuring quality or collecting data. If we think about them under a construct of how you can use an electronic health record to improve quality, there are things that will need to happen in conjunction with the straightforward quality measure data collection function, like patient experience, where we have a whole module that's now been tested and validated through the CAHPS consortium at AHRQ on Health IT, and that should be part of evaluating the meaningful use program.

But if we think about it a little bit more broadly than just a data collection platform and a data use platform and think about how other fees like a patient experience survey could actually feed the clinical decision support function of an electronic health record, then I think it takes us to a nice kind of marriage about, yes, this is about the EHR but we're also going to be leveraging other feeds of information to make the use of the technology actually achieve the goals of HITECH.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Any other comments? Yes, David?

Art Davidson – Public Health Informatics at Denver Public Health – Director

This is Art.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh, Art, sorry.

Art Davidson – Public Health Informatics at Denver Public Health – Director

Hi. I have a query about the way that we currently envision what the EHR really means. Up to now I thought that we said that there could be modularity in the approach that a provider or a hospital takes in trying to achieve meaningful use. I thought that, and what I heard from David, was a suggestion that there may be modules that exist outside of the EHR that achieve some of the quality metrics that would be desired. It may be that innovation and maybe the fact that there's a desire to really get the best of breed in quality metrics that someone would hook up their EHR to another module. I'm not sure if that goes against what Paul was saying. I look at it as just another tool, as you said, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think what I've been hearing from people's reactions is that they're trying not to excuse the EHR from having to participate in a robust fashion in capturing the data necessary to report quality measures. And not that it would be the exclusive purview of the EHR, and I'm seeing nods around the table. Paul, is that

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Paul Egerman – Software Entrepreneur

Basically, to respond to what Art said, I don't have any trouble with the concept of this being a module that does this, and I don't have any trouble with what Christine is saying, well, gee, maybe you capture patient experience information, but ultimately whatever the quality reports are that are required for meaningful use should be able to be produced by an EHR system. It should not require the use of some intermediary registry where you send all that data through that registry and it produces the report, especially if it's producing a report across entity boundaries. Then you have all kinds of technical challenges and privacy challenges, not to mention costs, because those entities don't exist right now. So it's got to be back in somehow with meaningful use, our focus still should be what can the EHR do, and that can include an expansion of the kinds of data that's collected. It can include the kinds of analysis that is done in the EHR, but it's still what can the EHR produce.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Marc?

Marc Probst – Intermountain Healthcare – CIO

And I just heard from the first time you said it, Paul, and I'm just trying to clarify, Paul Egerman, that we're on the same page, that what we're asking for is a submittal to some organization of a normalized set of data, those are the quality measures, from systems that don't have normalized data. And therein lies the problem, we all have data and through mechanisms we can then get it normalized so that it's meaningful to wherever you aggregate that data. So what I was kind of hoping you said, and maybe you didn't, was the way David Lansky has this bullet on the methodological issues is we really have to pay attention to the fact that not all EHRs do it exactly the same and we ought to get a set of data that the EHR can actually produce that normalized set of quality measures and send it on. Like Paul said, if we can do that then we can use it on a daily basis, and we can really modify our thinking. But if we get too expansive on those quality measures outside of what the EHR is either collecting, I guess it is collecting, then you create a challenge both on normalization and what you collect on the system. Is that what you were saying?

Paul Egerman – Software Entrepreneur

Sure.

Marc Probst – Intermountain Healthcare – CIO

If I say it long enough then you have to agree.

Paul Egerman – Software Entrepreneur

I can never disagree with you, Marc. Yes, and really ... Paul's comments that EHR systems need to be able to produce this information, which is similar, I think to what Christine is saying, is you need to go beyond just being able to process transactions. You need to be able to produce a lot of quality information. But when you talk about transmitting normalized data, what I'm hearing is basically transmitting to CMS normalized, quality information that says, for example, this is my central line inflection rate, and that what Intermountain Healthcare transmits is really comparable to, let's say, Sutter transmits because they're defining things in a similar way so that that data makes sense. But it also has huge value internally to start producing that data, because once you track that, even if it's not entirely normalized people know that they're tracking it and it hopefully has an impact on the quality of care that's occurring.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Judy, was it on this point or another one?

Judy Faulkner – Epic Systems – Founder

On this point.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay. I think you're up.

Judy Faulkner – Epic Systems – Founder

No, I don't think I was next.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Well, everybody else is waiting for another point.

Judy Faulkner – Epic Systems – Founder

Okay. I thought what Paul said at the very beginning of his comments here was one of the most important things that's been said in a number of meetings, but what really is our purpose and where should we be going, so I drew a picture of it. This is a triangle, and we have limited resources, the vendors have limited resources, and it's what do we do. This bottom here says government regulations, state regulations, HITECH, meaningful use, etc. That has to be done. That's right here.

The next level is the needs and voices of all the clinicians who use the system, and that has to be done too. The top is innovation, the ability to do things like playing with gesture control and all sorts of things that are down the road five or ten years that you have to start right now. I think, if I'm hearing right, what we're talking about is raising this amount right here, this bottom level, through the things we put into meaningful use, and that takes away from these two top levels, because there's limited resources. So what we really have to worry about is what if these two aren't the same, the needs and voice of the clinician and what meaningful use is doing, and then this is just happening. It has to go up here. We don't have a choice. Is that the right thing to do? We always have to keep that in mind and go back to the essential purpose mission creep what we were originally charged to do here and we have to keep that in mind that it does push out the other two.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Any other comments on this one? Otherwise, I think, David Lansky, you have some feedback from the rest of the group that doesn't conflict with what you're saying but I think it adds to it. I think Paul Eggerman was pointing out how it gave the impression that it was sort of leaving EHRs out or making dependencies for these data intermediaries.

Judy Faulkner – Epic Systems – Founder

Paul, that's a good articulation, so in terms of having the minutes reflect that. There are about 10,000 things I could say but we need to move the discussion on. But I do want to say one small thing, which is, Judy, I think it's important to understand your comment in the context of the vendor community, but that my client isn't the clinician voices as much as it is also patients and families who don't want medical errors, they want better quality. So I just want to be clear that your context is around the vendor community, and I think you make important points, but I think Paul has characterized the broader discussion well.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Paul, you said you had some more topics –

Paul Eggerman – Software Entrepreneur

....

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

... with some hesitation.

Paul Eggerman – Software Entrepreneur

My other comment was there's all this discussion, this letter and the presentation about SNOMED and ICD-10 and defining core sets of data elements, and I view that whole discussion as stuff the Standards Committee does. The Standards Committee already addressed diagnostic coding in Stage 1, although it said SNOMED or ICD-10, but that's really up to the Standards Committee. I don't view those as Policy Committee issues. I think what we should be doing is defining what the needs and requirements are and let them figure out the core set of data elements and the coding processes.

David Lansky – Pacific Business Group on Health – President & CEO

Can I speak to that?

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Yes, please, David.

David Lansky – Pacific Business Group on Health – President & CEO

I agree with you, Paul. I think the only reason it's on our list at the quality measures level is the specifications for quality measures, we need to be on the right page with what the availability of data is going to be in terms of code sets and so on. So I think it's just a synching up issue for us, not really to dictate the right answers.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

The other policy question is, yes, that's what we said in Stage 1, but that's not necessarily what's being implemented, so that does become a policy. Gayle?

Gayle Harrell – Florida – House of Representatives

Yes, I have a question. I wanted to know, with the e-mail transmission of what was sent out earlier you've listed a variety of measures and you have the core measures that you've listed and also then the various sub-sets of menu measures. Are these the specific measures that you are recommending, or is this an example? And if they are the specific measures, by that actual inclusion of those and no others, are there others to be developed, you are limiting who's going to be able to qualify. Is that your goal? Do you only want primary care physicians to qualify? Where's the ophthalmologist going to qualify in this? Where's the orthopedic surgeon going to qualify in this? There's just no measure there that they would be able to meet. I need a better understanding of the framework that you're developing and how these measures specifically are going to be selected. Then the second question is, on ones that are to be developed, who's developing those? And how are they going to be developed?

David Lansky – Pacific Business Group on Health – President & CEO

Very good questions, Gayle. The detail in the appendix of the letter I think is an inventory of what has currently been approved or is in the works to be approved by NQF and other bodies. The recently retooled list that's flagged there are measures that build upon the measure concepts that were included in Stage 1 but have now been retooled from the NQF library of measures to be eSpecified. So they can be used with EHRs. We are simply saying to CMS, here's a library of measures from which you can construct your specific menus that will be put in the rule presumably. If they follow the same format as in the Stage 1 rule they can develop a set of short menus either by specialty or by these categories and we have not, in this letter, indicated a particular approach to how the menus should be set up. We did some storyboarding early on in the committee of if you want to do this by specialty, let's say make a menu for cardiology or for radiology, how well can you populate it for the 20 or so specialties that were in the original draft of Stage 1, and so that is an option that CMS could consider.

So to your question of what is this list, it is everything we are currently aware of that has pretty much made it through the review process and the endorsement process to be used, plus, the I think blue tinted highlighting are the measure concepts that are out for development now, and those, in terms of who will be doing that, there's a list of federally qualified contractors who are considered to be expert in measure development and so on who had the opportunity to bid on a contract to respond to this list of measure concepts, and there's a publicly posted procurement for that. Those contractors will be bidding and CMS and ONC will select a vendor, which will in turn work with a number of academic and other researchers to try to provide endorsable, specified measures that could make it through the pipeline in time for Stage 3 and perhaps even for Stage 2. All their normal endorsement and review processes still have to be jumped through in order for any of these to make it into the public process, but they're trying to accelerate the technical development work so that we would have some appropriate measures that satisfy the goals that the Policy Committee has previously identified.

Gayle Harrell – Florida – House of Representatives

To follow up on that, yes, and if these are just in the process of being contracted out or developed, when the final rule comes out is there going to be adequate time for that all to be developed and built within the EHR. Because we just had a long conversation and we want the EHR to be able to do the evaluation, do the measurement, is there going to be adequate time for this to happen and the EHR vendors develop it, sell it, get it out there, implement it, install it, and get it functioning to meet Stage 2.

David Lansky – Pacific Business Group on Health – President & CEO

I think realistically we think the answer to that for Stage 2 is it's not very likely. There will only be a few, as I said, low hanging fruit that might be feasible for Stage 2, and we will know those in the next few months. That is the first job of these contractors will be to report back here is a handful of measures that might make it for Stage 2 and then the vendors and the committee and CMS can decide if they think that's realistic and then perhaps put that in the proposed rule. Then for Stage 3 obviously we have a longer time frame, and hopefully by getting everybody in the conversation quickly probably early in 2012

we'll have time to try to get a better set of measures available for Stage 3. But the concern you raise is definitely on the table.

Gayle Harrell – Florida – House of Representatives

And one more question, if I may, are you looking specifically at those 20 specialties and are you going to be selecting measures or recommending measures for specific specialties. Are we going to really encourage our specialists to be able to meet meaningful use? What is your intent?

David Lansky – Pacific Business Group on Health – President & CEO

I think that in the process we are essentially, with this committee's concurrence, sending this letter off to CMS for them to do quite a bit more technical work, in answering your question. I don't know whether they will choose to display the reportable measures by specialty or not. I think one reason to decide that would be whether there's availability of enough measures to make most of the specialties credible menu sets. And we did probably four or five specialties as an experiment to see if that was a feasible way to go, but we haven't done the detailed work in the committee or the staff, to my knowledge, to really flesh that out for the full list of specialties. I think that would be CMS' job if they decide to do it.

Gayle Harrell – Florida – House of Representatives

I'd just like to comment that I think it's very important that we want to make the meaningful use available to everyone out there, to have that totally integrated record. That to me is the ultimate goal is that you have it in a completely integrated record. What happens in an ophthalmologist's office is important to that primary care doc, whether it's for diabetes, the interrelationships are so significant that I was very disappointed when we dropped that in Stage 1, and I want to make sure if we can push it in Stage 2 we want to make sure we get that out there so that any specialty can qualify.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, Gayle. And the gentleman to your left may be in a position to at least give us some kind of perspective from CMS in addition to raising his other points.

Patrick Conley

It will be points from me. I don't know if they're points from CMS, A couple of these have already been brought up, so I'll be brief. This is Patrick Conley, David. I think the core plus menu is reasonable. I do think the point highlighted before, if you think about a core you need to think about is it a core for primary care broadly. If you make it broadly you literally will be excluding large proportions of EPEs and could get serious pushback on that. I would encourage the group to consider is it a core for primary care and it's a menu of options for other specialties? That's point one.

Two, on the timing issues, I think they're real, and at least for me it makes me incredibly nervous if I see a "To be developed" especially in something like a core, given that we want to give ample time for this, not only just for the vendor community but for providers to have uptake to understand the measures, to know what's coming, etc. I think this timing issue is real.

My next point is on this and looking forward it may bleed into the meaningful use Stage 3 conversation later. I think in some of our categorization here we've been somewhat disingenuous, so if you look at patient and family engagement, as an example, I would actually argue that none of those measures are actually patient and family engagement, they're various permutations of process measures, pain assessment, did your depression get treated well, but they're actually not patient and family engagement. I think we actually do us a disservice if we pretend they are, so I think we should identify that currently there's a lack of patient and family engagement measures collected from EHRs and then we can make a decision on do you collect that from EHRs, do you collect it through other venues, but I think we do ourselves a disservice if we mis-categorize and give the impression that we think that's measuring patient and family engagement.

Similarly, on efficiency people always want to categorize things on efficiency. I think some of the efficiency measures you have I wouldn't actually categorize as efficiencies. I think also we may do us a disservice if we pretend there's a long list of great efficiency measures to pick from for EHRs. And I think very similarly in care coordination I think at a high level what this goes back to coming from a health

system where honestly we were done with measuring process measures, like we did that ten years ago, we were done, and we measured outcomes experience and value, I think this gets to your point about the tiers. I think we have to set a reasonable achievable base and then also recognize that if we truly want to move outcomes experience and value it will be the higher levels of the best tier of health systems and industry delivering innovative solutions to do that. But I do think in our categorization we should highlight in some of these areas that we don't have that now so we need those higher levels to be developed. Just brief thoughts there.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Christine, do you want to piggyback on that?

Christine Bechtel – National Partnership for Women & Families – VP

On the patient and family engagement stuff, I couldn't agree with you more. I think just as a context, because I co-chaired with David the Patient and Family Engagement Tiger Team that worked on this, the first whole tranche, almost the whole first page that you see is the stuff that was already out there that NQF did the recent retooling on, so we actually didn't consider those at all in the Tiger Team deliberations. What we focused on was the last one on page eight and mostly on page nine. So we said basically there are three areas that we think for Stage 2 we're close enough that we could work with existing measures and get them so that they could be collected and integrated into an EHR. It gets to the point we talked about earlier, because most of these will need some kind of survey platform so the EHR will feed the survey but then the survey has to feed the EHR, but it can't all do one. So that's really I think what the focus is. I acknowledge and agree that these are pretty process-y stuff above that line that I described and hope that we can move forward with more meaningful functional status pieces.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay. Any comments from the phone? David, how would you like – oh, Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

....

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Larry, ... anything on the –

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

It's not a problem. I'll speak up.

W

....

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

It's peripheral vision, yes, that's right. And as you get older it gets worse.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Okay, I'll move to the other end of the table. It will be easy. I just want to clarify that we're going from a framework that we spent a fair amount of time discussing to a very rich appendix here, and that we're not actually endorsing this appendix as the targets for Stage 2, but really this is a jumping off point for additional work that I'm hearing is being contracted out. Then related to that, to reiterate the sense of timeline to develop this and do it right, that it feels like we're moving very, very fast in something that historically takes a long time to get good measures, to not just do them in a development mode, but actually put them out in the world and see how they work and get feedback over are these measures actually measuring what we want and what we care about. So I'm concerned that we're going too quickly into something that we're going to start nailing down as this is Stage 2 because it's technically definable, but the measures might actually be useful and that we should put in the proper time to develop good measures. One of my friends who ... pointed out that there are 150,000 elements in the measures as listed in the appendix, not that they're all unique, some of the things do get reused, but each of those

would have to be built into logic to be made executable, and so it's a huge amount of work in those if they did come to fruition quickly.

I think there's another piece here, timelines, development. I don't know. In the back of my mind there's something else to say, but I'll pass.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Gayle?

Gayle Harrell – Florida – House of Representatives

I would like to absolutely agree with what Larry just said. I think that the whole measures community out there takes a long time to develop measures and they need to be tested, they need to be field tested to make sure that they are valid. I think that's one of the big mistakes we make if we rush that too, and if this committee puts the pressure on the measurement community out there to develop these measures and retool them or develop new ones without adequate testing. We have to make sure that if you're going to bake this into an EHR, that we're doing something that's ultimately going to improve the outcomes. We're measuring the right things, where we're doing it correctly and we're going to get the end result we want. So I couldn't agree with you more, Larry.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think, as David Lansky was pointing out, the hopes that we'd have something dramatically different for Stage 2 is probably pretty low for a lot of the reasons you said. All of the measures, as they go through NQF, do require field testing, as you know, there is a time limited endorsement, but without the field testing you don't make it to full endorsement. I think people have intimated that it's likely to be only the retooled, retooled means you use definitions that include electronic data in the EHRs but you don't change the concept. So those have already been passed and had field testing.

With that caveat, David, do you want to respond to close up and what you would like from us and what's the purpose of the letter and how does the appendix relate to that?

David Lansky – Pacific Business Group on Health – President & CEO

You said, Paul, that the important thing for us now, I think, is to send a directional signal that will guide the work of a number of our partner agencies over the next couple of years so that by Stage 3 at least we have begun to populate this framework with some of the measures that we think are appropriate to the EHR adoption process and to our overall charter. If we don't get started, which is kind of the signal now, then we'll probably miss our entire opportunity as a committee given the timeline that we're working on, and for the reasons you all said, it does take two years or so to get from where we are in identifying an important concept to where it's feasible to be implemented in the program.

Our committee is certainly hoping that understanding what's in the appendix is not a proposal for what should be in the rule and it's not a proposal for what should be implemented in all EHRs, it's a library from which CMS should collect appropriate targets for reporting, and that will be contingent on feasibility and availability of tested and endorsed measures and so on. I think those understandings should be part of this, and if people feel we should add a sentence or two to the main letter, sharpen that distinction between the role of the appendix and the directional signal we're trying to send, that's certainly something we could do. But otherwise I think your comments are very well taken and I'm sure will be reflected in the record and the understanding of CMS and others.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think that would be helpful, David, to make clear what the appendix represents, that it's a library, and that, in answer to Gayle's question, it's not the super set, is it, it's not the exclusive super set, is it, that you're proposing for CMS?

David Lansky – Pacific Business Group on Health – President & CEO

Well, I think it is super set. I think, except for those to be developed potential exceptions we'd be surprised if much enters into the CMS rule making that hasn't been reflected here, since this does list all

the retooled measures that we're aware of, all the Stage 1 measures that are already populating, and the other ones that have been surfaced through a public comment period. We'll be surprised, and certainly CMS may have a better idea but we tried to capture what's out there today.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

And when you say that as far as being a super set you're referring only to Stage 2, is that correct?

David Lansky – Pacific Business Group on Health – President & CEO

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. That might be also clarified, so we're not pinning down Stage 3 as the exclusive super set at this point, but for timing alone there's only a certain amount of things you can do for Stage 2. Then the other comments that Paul Egerman started out, that may be something that requires some adjustment in the text. Is that fair? We're referring to the ability of EHRs to calculate these quality measures.

David Lansky – Pacific Business Group on Health – President & CEO

I'll have to look at the text and see if that ... is alluded to in the methodology section. There's a section toward the end of the transmittal letter regarding EHRs' capacity to compute quality measures.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, I think there's a nuanced illusion about, that's an "A" and not a – about whether the calculation of quality measures should be transferred to HIE organization versus being a capability in the native EHRs.

David Lansky – Pacific Business Group on Health – President & CEO

I'm just trying to see if that's actually in the transmittal letter or in my comments today.

Deven McGraw – Center for Democracy & Technology – Director

David, this is Deven. I didn't see it in your transmittal letter at all. I think it was just in your comments.

David Lansky – Pacific Business Group on Health – President & CEO

The transmittal letter does typically talk about the methodology question of EHR capability which is implied in Paul's comment. I suppose it's a question for discussion, not a recommendation.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, it says "Establish ... should be a core function of the EHR product." It seems to me it should be a core

W

It's in there.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, good. So it's more of a discussion. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

My slow recall has finally kicked in. We're talking in some ways about the vending side of this process generating the quality measures. I wonder, as a Policy Committee who also should be at least acknowledging the recipient side here, so CMS' ability to actually receive this information, my understanding is that it's from some of the other rules that have been issued for quality measures that CMS is saying that the Stage 1 standard is not sufficient to actually be able to receive the measures, plus they don't have the technology in place to receive them. And perhaps that should be part of our timeline discussion as well, that there's not just that the systems have to generate and then we want to move out of attestation to submitting these and what's the appropriate timeline for CMS to be able to receive them.

Christine Bechtel – National Partnership for Women & Families – VP

David, you may have a comment on this but my sense is that the bulk of these recommendations don't actually focus on send or receive, it focuses on generation and collection of data. I know that in terms of the Tiger Team that David and I led we didn't talk about sending and receiving as much as how do we take quality measures that have been identified as already existing either through NQF or the public comment process, and make sure that there's something that an EHR is capable of generating. But we did not talk about then the send and receive. David Lansky, I don't know if that is consistent with your view.

David Lansky – Pacific Business Group on Health – President & CEO

Yes, it is. We were sending a policy signal, I think, about what the content was, what information is important to collect for quality measurement reporting for the program. The implementation issues, and perhaps Patrick can speak to it, they're all very complex questions as to can and should CMS be collecting, and then of course how is it used or reported externally. And we have not talked about that and it may be a subject worth raising and having some consultation. The policy questions that several of you have alluded to about whether, for example, what's to be reported from the EHR, is it a numerator and a denominator, is it their ability to audit or track back to verify the data, what data does CMS then collect at its end, and what capability does it have to do that over time. So those are all questions we have not taken up but we could.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

This has been a very rich discussion. It's certainly an important topic. I don't think it substantively changed the letter per se. I think characterizing the appendix could be well worth the few sentences. Patrick?

Patrick Conley

David, sorry, just briefly to comment on your last point, the timelines for all these things, it's all about cycle time and timelines, sadly, like many things in life, so literally on these things we have timelines that are day three, day six, day eight, day ten, to like the infinite level of detail, and I can just tell you, you will never go wrong. If you think well, we've been pondering this but maybe we don't have to make that decision, that's usually wrong. We actually do have to make that decision because we can work internally on moving our cycle time. I'd also say, let's be honest, a decision on are you going to correct ... level or aggregate data affects everything and until you make that decision you can't build the systems. I think if you're pondering should we weigh in on a particular question and can we wait another six months, the answer is probably no. If you think it's an important question and you want to weigh in, now would be the time.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

So I think, what the Quality Workgroup is requesting and what Patrick just alluded to is they need some sense of direction, and having some approved framework, as is included in this letter, is helpful to start that set of activities going. Paul, you have a quizzical –

Paul Eggerman – Software Entrepreneur

I don't understand why we need to have this letter approved, though, Haven't our comments been guidance to this committee? I don't understand what –

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

As an advisory committee that ONC and CMS have really leveraged well, I think they would like an official voice going forward and that's just helpful to them. It's a basis to start. It provides a rationale for getting started on some of these activities. If there's anything in the letter, the recommendation or the framework that we disagree with, that's a point to pause at, but I think when we've seen the framework before too we agree with the direction, we agree with what it's saying about Stage 2, which is not much. It's really posing a direction for Stage 3 which actually has to start now, for all the reasons we've said. That kind of guidance would be useful in a formal way from this committee. That's what they're asking for, both parties, the workgroup and CMS.

Christine Bechtel – National Partnership for Women & Families – VP

... appropriate time to make a motion to approve the letter?

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

I think so.

Gayle Harrell – Florida – House of Representatives

One question before we move forward on this, is there going to be an additional paragraph added about the appendix –

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

David, you would agree with that, correct?

David Lansky – Pacific Business Group on Health – President & CEO

Yes, I think that's good to

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay, so it would be with the clarification that these quality measures have to be done in such a way that the EHR system can produce them.

Christine Bechtel – National Partnership for Women & Families – VP

... for it and it's –

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Can we just make sure, David, as you review the letter, that that policy point is clear?

David Lansky – Pacific Business Group on Health – President & CEO

Yes. I think we can make clear that this proposal for Stage 2, these are all measures that can be generated from the EHR, either hospital or EP setting.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

I think that was ... point. Any other further discussion before we take a vote? All in favor of moving the letter forward?

M

Aye.

W

Aye.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

And any opposed? Any abstentions? Okay, Judy's abstaining. Okay, very good. So we have a letter, David, and thank you very much for the work on this. It's been over a long period of time and it really sets a direction where, it's not the final word, but it's something that also CMS can help use to move forward.

David Lansky – Pacific Business Group on Health – President & CEO

Thank you all. I appreciate it.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

I realize on we're behind in time, but I think we have a little bit of bufferability and I know my remarks will be shorter. Let me check, is Dr. Mostashari on the line, since we were originally scheduled to have you around noon?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Hi, can you hear me?

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Yes, we can. Why don't you take the stage?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Great. I don't, particularly since you're running a little bit behind I won't take too much of your time. I just want to report that I'm at the third of four regional meetings of all of our grantees, ... centers, health information exchange and HIT coordinators ... as well as some SHARP research grants. And just to reflect what I'm hearing in the field and from folks that are in the field is that there is an incredible amount actually of movement that's happening. As the Policy Committee has set the guidance, the guidelines and the policies and we've moved ahead, those policies are finding purchase in the real world and the changes that are happening are perhaps difficult to see day to day but as we look from where we are today to where we were just a few years ago, the transformation is real and it's happening and the movement is so real.

The secretary visited Joplin, Missouri and spoke about how electronic health record had made such a difference for the ability to deliver continuity of care after that disaster, and thinking back to Katrina just a few years ago we only heard about the folks in the VA who were able to get care and for so many other people they lost a big part of themselves in the hurricane and they lost their physicians and they lost their medical records. The surgeon general talks about putting out the records in the sun to try to salvage some of that information. So what happened in Joplin already was different. Yes, there were practices who were still paper-based who actually had to close, they closed their offices, they gave up the practice and some of them joined the hospital, but many, many, many more at St. John's Hospital there had just converted to an electronic health record and they were able to not miss a beat. And when they set up a temporary hospital and to be able to send that information to the new facility there were practices, small practices, there was a substance abuse clinic, there were dental clinics and all of that information was able to be used and maintained and preserved.

The change is happening. The change is real. And it's not just about electronic health records. While the discussion reflecting on the discussion we just had, while we have to be clear about the ... when we're discussing meaningful use and the health IT incentive program, the mission for the health IT policy committee and for the Office of the National Coordinator goes beyond the health IT incentive program. It's really to provide the health information that ... the collection, the transformation, standardization, and the flows of that information. And all of the activities were engaged with ranging from meaningful use to the health information exchange to the governance rule around intermediaries to privacy and security and trust frameworks, they all have to work together to be able to provide that foundation for transformation of the various systems. We are not the transformation, but we enable the transformation to happen and we should not stand in its way.

I think probably the area where this is most, quality measures and care transitions are two where the connections between what we do and the broader picture of ... and delivery system ... is most clear and most sharply drawn. We need to be able to deliver on that promise that we will be able to provide better measures that matter. We heard the dissatisfaction in everyone's voice, whether it was Gayle talking about the lack of measures that are appropriate, or Patrick talking about the efficiency measures, and Deven and Christine talking about the patient engagement measures, and we need better measures that truly reflect outcomes and values, and yet we also know how difficult it is and how there's really no time to spare if we want to get there in time and with the urgency, balancing that urgency and what we actually need.

We also have to recognize that there are different goals for different participants and we have to reflect a broad set of priorities and a couple of benefits. There are the requirements for accountability that the payers need that the information be reliable, and reliable not just for transparency purposes but for real dollars, for potentially billions of dollars. ... on those measures, and there needs to be a high level of servitude regarding the process by which and the validity of those measures. But the measures also need to be usable for quality improvement purposes, as Paul described, in a daily basis to be reflected back in real time and that balance between, not to mention the population health management across tracking. So we have at least three goals and the information architecture that we collectively built that is comprised of these critical building blocks of meaningful use of electronic health records, of information exchange services and protocols and policies and trust framework and governance, those collectively

have to meet all of those and to do in a coordinated way. So the kinds of discussions that you the Policy Committee have been having and the guidance and recommendations you've been offering us have been just absolutely essential and nowhere else ... this level of discourse happening around how health information has served the needs of the American people, and I thank you for it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you very much, Farzad. Any questions or comments for Farzad? Thanks so much for your leadership and for being out there in the field and taking back all of this feedback. It's gratifying to know that things are moving and things are being helped. I appreciate it. Anything more, Farzad?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

No, thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you now. Okay, let's go and hear from the field, so Robert Tagalicod and Elizabeth Holland are here from CMS to bring us up to speed about what are some of the early experiences in the meaningful use program.

Robert Tagalicod - CMS

Thank you, Paul. Again, my name is Robert Tagalicod. I'm the new Director for OESS at CMS. And while I'm new to this position I'm not new to CMS or to EHRs or to the conversation on value and outcomes, and I think it's heartening to hear that. Clearly I'm also not new to cycle times and needing to get certain things and attending to the inter-dependencies that we need to move things forward. Finally, I'm not new to transparency so we'll certainly let you know what those cycle times are and how we can use the conversations that are being had around the table to move this forward a lot more definitively in a kind of project management paradigm. I'm glad we'll be working with you and with my colleagues at CMS as well as ONC to move that forward.

Regarding this presentation on meaningful use, a caveat: the caveat is it is a very preliminary analysis. I would like to say that part of the caveat is that it would be too early to draw certain programmatic conclusions, but nonetheless I think we'll be working closely with you folks in the Policy Committee as well as ONC on understanding what these data say to us and how we should interpret them so that we can translate them into something much more programmatic. I'm very happy to have my colleague, Elizabeth Holland with me and we'll be working very closely together to understand these sets of data as well and we'll be presenting this jointly.

First of all, I'd like to give you an update, and this information will be, if not already, on our Web site, the EHR Incentive Program Web site. Over 77,000 have registered for both the Medicare and Medicaid EHR Incentive Programs. Twenty-one states are now open for registration, and this includes four new states since our last report, and those include Arizona, Connecticut, Rhode Island, and West Virginia. The Medicaid EHR Incentives paid has been paid over to 3,500 eligible professionals and hospitals for specifically adoption, implementation, and upgrade of certified EHR technology. In the Medicare realm 1,000 eligible professionals and hospitals have successful demonstrations of meaningful use. In total, almost 400 million in incentive payments have been issued. We, again, as I said in the beginning, we'll be releasing the July report and posting it on the EHR Incentive program Web site.

Elizabeth Holland – Centers for Medicare and Medicaid Services

I was just going to add, I spoke about the numbers last month, and so I wanted to point out that for eligible professionals for Medicare we paid 229 EPs and for July it has risen to 566, so the numbers are appearing to be increasing and so we're hopeful that that will be a continuing trend. I also wanted to add that on the report that we're posting we did include for the first time the medical specialty associated with the EP, and so the year-to-date number for that is the two top specialties are Family Practice and Internal Medicine, just so you know.

Robert Tagalicod - CMS

So on to the highlights of this report, again, that preliminary report. Again, this is based on July 8th on attestation data of early adopters. As the slide deck says, on average all thresholds were greatly exceeded, but as you know, with all averages there are highs and lows, and in terms of the lows every threshold has some providers clearly on the borderline. Again, an observation, not necessarily specific conclusions around that.

What we've also seen, as again the slide indicates, the most popular ... objectives drug formulary incorporating lab test results and patient lists, and the least popular of these is medication reconciliation and summary of care record. Again, I would hesitate to draw any kind of conclusion regarding that. It's just simply what are the greater numbers and the least numbers. There is a little difference between eligible professionals and hospitals and a little difference among specialists in performance by differences in exclusions.

I'd like to punt it over to Elizabeth to tell you what the rest of the report says, but before we do that the next slide is "Are the Providers Included?" Two thousand three hundred eighty-three EPs have attested, and you see the numbers, but again I think you have to know what the numbers are. There are several hundreds of thousands of eligible professionals, so again very preliminary, not enough to draw conclusions, and again 1,000 hospitals have attested, all successfully. If I say anything and if there's any take home points it is really only a data analysis and its caveats again are in order about drawing any conclusions. We will be working with you folks as well as with ONC to begin to look at real trends and what those trends mean going forward.

I'd like to punt this over to Elizabeth, particularly to talk about what we mean by performance exclusion deferral and these subsequent tables.

Elizabeth Holland – Centers for Medicare and Medicaid Services

The analysis, we did include the providers who were successful and unsuccessful, but we have not drilled down yet to look at the unsuccessful. And so I don't have that to share with you today, but that's definitely one of the areas that we're going to be looking into. Just on the next slide, I just wanted to explain to you all the slides are in the same format, so I was just going to walk through one of the slides so that you would understand what this means.

The first objective here, we actually lumped several objectives together because the results were very similar. If you read across, the first three objectives listed are core objectives and the average means that's the average of their performance, so it's when you average out when they enter the numerator and denominator to get a percentage and then we average the percentage across all those providers. The exclusion is the percentage of all the providers who attested who applied for that exclusion. And because these are core measures, there are no deferrals allowed because they're core. So just to point out, for CPOE the average was 87% and the threshold for that was 30%. So it appears that they're exceeding the threshold by a lot.

Again, the data's just really for your sharing. We're cautioning everyone that it's too early to use this data to make foreign policy decisions, but I do need to point out one thing on the next slide there is an error. The office visit summary, which is the provided clinical summary for patients, that is actually a core measure, so the deferral number should be an "A," not 26%.

W

Elizabeth, can I ask you a quick question to understand the percent on performance. Is that 90%, so ... health information 92% have successfully met the threshold, or is that an average of the threshold that they've met?

Elizabeth Holland – Centers for Medicare and Medicaid Services

It's the average of the threshold that they've met.

W

So they've provided eCopy health information to 92% of their patients on average, of patients who ask for it. In other words, 78% attested successfully to being able to do a visit summary, versus visit summaries were provided to an average of 78% of the patients, which were meeting the threshold.

Elizabeth Holland – Centers for Medicare and Medicaid Services

It's the average that they gave us, so it's the average of the numerators and denominators.

W

It is their threshold that they met. Great, thank you.

Gayle Harrell – Florida – House of Representatives

And clarify exclusion, too. I'm still not understanding what the exclusion is.

Elizabeth Holland – Centers for Medicare and Medicaid Services

Exclusion is the percentage of the providers who attested who applied for the exclusion. So they're very different.

Gayle Harrell – Florida – House of Representatives

For instance, they excluded from their attestation office visit summaries, 4% of providers did not provide –

Elizabeth Holland – Centers for Medicare and Medicaid Services

In our attestation module there are criteria for applying for the exclusion for that particular measure, so they went through the questions that we asked them and they believe that they qualified for that inclusion and applied for the exclusion.

Gayle Harrell – Florida – House of Representatives

I got it.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

This is Larry. To add an interpretation here, it is not unreasonable to think that the early attesters are people who have a lot of experience and have systems up and running, and so to see these numbers be high at the beginning may not be indicative of what we're going to see as we go down the

Elizabeth Holland – Centers for Medicare and Medicaid Services

Absolutely. And that's why we caution using these numbers as gospel.

Neil Calman – Institute for Family Health – President & Cofounder

This is Neil. Can I just make a comment? I think it also says something else that we've been saying all along which is once you have the capability of doing something in your system I think people tend to do it much more than these thresholds that we've set. So once you're doing ePrescribing you tend to do it on everybody. After visit summaries you keep doing it on most of your patients, I think that's also another possible interpretation ..., so I wouldn't be surprised if these high levels are maintained as people qualify.

Robert Tagalicod - CMS

We'll certainly look at that point as we go along. And we hope that is the case.

Elizabeth Holland – Centers for Medicare and Medicaid Services

Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's it?

Robert Tagalicod - CMS

Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. Thank you for this report. We understand the caveats for sure, clearly the early adopter's already been there, done that, and we look forward to an ongoing update. Is that correct?

Robert Tagalicod - CMS

Yes, there will be ongoing updates. This is about a dialogue with you folks. If there are ways of displaying and understanding the data, it would be helpful through formal meetings like this meeting or through informal meetings it would be helpful to hear that so that we can give you a better set of data for you to consider.

Neil Calman – Institute for Family Health – President & Cofounder

Paul, can I ask a question? This is Neil again.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Sure, please.

Neil Calman – Institute for Family Health – President & Cofounder

Are you doing anything to look at who the providers are in relationship to geography? One of our concerns early on was that providers in remote rural areas, providers who serve underserved populations would be qualifying at lower rates, or at least later. I'm wondering if you're looking at any of those things in relationship to geography or population served using geo coding or anything like that to just determine whether or not those providers that were concerned about both on the hospital side and on the EP side are those that are qualifying.

Elizabeth Holland – Centers for Medicare and Medicaid Services

We're actually just starting to look at that. Someone in our Dallas regional office just sent me a cool map of Texas that shows where everybody was, and so we haven't done it for the whole country yet, but we do have Texas.

Robert Tagalicod - CMS

And the capacity is there.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Another thing that might help perhaps in an appendix would be some of the criteria for exclusion, as an example, so how do 4% get to exclude themselves from ..., I mean, those kinds of things in an appendix would be useful for us. Thank you so much.

Robert Tagalicod - CMS

Thank you.

Art Davidson – Public Health Informatics at Denver Public Health – Director

Paul, this is Art. I have a question.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Sure, go ahead, Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director

I'm looking at the eligible hospital improved population and public health slide, and I'm just trying to get an idea, I know that it says that they need it to test, but is there any current estimate of how many actually passed the test and now sending the data, like the 38% immunizations. Then one from the last point that was just made, it would be helpful to understand how 13% of hospitals believe they need some exclusionary criteria for reporting lab results and where in the country that's occurring.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

We'll start getting some more of those details as we go forward.

Robert Tagalicod - CMS

Right. And we'll begin to contextualize some of the data, the recordings so that one understands how it's seen against other things.

Elizabeth Holland – Centers for Medicare and Medicaid Services

Right. Just to point out the exclusions, we have the meaningful use spec sheets that list each meaningful use specification and then objective and measure and what it means, and those are all posted on our Web site and it does list out there exactly what the exclusion would be for a particular measure, if there is an exclusion.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

It helps some of us who haven't memorized

Elizabeth Holland – Centers for Medicare and Medicaid Services

Right, but it's not like it's something new that we made up for this.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

No, I understand.

Elizabeth Holland – Centers for Medicare and Medicaid Services

It is something that has been out there.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Thanks again.

Elizabeth Holland – Centers for Medicare and Medicaid Services

Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay well speaking of Meaningful Use Stage 3, I'm just going to give you an update on some of the things we're working on in the Meaningful Use Workgroup. A couple of topics, one is we formed a new Tiger Team at the request of ONC. For Meaningful Use 2 we had some – well actually even in Meaningful Use 1 we had a couple of concepts, clinical summary, which is meant for this patient and in fact we just saw the office visit summary, and the second is the summary of care, which ... as they covered transitions from one provider to another. Both of those were concepts in the sense that they were not completely defined. Part of our thought was that we would turn this over to the Standards Committee and they would flesh it out where we couldn't. They said, well, we think it's a policy issue so it's back in our court. It's fair in the sense that these are not industry standard definitions at this point and so they've asked for more help as they go through their rule making process, so I think that that's fair. We formed a Tiger Team to work on this. Christine?

Christine Bechtel – National Partnership for Women & Families – VP

..., so we actually did 95% of the work in the Meaningful Use Workgroup and it just hasn't been collected and aggregated and organized across the different vehicles that we did. So I've been working with George and Charlene to just pull the stuff together, so I don't know that I would go so far as to call it a Tiger Team yet. We're going to start, first, give everything to ONC that we've already done that was already a part of the Meaningful Use Workgroup, and then they will help us identify if there are further questions that they need answered.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Sure. And that might apply more to clinical summary than summary of care, is that correct?

Christine Bechtel – National Partnership for Women & Families – VP

No, it's both. Because it's actually pretty much the same data set, so it's both.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay. Is that a fair assessment from ONC? Okay, good. The second point is Stage 3. We talked about this a couple of meetings ago in terms of it may be a good time to step back and reassess even the strategy for developing Stage 3 measures, much like the conversation we just had with quality measures. We all know what short timelines we had with Stage 1, it was basically a six week process. The good news is that I don't know anyone who has disagreed with the framework that was set up then. We've heard both the testimony in front of our workgroup a couple of months ago, and we've been hearing from the field how much people appreciate the framework and how when you do this you're actually improving care, so that's very gratifying.

We have a number of remaining questions. You know that Stage 2, just like we talked about in quality measures, we had to do fairly quickly too before even getting experience from the field with Stage 1, and that's just the way the timeline goes. But Stage 3 we no longer have that ... and we want to take advantage of the time we have between now and 2015 to really do a comprehensive look at, one, what's been going on in the field; and two, what is the strategy. We heard, I think it was Patrick that talked about, okay, process measures, that's a been there, done that and it's time for the world to move on and hopefully by 2015 the world can move on.

We're setting ourselves to look at Stage 3 with that perspective and let me just remind ourselves that Stage 3 isn't the end. It is 2015. That's the end of the incentive. But the statute does permit the secretary to have further stages with increasing at least stringent requirements that would prevent you from getting the penalty side. This notion of where it's needed to advance the nation's health and the federal initiatives, she may or may not choose to use meaningful use as a way to put this infrastructure, these tools into place. So, our thought is to have a hearing, which we've tentatively scheduled for October 5th and 6th, to look at a number of questions. One is how is it going? What are the needs, both in terms of health reform and the various CMS programs, and what are future levers? What levers would help overcome some of the barriers to achieving some of the objectives that we have and accelerating the progress.

Some of the things we want to consider from an experience point of view is it playing out according to plan? We had a framework for the meaningful use criteria, we had a notion of phasing and is it going well, and it was very gratifying to hear Farzad's comments from the field this morning. Did we get the objectives correct? Is the timing correct? Timing is not a reflection of how hard is it, but is it going to meet the needs of health reform not the needs of HITECH or meaningful use, and are there unintended consequences. We did talk about safety issues with EHRs in the past, and ONC followed our recommendation in terms of commissioning an independent body, and that body was the Institute of Medicine, who's working on recommendations in follow up of our recommendation.

What about vendor performance, what are the challenges for vendor? We keep getting reminded about those. We also heard about challenges with vendors. In our hearing there were some providers who had challenges with their vendors in terms of either what's promised and potentially not delivered, those kinds of mismatches, and we did promise ourselves to get back to that question as well. What infrastructure can we expect to be in place in 2015? We know that the HIE environment is clearly not mature. What do we envision it to be in 2015? And we'll probably need to hear about what's going on in the field, both from the RECs as well as the state designated entities in that program.

Quality measures have become far more front and center than they were when we started in 2009. With the Accountable Care Act it means that there's probably going to be a different way that we construct our delivery system in a different way than we pay them and chances are it's going to have something to do with quality and performance measures. So we want to get those in shape. We clearly want them to come out of EHRs, among other things, so that they flow instead of this retroactive, retrospective way of going and gathering some data about our performance.

Those are the kinds of things we're looking at. We definitely want to hear from CMS on all of the programs they have going on, whether it's the National Quality Strategy or a partnership with patients, patient centered medical home, all of these things are going on. They have a commitment to align them and they've already, in their ACO NPRM aligned with meaningful use in a huge way, 50% at least

proposed, 50% being qualified in meaningful use by the second year. So there's a lot of alignment that we're trying to have happen and we want to make sure in Stage 3 we go in with our eyes open on all of these things and try to give it a very rational, very deliberate kind of road map towards measures criteria that would advance the field at that point in time.

That's why we're taking a pause. We don't want it to be just another increment on Stage 2 and we're trying to be very thoughtful. So we will keep you posted and involve you as we go forward, we being now the Meaningful Use Sub-Committee. George, if you're still on the line, any additional comments?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair

No, Paul. I am on the line. Thank you very much. That sounds great.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

Okay, and Paul Eggerman's got his card in his hand.

Paul Eggerman – Software Entrepreneur

... George's terrific work, of course, and I appreciate what you're doing. My question is about time frames and major milestones. I want to make sure that we don't repeat with Stage 3 what happened with Stage 2, where we somehow suddenly wake up and realize we don't have time to do everything. So my question is, are we establishing what I would call major milestones that sort of says based on this schedule for Stage 3, we've gone through the release of NPRM and as a result here's the date on which the Policy Committee has to finalize our recommendations for what's in Stage 3. It seems to me establishing those milestones now would help us in terms of directing our work, because it sounds like we have this luxury of time because of 2015, but it may be that we don't have as much luxury as we think when we actually look at the schedule.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

That's an excellent question. Let me see if either Patrick or Robert want to chime in. We proposed to come up with both a set of goals for Stage 3 that may or may look like an increment of Stage 2, and a strategy or road map for getting there. I think the question that would be called is, is there an NPRM process that can happen sooner than right before 2015? That's an open question. We've been going on this two year cycle, but that's not the second statute, so let me turn to CMS to comment on that.

M

We are already looking at that, so that all the lessons learned in anticipation of Stage 3, we would do that much earlier. I think part of my quasi-commitment, but I have a more formal commitment, is really part of this transparency is letting you know and in the planning of that what that would look like and where the Policy Committee specifically, and the Standards Committee, for that matter, as well as our colleagues in ONC will plug in, in order to do that. We do have a project management tool and team to help us manage that. I think part of that is you don't want to throw data out here, but it's clearly about identifying what common milestones and what discrete activities need to be met and time frames, and who's responsible, including understanding who's responsible for those in order to move it forward. So I would suggest to this committee certainly and to my ONC colleagues is that we kind of move that into a much more project management, I say paradigm discipline, and use this at this committee. Patrick, do you have a –

Patrick Conley

I agree, and I think we can outline those timelines in general. As was alluded to earlier, so the rule making cycle takes a while to go through all its steps and so if you're looking to publish a rule this spring, as an example, you're actively working right now, so if you think you want a meaningful use stage rule published in the spring of next year, so the spring of 2012, you would actually be working --, sorry, 2013 is what I meant, you'd be starting working like August at the latest of 2012, and to get recommendations

when you're six months through a reg process just to make sure everybody hears it and understands it is actually not that helpful because now you've vetted it through everybody and it's in OMB White House land and you're about to publish it and in fact making last minute changes is not seen as a good thing, nor does it help –

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

So right now the NPRM expected in this year, the final rule, the spring or late spring of next year, is for 2015. So that's for 2013. So 2015 can we target publishing the final rule in 2013 instead of 2014?

Patrick Conley

... possible, so we need to look at all the other things that are in the hopper in order to manage that correctly, and so that we don't do violence to one process versus another.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

But our current quandary in terms of the proximity of the final rule, we can change that?

Patrick Conley

Yes, and we hear that a lot in So I think we're already thinking about it in our thinking so that we don't

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

The upshot to your customer, Paul, is we're starting to work now, or already yesterday, and moving towards as quickly as possible honing in on the sites for 2015, and where prudent and working with CMS on the project timeline, where prudent getting a recommendation from this committee that pre-dates its implementation with a lot more lead time than we've had before.

Paul Egerman – Software Entrepreneur

So basically another way to phrase my question is that I'm encouraging the exact discussion that we had, and the way I like to see it back up to the point where we say, and therefore the Policy Committee has to complete its deliberations about Stage 3 on "x" ..., October 1, 2012, whatever that date is. So we may discover we don't have as much time as we think. I think we need to have a sense of that entire time frame.

Paul Tang – Palo Alto Medical Foundation – Internist. VP & CMIO

We already know we don't have as much time as we like. So actually one of the delays is actually getting enough information from the experience in the field. As you know, there was a bit of a timing problem that may have held up people from attesting in calendar 2011 and so we need to flesh the field experience out a bit, which will probably occur more in 2012, and then set that timeline. But anyway we'll work with CMS on what a feasible and reasonable timeline is. That's a really good question. Gayle?

Gayle Harrell – Florida – House of Representatives

I do want to comment that certainly the earlier that we can get our recommendations on Stage 3 out there gives the healthcare community the ability, first, the vendors to develop; secondly, to get people to implement, providers to implement. However, I want to caution us that we learn from this experience and that we get the feedback. If we just bulldoze ahead and do not wait and get so anxious to get out there with Stage 3 we do not wait to get feedback, and that to me is going to be absolutely critical that we make sure we do the public hearings, we get the feedback, and that we really hear what is going on out there. I'm hearing it every day, and I hope that everybody else is hearing it every day. So, yes, you want to hurry up, but I want to caution everybody let's make sure we're going in the right direction and we get the feedback.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'll just add to that that in addition to the feedback from the past, boy, this scene is changing very significantly. We may have another piece of legislation in terms of health reform that we want to make sure we're able to support, so that's why you're always between a we want to make sure we're relevant in 2015, you can't be relevant if you're planning in 2005 and so on and so forth, so we all understand that.

Gayle Harrell – Florida – House of Representatives

And you also want to understand the politics of this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, there's something happening next year. Judy?

Judy Faulkner – Epic Systems – Founder

Just a little bit on feedback and just to jump to a previous topic, which was questioning whether the quality outcomes were feasible for the vendors. And I did get feedback on that, which is "Generally I'm concerned with the volume of measures proposed and the timeline to have them all developed and implemented when some of them are still not yet defined," was the comment that I did get. And I think it's important to pass that feedback on. I don't know how much we're checking with the various vendors to say is this feasible. I think it may work the other way around in that there's a wait for the vendors to get back, but it might be wise to be proactively doing more checking.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Marc?

Marc Probst – Intermountain Healthcare – CIO

I think you covered it, Paul. I think the hearing is going to be great. But we talk about measures and data, are we defining that, or is someone going to define in that what we want. We're going to get all kinds of data, what are going to be meaningful measures that we can look at that would shift our thinking on where we're going. I think kind of related to that, we've talked a lot about updating the plan or getting more specific about what our vision and plan is for the end state, and is that built into the process of the hearing or is that a separate path that we need to take?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think it is part of the process, so the hearing is information gathering but we are looking for more of a strategic plan for Stage 3. That doesn't encompass all the work that the HIT Policy Committee does, for example. One of the things I think we're going to do next month in September is get an update from ONC on their progress towards their strategic plan. I think that will generate some discussion and we'll see, I think the question you raise will be relevant then. Does that make sense?

Marc Probst – Intermountain Healthcare – CIO

Yes, it does now.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I guess I'm feeling the need to talk about forward planning and – where are my notes – and backward planning. We heard CMS saying they do backward planning in order to rule out by the state here are the things that need to happen and put some more breathing room into the process between the proposed rule and the final rule. So it's not unlike a lot of project management activities, to do it right, where's the endpoint, what do we need to back up? I'm also hearing the use of forward planning talking about the need for feedback and what does it take to get good feedback from what's being done and all the constraints around that. They're going to collide, so my request would be that we don't get the synthesis, that we get the collision, so that when you guys report back that we see here's what we think we need going forward to get the feedback and here's how much time that would take, and here's how much time

we need for the timeline to happen. Then we can be part of the discussion of how to resolve that conflict, because I expect that they're going to overrun each other.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

If you think about it, it's probably already being, if you look from the forward and the back there's only a narrow window that we can even wiggle this one. So the default case would be if you followed Stage 1 and Stage 2, so take the year to go through NPRM and then final rule making process. If we were to use the Stage 2 timeline, for 2015 that would be the final rule in, let's say, June of 2014, starting the NPRM process in June of 2013. Feeding forward, we're really not going to get substantive experience from the field until at least the first half of 2012. To speed it up we would basically, during the latter half of 2012 to give another six months lead time. It's not as if we can move mountains in a sense, we're sort of boxed in on both sides, as you said, but six months is still a long time and we would love to be able to give people the flexibility and the lead time in planning to do this.

M

... where we can compress schedules, but again not doing violence, because there's a lot of alignment and will we have enough information in order to feed that next process is something which you just identified is important to us. We don't want to move too fast, too forward, because we do need that information in order to determine what Stage 3 is going to look like.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

The other piece we've talked about today, I think quality measures is really a huge deal, particularly in the new world, because it's not going to be just a publicly reported measure. It's going to turn into payment qualification. And we already heard that the quality measure developers, particularly for the new measures, need a lead time at least 18 months, so it's the same issue. That's what's squeezing us into this box. We want to give as much direction and guidance to the ... developing not only the product, but the quality measures that we're going to want to report on, as we said, want to report on from the EHRs so that the providers get that benefit every day. And we've got to give as much warning as we can, so I presume the ONC are seeing this contracting that's going on, measure developers is going out soon, but that's a guidance that I think the more we can provide the better.

Neil Calman – Institute for Family Health – President & Cofounder

This is Neil. Can I make two quick comments?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Absolutely, Neil.

Neil Calman – Institute for Family Health – President & Cofounder

The first is that while I agree that we should stay grounded in where people are at in our experience, if we publish anything in 2013 by the time 2015 comes around the market and the processes and the things that people are doing are moving so quickly that we run the risk of providing a set of criteria that will have already been surpassed by the market and what people are actually doing. This morning I was on a conference call and 93% of the 60 health centers in New York State already have fully adopted electronic health records. Who would have predicted that two years ago. I think that we're in a place where we also need to be thinking about where the puck is going three years hence. So that's the first part. I think that it's really important from the perspective of trying to use whatever clout we have to figure out what the gaps are and where things would not move naturally, because you remember we talked about this many times, we have some ability to move things in a direction where we think there may not be enough natural movement, so for that maybe quality measures are going to be critically important, but for that maybe the patient engagement and other kinds of goals that we've put forward are the ones that are going to be lagging behind some of the other uses and we might want to focus there.

The second comment is I think one of the things we've had the most difficulty with is part of the first goal of improving efficiency and reducing cost, and I think as we move forward we hear the country focusing on that more and more, and I think we should reopen that issue in a big way as we look forward and think about the kinds of ways that electronic health records could potentially really focus on that as a very

important outcome, and maybe also think about how integrating payer information into electronic health records and figuring out where the synergies are between them could be one opportunity that we haven't really approached yet for how we could address that goal.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good points, Neil.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair

Paul, this George.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Hey, George.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair

Neil's comment, I agree and I think two things about it. First, we've learned in the last year that we can separate things like new functionality from thresholds and we can be clever about how we've advanced them in such a way that doesn't set the vendors back because something gets advanced close to the time that it gets implemented. But the other, I think more important is what Neil is saying, I think we have to pick the themes that we really need to advance, because, A) they're so important; and B) they wouldn't happen otherwise. That's the criteria for I think an essential theme, that it's really important and it won't happen unless we do it. Those are the things that we really need to focus on, and then see everything else we do in that context. I realize that the big theme is healthcare reform and we need to see it in that light, but still I think we accomplish the most when we feel like this is what we need to get through in the next two years. It won't happen otherwise.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Just to pick up on that theme, because I think Neil's counsel is very wise, we want to have timely recommendations. We don't want to just seize the moment and do something specific to an initiative. An example, just to throw out, it's just the kind of thing that we might want to think about, instead of focusing on a quality measure, I think the infrastructure is what's getting in people's way, so the challenge of getting quality measures out of EHRs or from wherever they come from is all these data with different definitions entered by different people and different workflows is what's getting us, because we do not know what we have in our system and hence we can't create these comparable measures. Potentially a lever could be to set up this quality measure and quality data element infrastructure that's in common used by all the EHR vendors, then the rework done by each vendor would be much lower and the rework done by each provider using those vendor tools would be lower. It's things like that, where I think we want to go at the infrastructure level so that we have a platform to build on in the future rather than taking on individual measures at a time.

Another example was getting information like functional status or experience of care from patients, understanding the infrastructure for how we get patient entered data in a consistent, standardized way, that's yet another kind of infrastructure piece that we would have an influence on, and that would serve us in posterity rather than picking on specific things. So those are the kinds of things I think we're thinking about for Stage 3 rather than some of these process or individual functions. That's a thought offhand. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I want to build on that notion of maybe the focus needs to be more infrastructure. I think that that actually gives us a lot more flexibility going forward, especially as we're going to be seeing much more broad use of all kinds of outcome measures. I also want to go back to your comments about taking a look at strategic planning and where we're going. That conversation actually might be a very helpful one for going from let's look at the broad picture and then do something that happens in enterprise architecture kinds of things with what's called traceability. So take these broad notions of strategy and then start to trace how they get implemented so that we can look back and say what aren't we covering well. So similar to some of today's comments that the measures of patient engagement are actually measuring patient engagement, that we should look critically at how our strategy is mapping toward what we're trying

to achieve and be able to ask broader questions of, so, if our goal is to have a learning system, are we missing that goal by all of these particulars and what would we want to have that addresses learning. And maybe we have the conclusion of it doesn't show up in the technology, which could be fine, but we should have the discussion and reach that conclusion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think we're wrapping up this discussion. I think the discussions this morning have been very helpful and like usual, there are so many good ideas and good perspectives to the topics that we talk about that it's very useful. It did put us a little bit behind, 20 minutes, but I think it's been well worth it. So let's move on to the update from ONC with the Beacon program.

Jodi Daniel – ONC – Director Office of Policy & Research

Thank you. We wanted to give the committee some updates from our programs and as you heard from Farzad, we're in the process of doing regional meetings across the country, so we had a hard time getting our program folks to find the time and actually to be in D.C. to do this, but Craig has generously offered to talk about the Beacon program, I guess he's holding down the fort while everybody else is traveling, so we're looking forward to hearing his comments and to give you an update on that.

I also wanted to just address a couple of issues and things that folks have been asking about and that hopefully you'll be hearing more about in the future. One, I've gotten some questions about strategic plan. I just want to let folks know that we're just in the final stages of incorporating comments that we received, so hopefully that will come out in the next month. That's it ..., so looking forward to talking more about that if folks are interested in hearing more about it.

I've heard questions and follow up to the Certification Adoption Workgroup on usability. I just want to let folks know that we really appreciate the input of the Health IT Policy Committee, and holding the hearing and giving us some of their thoughts on that. We are currently working with NIST on a draft "EHR Usability Protocol" that they're coming out with, looking at the science and human factors related to usability. When they do come out with a draft of that it will be available for public discussion and input, I think they're planning to have a Wiki to give people an opportunity to provide input on that. So that's still in the works. That was something that they said that they were going to be doing and talked about it at their public meeting. The expectation is that some of the things that were discussed in the letter will be addressed by that. There will probably be some opportunities though for input from this committee, and I could follow up more with Paul and Larry and Marc about how the committee can provide some more input.

We're still looking, ONC's goals, or at least the way I've been looking at the policy related to usability is that we both want to increase transparency on the usability systems as well as increasing the usability of the EHR systems while not impeding innovation. So we'll obviously be asking for more input from you all on how to do that. But it is still in process, NIST is still doing their work, and we are talking with them, and there will be plenty of opportunity for input on that before any decisions are made on how to proceed with that. So I wanted to give that update.

The last thing I wanted to mention is that with respect to consumer eHealth, and I'm sorry some of our consumer focused folks are not sitting here right now, but ONC will be coordinating several events and activities starting in early September related to consumer eHealth, and this committee in talking about the strategic plan, did identify consumer eHealth, it kept coming up over and over as something that was a ... priority. Again, we always appreciate the insights of this committee. We will be doing some events and activities starting in early September, including as Christine alluded to and I mentioned, a new consumer facing Web site that will be launched at about that time. Our goal is to increase awareness among consumers on how health IT and getting access to their information can help them partner more effectively with providers to improve their health. Hopefully we can give you some information and insight at the next meeting about our consumer eHealth plan. Thanks.

With that, I'm going to turn it over to Craig to talk about the Beacon program.

Craig Brammer – ONC/Beacon

Thanks, Jodi. Do you folks not eat lunch? That's my question.

W

No breaks, no lunch hour; we work them very hard.

Craig Brammer – ONC/Beacon

Well, thank you for the opportunity to join you all here. I have two aims today. One is to briefly give you an update on where the Beacon community program is and where we're headed. Then my second aim is to share with you some opportunities that we are leveraging to have a close relationship with leaders out in communities out in America and maybe to have a dialogue about how that relationship could be useful to you all in your deliberations.

The Beacon program aims are three. One is to build and strengthen; two is to improve; and three is to innovate. The HITECH Act has spread across the country like peanut butter. There's meaningful use across the land and an REC everywhere you turn, and states working on Exchange, etc. The thing that attracted me to the Beacon program and then our little team is that there's a little part of HITECH that said, let's find the early adopters, let's find the innovators, let's learn from them, let's see if we can accelerate their work, let's use those as learning laboratories, and so as you know there are 17 communities across the country that received an average of \$50 million over three years, technical assistance from leaders in the field, and the opportunity to learn from one another at the Learning Network. Their aims are bucketed into these three categories: build and strengthen each of these communities at a trajectory. They had already been doing this work. Beacon is a blip in their lifetime of long effort in their regions to improve healthcare with IT enabled strategies, so these include things like adding a Master Patient Index that's new and improved, or data repository, or leveraging their HIE that's been long standing and building up the function of the analytic functionality of that Exchange spreading CDS, and I'll go through some of these examples.

Two of them proved they literally had two set targets in quality cost and population health, so three parting goals, and so they're working diligently to drive improvements in things like hospital readmissions, measures on chronic disease like A1C levels and blood pressure levels, etc. Doing improvement work within a closed system in a three year time is difficult, doing it in an open system like a community is a mind meld challenge. So they are feeling the heat, let me just tell you that. We're about halfway into this and they spent a lot of times on measures and aggregating data, just that step alone is monumental, but actually driving improvement with that data is a huge task. So we're very excited and happy to talk about some examples.

Third is innovate. We challenged them to do something new, something novel. These include things like mobile health applications. I'll talk about some new data aggregation analytic models, etc. So what are they doing literally? Well, I won't read all of this, but I just wanted to give you a flavor. Many are working on transitions of care, there's a lot of work around care management, and I'd say a good portion of Beacons are designing centralized care management infrastructure often established on top of an HIE. So take the keystone project, for example, where Geisinger Health Plan has done a lot of terrific work within their system and is now working through Beacon to extend beyond their walls to other participating community hospitals throughout central Pennsylvania, and leveraging their intellectual capital of course as well as the Health Information Exchanges in that region to deliver centralized care management functions. The decision support work, both within EHRs and also centralized, so Grand Junction, Colorado and Tulsa, Oklahoma are deploying Archemides, for example, in a central fashion, so each night in Tulsa there's calculation on patient predictive models calculated and then the physician has real time as he's sitting there with the patient on the whole suite of Archemides in the go tools to help patients understand the risk profile, what would happen if they took a statin, for example, changing their risk profile.

There's a lot of work on measurement and reporting that we can go into, both at the EHR level but also, as you discussed today, at the centralized level. So an example there is Indianapolis, which has a long

history of aggregating clinical and administrative data, long being a relative term, over the past few years. They are part of one of the Medicare 646 demo sites, so they have CMS data, as well as WellPoint data, Medicaid data that they aggregate, and simultaneously they're getting laboratory and other clinical data from a large number of providers. They calculate a suite of metrics that are used to feedback to providers, but also used by payers to drive incentives, so WellPoint, for example, bases their incentives on the results of those announcements. So their Beacon project is largely to expand that effort from 12 counties to 42 counties in central Indiana.

They're doing some other cool work around remote monitoring, etc. There's a lot of work around linking public health registry data, population health analytics, looking across the community, I'll give a couple of examples there, and some work on PHRs, telemedicine, telehealth. Some core interventions on that improvement dimension about a dozen are working on transitions of care, touching about a quarter of a million patients. A lot of care management. A lot of primary ambulatory care redesign kind of work, medical home type efforts. Again, a lot of CDS measurement and reporting is pretty much ubiquitous. I actually think that numbers a little low. It's more than 12. And again, a lot of work around aggregating multiple data sets across the region. For example, on the big island of Hawaii, which I tell them it's like the Galapagos Islands of healthcare, there's really no natural predators out there and it's just evolved in a very curious way, but they are pursuing a partnership with Microsoft, ... and others in a major health plan really aggregating a lot of population level data and so while we don't see that a lot in the country, I think that's the place to watch to test out this more aggregated approach.

So, we tell them to show us the path. What are you going to deliver? And I just thought I'd give you a couple of quotes here. In May some communities with small end results, and this would mostly be anecdotal, so we don't expect them to have P-values in the spring of this past year, here's what we're trying to accomplish. Here's an example from the Geisinger team, so far Beacon care managers have touched about 1,800 chronic disease patients deemed to be at high risk. We identified 500 care gaps, including 30 serious medication errors. We'll continue to track this and by the winter we'll be able to say with more confidence how many readmissions we think we've avoided in the first cohort of patients.

Here's an example from Tulsa. They say by December of '11 we'll have 15%, 202 of our targeted new physicians using the online doc to doc specialty referral system. That's a very interesting, novel way for primary care physicians and clinicians to coordinate care even if they use different electronic health systems.

We'll be able to report counts of communications between referrals and report outcome measures for these interactions, and it's gaining a lot of attention. We've brought them up to CMS and there's a lot of attention within CMS and the innovation center about this, particular model in Tulsa. In Southeast Minnesota the Mayo team and their partners say by April of '12 seven thousand asthmatic kids will have received documented asthma action plans from providers, obtained consent and registered across all 47 school districts in the community, achieving 25% of the target population. This number will grow to 18,000 by April of '13, so it's a pediatric asthma project that links public nurses and schools with their clinicians.

Just some examples, some examples of eHealth efforts, again, I'm not going to read all this but a lot of remote patient monitoring work, a lot of work around PHRs. I'm looking at Judy down here, and one of the Beacon sites is Cincinnati, that happens to be my hometown, and I know in some corporate office of your shop there's a map of the United States with a big bull's eye on Cincinnati, Ohio, and congratulations for executing on that map. Cincinnati is now an epic town entirely. And the PHRs are, each system's standing up my chart and so the community is saying, how do we promote the use of PHRs in our community.

We have the full engagement of the ten Fortune 500 companies based in Cincinnati, Procter & Gamble, GE, Macy's, etc., who want to engage their employees in using PHRs. So this is an example of how Beacon is thinking about this. The thinking is, let's put on a public campaign to promote PHR use and help consumers understand how to use that. A lot of patient engagement work, mHealth work, that last line you perhaps read recently, a partnership with some Beacons that we organized with ADA and the

CDC and ... that does the text for baby and some other mHealth work to in those Detroit, New Orleans and a couple of other communities launch an mHealth application where pre-diabetics take a risk profile on their phone and then are linked to community specific resources. So you have a risk profile of this and we encourage you to contact a diabetes care manager and here are the numbers in your zip code kind of a thing.

These are just examples. I also wanted to share with you the technical assistance priorities that we have. We have a terrific team that includes Booz Allen Hamilton, Brookings, Dartmouth, Institute for Healthcare Improvement, and quite a few others, focusing on five dimensions: clinical transformation, a lot of transitions in care work, so what does the IT strategy that sits beneath the strong transition strategy, a lot of work on meaningful use IT measurement, leadership and governance, which turns out to be pretty hard, how do you get health systems in San Diego, for example, CEOs in a room together to talk about data sharing for very specific use cases. And finally, the sustainability business plan that is of course the payment reform discussion.

What are we learning here? ... in health fairs recently, but some fairly straightforward learning so far, a clearly defined population is important, you have to know which patients you're really trying to work with, Strong leadership and governance is obviously essential, and we see terrific leadership in Louisiana, as an example. Secretary of Health, Bruce Greenstein who's Bobby Jindal's top health guy, was a former Microsoft global health leader and was known to be a very strong leader, has said the New Orleans Beacon is the prototype for our strategy in Louisiana using IT to drive improvements. So we see that increasingly strong leaders coming to view this Beacon opportunity as a proving ground. Now, again, measurement and feedback systems are essential evidence-based interventions, obviously and local learning system notions.

That's where we are. I'm happy to answer any questions. We can go on, but what I also wanted to just address is this function that these Beacons are serving for us at ONC that I think we under-appreciated going into this program, and that is that they're on our team, all of our team, they're believers, they've drunk the Kool-Aid, but they're real Americans. They're out there just slugging it out. They're in Tulsa, Oklahoma; and Cincinnati, Ohio; and Buffalo, New York, and so what we've come to appreciate more fully is the tremendous luxury of having a close relationship with those people. The reason I'm here is that some of our team members that might have spoken are actually out on the road sitting down face-to-face with CFOs in hospitals really talking through the things that we all care about.

Let me just give a couple of examples of what we're doing to leverage this asset and then pose to you the question of how you might similarly use this resource for some of your deliberations going forward. Performance measurement, an example there is we are launching now, have launched a patient report outcome strategy, you've discussed this today, this was with Geisinger Mayo and Elliott Fisher and team at Dartmouth. David Lansky has been an adviser to this process, but we want to get started. These are health systems that want to get started. They want to use this Beacon opportunity as a way to begin to learn how to capture patient report outcomes in electronic form.

Measures, again, we are constantly facing this chasm between the people who are very smart about measures in the abstract and the people who are very smart about measures in the implementation. I think about theoretical physicists and applied physicists, we have theoretical measurement folks, and applied measurement folks, and often they're not in the same room. So we'll be hosting an invitation meeting on the west coast this fall that will bring those people together, folks from the AMA and National Quality Forum, as well as people in real hospitals, real large IPAs that are actually trying to implement this and try to just work through this intersection in a very deliberate way.

Work on vendor interfaces has been an ongoing challenge and the Beacons has committed themselves to this and have spent a non-trivial amount of their time, energy, and resources to investigating how to consistently aggregate or receive data. Most of these are health information exchanges that have been well established, so they're not new to this space, so folks like Indianapolis, Cincinnati, Buffalo, and other markets where there's long standing exchange. They have done a lot of work with the vendor community, had a big meeting at the HIMSS with the vendor community about agreeing on some

common strategies to test interface deployment. They are, however, helping us at ONC appreciate the tension between their work, the early adopters and this kind of work, with the S&I framework, which is on a different timeline. So a lot of the Beacons are participating in both and recognizing that we have a short term Beacon name we have to get a blood pressure because we said we'd measure blood pressure. We've got to get this. We don't care if it's clunky. Meanwhile, this elegant S&I framework, and so you can appreciate the tension within our office actually, not Jodi of course, so examples of the real world challenging our thinking, which is absolutely healthy and terrific.

A couple more examples, CMS has leveraged this opportunity with the Beacons, so just recently we held an event in Indianapolis where John Blum and some other senior leaders from CMS came to meet with hospital CEOs, health plan leaders like WellPoint and others, and Informatics leaders, Regenstrief and others, included folks from Indianapolis, Cincinnati, and Geisinger. We spent an entire day in a very structured way going through the ACO rule and what are the IT and information implications of the ACO rule, and working through this very tough set of questions. CMS has followed up on that ... visit a couple of weeks ago, we've had two meetings with CMS since that now, and again using this opportunity of these canaries in the coal mine that I always invite you to consider.

Just a couple more, just to whet your appetite a little bit more. We had some communities that are committing to cost containment. Well, it turns out that our belief is that not just the Beacon communities but across these United States of America there's a little bit of magical thinking about cost containment strategies, and providers sometime saying if I get a 9% reduction in readmissions I should get a big Publisher's Clearinghouse check. So we're challenging their thinking in these communities and we have three in particular that have pretty robust business plans about the ROI of their work. And so we now in the fall will be having a meeting with CMS actuaries and actuaries from health plans and elsewhere who will actually just kick the tires on this and really challenge the thinking of a lot of these cost containment ROI analyses. We're looking forward to that and the output that will come from that that will spread to other communities.

A couple of other examples of work we're doing, but I would just encourage you to think about it, what a mechanism would be to bring some of those folks. They're out there. They're committed. They're struggling. But they're fully passionate and I think a tremendous resource to this community, to this effort here.

One last thing I will mention and then I'll conclude. This is a novel. This is not in the original Beacon plan, but when Erin McKeeseon and I got to ONC literally our first week we started meeting with CMS lawyers about accessing claims data. It's a national treasure. It would be like the Washington Monument that says only a few people are allowed to visit. We've got to unleash the power of this data set, and obviously appropriately, with safeguards in place. I'm happy to report that on August 15th, a few short days, will be the first release of our analysis for the Beacon region. So we're able to jump through an unbelievable number of hoops, but with partners at CMS figure out a pathway to actually receive beneficiary level data from the chronic care warehouse in real time. So this is not 18 month old data. This is quarterly updated data. What are we doing with that? We have a series of subcontractors that include Booz Allen Hamilton, Buccaneer and Brandeis University, that are receiving those data, have built an analytic tool that precludes the communities and their providers from getting beneficiary level data, but allows them to do some very sophisticated analysis on those data sets.

Here's an example of some of the measures that they will be able to calculate. Our first release will be at the regional level, so it would be for 42 counties in Indianapolis, interesting, but we need more granularity. Over time we will evolve this model to the point that, our aim is that individual provider systems will be able to identify hospital, for example, that is in a ... ACO frame of mind, will be able to identify the physicians associated with that health system, attribute patients to that proto ACO and actually get some intelligence about how they look relative to some of the ACO rules. It's really an ACO model as well as other things and it helps communities understand how they're performing over time against their aims. That's it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you very much. That's very fascinating about some of this work that's going on in the Beacon communities and I think your offer in terms of using some of their experience to end their ongoing work would be very helpful. We've come up with some policy questions, whether it's quality measures, privacy, the view and download, I wonder if there is a mechanism, a channel which we can put out some of these questions we'd like to get some input from the field on, recognizing these are the canaries, these are the Beacon communities and they won't necessarily generalize to the rest of the country. But I wonder if we can develop a channel to filter some of these policy questions we have.

Craig Brammer – ONC/Beacon

I'm sure Jodi and I would be happy to work together with some recommendations on –

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That would be good. Other comments, questions?

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Sure, I'll jump in. Let me take Paul's notion of engaging a richer dialogue here. I expect that since these people are out there in the coal mine, as it were, that they're going to see things we don't know to ask about. So I think the dialogue needs to go both ways. So questions or insights they have that they think might affect policy that they'd like to tell us about, no one's talking about this. We don't know why it seems to be really valuable. So those kinds of comments coming back to us would be great.

Art Davidson – Public Health Informatics at Denver Public Health – Director

This is Art. I'd like to return to a couple of earlier comments from the day and see how they match up with Craig's canaries scenario here. Earlier today we spoke about the quality measures and how they should be, and I think Paul Egerman had suggested that they should be built into the EHR, and I think that Craig has given us some examples of these Beacon communities that have found a different way to sell some of these quality metrics; one in my state and another one in Indianapolis serving Indiana. There were a couple of comments earlier today about, and sort of a question in David Lansky's letter, about how we would use PRO, patient reported outcomes, in an EHR. And I think Neil also brought up the issue of how claims data could be used. What I heard in Craig's comments is that there are places where there can be aggregation of data to benefit the patient and the provider in improving the care. It seems like the last thing that he mentioned was that there's an opportunity for benchmarking, which might not be possible if we built all the analytic capacity right into the EHR. I agree. At the point of care when you're seeing the patient the next day is when you need it, but it sounds like some of the models that Craig has described offer that to the providers in those communities.

Craig Brammer – ONC/Beacon

I believe that's right. I think we're all wrestling with where's the locus of aggregation, attribution, and analytics. So there are communities that are working at that at a higher level than the EHRs. I'm sure our colleagues would agree with the notion here that should not excuse the EHR products from being able to do those analyses.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. Anything else? Thank you so much for the update. It's very, very interesting, ... the Beacon. Before we turn to public comment I just want to ask a question, and this might be an opportune time to ask a question on this experiment of a short agenda going through lunch instead of breaking for lunch. What do you all think? Actually, everybody likes it. Okay, that was just some feedback that we wanted.

All right, let's open it up to public comments before we –

Judy Sparrow – Office of the National Coordinator – Executive Director

If anybody in the room wishes to make public comment please queue up at the microphone. A three limit time limit and please identify yourself.

Laurie Bowman – Hospira – Director of Federal Government Affairs

Great, thank you so much. Good afternoon. My name is Laurie Bowman. I'm Director of Federal Government Affairs for Hospira. Hospira is a global generic injectable pharmaceutical, clinical information and medication delivery company. We're headquartered in Lake Forest, Illinois with seven manufacturing sites in the U.S. and 14,000 employees worldwide. Today I'd like to talk about the importance of clinical surveillance in addressing healthcare associated infections and antimicrobial resistance, both of which have become health crises and major healthcare cost drivers. This issue is closely aligned with two proposed Stage 3 Meaningful Use objectives, first to include a public health button for eligible hospitals and eligible providers, and second, to include patient generated data submitted to public health agencies. As you all know HAI is a major public health threat to public health and healthcare financing. According to the Institute of Medicine, HAIs cause or contribute to nearly 100,000 deaths annually and add as much as \$33 billion annually to the cost of healthcare in the United States. On top of the growing problem of HAIs these infections are becoming increasingly resistant to antibiotics. Infections with resistant bacteria are resulting in longer and more costly hospital stays. Overall antibiotic resistance is responsible for an estimated \$16.6 billion to \$26 billion per year in extra cost to the U.S. healthcare system, while national awareness of HAIs and antimicrobial resistance has increased over the last few years, there's still a major obstacle that is hindering progress in these areas: the obstacle is lack of surveillance as well as timely and accurate data of HAIs and antimicrobial resistance. A wide range of stakeholder groups as well as several federal government agencies have come together to address a serious public health, healthcare financing and healthcare delivery problems, and you can read more about that in my full testimony, which you all will get copies of.

Electronic surveillance allows healthcare facilities to identify HAIs faster. One prominent hospital reported that real time electronic surveillance improved identification of patients requiring isolation and timeliness of isolation for patients with 11 different multi-drug resistant bacteria and viruses by an average of 72 hours per patient. They also reported that electronic surveillance reduced clinician time spent on surveillance activities by 80%, HAI confirmation time by 50%, while achieving a 98% accuracy in identification of HAIs. By diagnosing infections and providing appropriate treatment earlier, an average 200 bed hospital could save close to \$185,000 per year, which would translate in approximately \$800 million in savings per year to the U.S. For these reasons Hospira urges the committee to add use of electronic clinical surveillance systems in Meaningful Use Stage 3. Hospira thanks the committee for allowing us to raise this important issue today. We'd be happy to provide formal testimony at some point in the future, and please consider us a resource moving forward. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Ms. Bowman. Next?

Dr. Cheryl Whitaker – Illinois Health Information Exchange Authority- Chairman of the Board Thank you, I'm Dr. Cheryl Whitaker. I'm wearing two hats. One as the Chief Medical Officer of Merge Healthcare, it's a healthcare software solutions company. But today I'm here as Chairman of the Board of the Illinois Health Information Exchange Authority. I'd like to present a problem to you that we're having. I notice that in the conversation today this is an issue that I hope that we're actively tackling at this level. As we attempt to stand up our health information exchange in Illinois here we are noticing and hearing complaints from several of our downstate partners that several EMR vendors are charging very large sums for interfaces from the EMRs to the HIEs. This is an important problem because the level of EMR penetration that we get will help us with our sustainability issues. It's a very important part of our sustainability equation.

The more people who are engaged in EMR implementation satisfactorily will determine how successful we'll be in standing up our HIE. These cost us so much that they can actually absorb all of the incentive monies that are available to providers. We find it difficult to understand how EMR can be certified to be interoperable when the providers are going to be charged large sums of money to make the products that they purchased under the assumption it would satisfy the meaningful use turned out not to be able to be meaningfully used because they are not interoperable. The standardization issue figures here very prominently. EMR vendors also have concerns about having to construct point-to-point interfaces because the current standards are so loose. That is one of the reasons for the large interface cost. If uniform standards were adopted a vendor would only have to write and maintain one set of interfaces that

all of their clients would use guaranteeing that interfacing costs would not drive the vendor out of the market or damage his profit in any significant way. We are suggesting, we're encouraging, we're hopeful that there will become an annual process where new standards are added according to a public schedule and that EMRs are incrementally recertified based on these additions. We'd like to suggest that this issue be strongly considered. I know that it was considered the last meeting and I'm bringing you some input from the ground. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. We do have somebody on the phone, Julie Cantor-Weinberg.

Julie Cantor-Weinberg – College of American Pathologists – Dir., Public Health & Scientific Affairs

Thank you. My name is Julie Cantor-Weinberg and I'm with the College of American Pathologists and I want to commend the Policy Committee for getting a report from CMS on the experience thus far, the adoption of Meaningful Use. It was interesting that the highest uptake is among family medicine practitioners and internal medicine physicians, and that points to the fact that in early June the Meaningful Use Workgroup had pledged to come back to the committee and HHS with the recommendations on how meaningful use Stage 2 and the recommendations the committee made would map to specialists. I think that highlights the urgency of getting to that work and the specialist community is very interested in hearing what the status of that body of work is. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Julie. We have one last caller on the phone, Tom Leary.

Tom Leary - HIMSS – Senior Director, Federal Affairs

Good afternoon. This is Tom Leary with HIMSS. Just two quick comments. One is I'm very encouraged by the discussion today and the announcement of the public hearing on October 5th and 6th and would encourage the committee to consider inviting participation by the seven organizations that submitted observations in a letter and presentation to Secretary Sebelius on June 16th. The seven organizations quickly are AMDIS, AMA, American Hospital Association, EHRA, CHIME, Federation of American Hospitals, and HIMSS.

The second comment is just to point out to the committee that September 12th through the 16th is National Health IT Week and we already have 84 organizations signed up to support the weeks' activities, to include organizations from academia, non-profits, and for-profits. So I look forward to the committee's participation that week as well. Thank you, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Tom. Thanks for that information. And thank all the public. I'll turn it back over to Dr. Tang.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I want to thank the committee for participating in an August meeting. And thanks for the rich discussion. We just had another example of a productive discussion and hopefully we'll keep advancing the ball. See you in September. Thanks.

Public Comment Received During the Meeting

1. We applaud the work on view and download. Access and viewing records by the patient will require a clear understanding of the records as acknowledged in the “patient specific education materials” in MU. The Blue Button Project does provide for some context that can allow for the attachment of contextually aware patient specific education materials. Will access to patient specific education materials be considered in download requirement?

2. Timely to this discussion - I should like to point out that CMS in their proposals for EHR based submission in 2012 is of identifiable patient data that CMS then would use to actually calculate the measures - does that change the focus of certification for the future to be on specification compliance for the detailed patient data required versus measure calculation that is the case with the Stage 1 temporary certification program?

3. And CMS also allows for use of registries and is describing a new type of entity for quality measure submission in their proposed 2012 rule making of a type of intermediary that uses data sourced from EHRs

4. Is that new kind of intermediary one that can be a vendor who can be certified for EHR based measure submission?