

# HIT Policy Committee Transcript February 6, 2013

## Attendance

### The following Committee members attended this meeting:

- Farzad Mostashari
- Paul Tang
- Christine Bechtel
- Christopher Boone
- Neil Calman
- Arthur Davidson
- Connie White Delaney
- Judith Faulkner
- Gayle Harrell
- David Lansky
- Deven McGraw
- Marc Probst
- Scott White
- Terry Cullen for Madhulika Agarwal

### The following Committee members did not attend this meeting:

- David Bates
- Richard Chapman
- Paul Egerman
- Charles Kennedy
- Frank Nemec
- Joshua Sharfstein
- Latanya Sweeney
- Patrick Conway
- Thomas Greig
- Robert Tagalicod

## Presentation

### MacKenzie Robertson – Office of the National Coordinator

Thank you, good morning everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is the 45<sup>th</sup> meeting of the HIT Policy Committee. This is a public meeting and there is time for public comment on the agenda there is one before lunch and there is another session at the end of the day. The meeting is also being transcribed so for the transcript please make sure to identify yourself when speaking. And I'll now go through roll call. Farzad Mostashari?

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

Here.

### MacKenzie Robertson – Office of the National Coordinator

Thanks, Farzad. Paul Tang.

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Paul. David Bates? Christine Bechtel?

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

Good morning.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Christine. Chris Boone? Neil Calman?

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Neil. Richard Chapman? Art Davidson?

**Arthur Davidson, MD, MSPH – Director – Denver Public Health Department**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Art. Connie Delaney?

**Connie White-Delaney, PhD, RN, FAAN, FACMI – Professor & Dean – University of Minnesota/School of Nursing**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Connie. Paul Egerman? Judy Faulkner?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Judy. Gayle Harrell?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislator**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Gayle. Charles Kennedy? David Lansky?

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, David. Deven McGraw?

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Deven. Frank Nemec? Marc Probst?

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

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Marc. Joshua Sharfstein? Latanya Sweeney? Scott White?

**Scott White – Assistant Director – 1199 SEIU United Healthcare Workers East**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Scott. Madhulika Agarwal? Patrick Conway? Tom Greig? And Robert Tagalicod? Okay with that I'll turn the agenda over to Dr. Mostashari for some opening remarks.

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

I wanted to talk a little bit about some of the comments I made at the first policy meeting of the year that caused some...maybe touched some nerves on the part of our good partners in this voyage who are the vendors. And I was talking about the need for us to have self-regulation as well as government regulation and something that stands between pure competition and government regulation and kind of codes of conduct and things of that sort.

And I got a number of calls since then from people who are really working hard to do the right thing every day, who are part of kind of the real engines of implementation and innovation who are meeting the needs of customers every day, who are in this because they're committed to health and committed to patients often times its personal experiences, who are professionals with high standards of excellence and customer service and right now said, look we're working really hard to get to meet this national movement and to get certified and to help our customers and it seemed like you were singling us out and saying, you know, that we're not acting in a moral way. And I just wanted to clarify what I did mean to say and what I did not mean to say.

What I certainly did not mean to say was that vendors as a whole are not doing the right thing or are not acting well and as I mentioned they really are doing really the bulk of the heavy lifting in the terms of implementation standing alongside their customers the providers in making the progress that we are making.

What I did mean to say is that there are times when we are part of a society, we're part of a community and we're not just individual actors and there are times when competition on its own does not yield the best results and surely we can use government regulation as one way to moderate when things are not in the...when that competition is not going to be in the public interest.

But we would much rather not need to and in fact it's not the most effective way to achieve progress is to use government regulation for everything. And there are some, certainly not all, not most, but there are some vendors who are "beyond the pale" in their conduct in certain areas and it is partly the job of the society to create norms, to create whether you call them, you know, mores or codes of conduct to say this is what we believe in and this is what we do not believe in and to create movement that does not require government regulation.

This could be around billing functionality that goes beyond the pale and we've talked about having the policy committee look at are there some functionality or some marketing, some activities that some vendors, not most, not all do that is beyond the pale. And I think beyond the pale actually, the anemology of that is, relates to a village's boundaries, right? Beyond the boundaries of what our village, our community considers proper.

Are there pricing and business practices, and we don't want the government to get involved in people's contracts, right? But are there some ways whether it's opaque pricing, these are the things that I'm hearing daily from other parts of our body, right, which are the providers who are saying to me every day about some pricing or contract requirements where they feel it is unfair to them. And wouldn't it be great if together if together there were some norms established around transparency of pricing or having pricing reflect more the costs that are incurred.

Data lock-in, clearly not in the patient's best interest and often times not in the provider's best interest and yet we continue to hear concerns on the part of providers about data lock-in and yes we can, and we will take regulatory action where needed and set policy levers where needed and have certification where needed to do that, but we can't have it purely be a function of I will do exactly what is legally required of me, no more and no less.

Portability when people want to move systems, reporting of adverse events we've even heard that some customers perceive that there is a chilling effect in terms of the language in their contract, there is not clarity about their ability to report safety events. And our approach in the ONC Health IT Safety Surveillance and Action Plan for Safety quite explicitly says we will use regulatory levers, we will use authorities, but we're also counting on vendors and providers to step up too, if they don't then we can always go back to more classic regulatory approaches, but what I'm saying is I would like us to have the community define the norms of the community and use that as a way to get progress as well.

So, I just to clarify that, I want to apologize to any of our friends who are working very hard who feel that I was with a broad brush painting a story of a vendor community that is not meeting the needs of their customers, by and large they are, by and large the vendors really are the engines for innovation and implementation and are doing right by their customers. But, I am asking not just the vendors but also their customers to act together as part of a community to get us to where we need to go on data, on usability, on safety and on so many other issues where we really need to act together. Thank you.

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

Thank you, Farzad. Before I move on to review the agenda if I could get an action on the minutes that were distributed.

**W**

Move to approve.

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

Okay and any other editions?

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

I may need to review those minutes to be sure that it captured my tone accurately.

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

Okay, well we'll have a contingent approval on Farzad's review. Okay, all in favor?

**W/M**

Aye.

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

And opposed or abstained? Thank you. Just a couple of words about things that just recently happened and are about to happen, so last week we had a hearing on HIE and got to hear a lot of the success stories and some of the challenges some of which Farzad referred to and we'll have a full report out next month in the March meeting.

The second thing is coming up next week is a hearing on clinical documentation, it might have been motivated by some of the concerns around fraud and abuse, but we've expanded that to talk about really clinical documentation. It is a challenge, it's one of the bigger challenges in this implementation but there are also some opportunities and best practices there and how can we use clinical documentation like it was intended which is to record and advance the care process.

So, we have a very full agenda this month. We're going to start off with spending the whole morning on the public's response to the RFC on Stage 3 preliminary sort of draft recommendations that were put out there for public response. HIT Standards Committee will respond right after lunch, John Halamka is going to walk us through that.

Then we'll hear our update from CMS, Robert Anthony, and then move onto the Certification Adoption's Workgroup response to the HIT Safety Plan that was issued a couple of months ago by ONC. And then conclude with an ONC update and public comment both at the end of the morning session and at the end of the afternoon session. Any other changes or amendments to the agenda? Okay, a lot of time for input from the committee.

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

MacKenzie, Hashtag to use for folks out there listening or in the audience?

**MacKenzie Robertson – Office of the National Coordinator**

The Hashtag is actually listed at the top of the agenda in the right hand column, it's Hashtagitpolicy.

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

Thank you.

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

Okay, so we're going to begin with essentially a high-level review of the public's response to the RFC that came out of this committee in December and responses were closed I think it was January the 14<sup>th</sup> and have been reviewed by staff and summarized for us.

So we'll go through all of the summaries first in all of the areas from the RFC and then we'll have plenty of time for comments around the table from committee members. And this will be...we won't be addressing all the comments at this point. We're going to use this as further input into the Meaningful Use Workgroup and the Quality Measure Workgroup's digestion of both the public's comments and the committee's comments and bring that back to you in April. Okay, so who is starting out first?

**Jodi Daniel, J.D., MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

I am.

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

Jodi?

**Jodi Daniel, J.D., MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Good morning everyone, I don't have the slides, the clicker, okay, thanks. Anyway, I just wanted to start out by just giving a quick overview of where we are today in talking about this before turning it over to all the folks at the table who have the deep dive expertise on what we heard. Just to remind folks, we posted the RFC for the Policy Committee on our website on November 16, 2012, the comment period did in fact close on January 14<sup>th</sup>, it was a 60 day comment period, which we made 60 days based on requests we heard here that we keep it open longer and particularly in light of the holidays. As a result we did get many comments.

And I want to personally thank all of the ONC staff that have been working to review and summarize these comments that we did get...we are a small office, but had a pretty sizable team working through these comments and folks spent countless hours working extra, well above and beyond the call of duty to be able to come here today to provide summaries of these comments, and to be able to provide some of the high-level trends that they have seen in reading through the comments. So, I do want to publically thank folks for all of their hard work, the four folks at the table are just a subset of those that were diligently reviewing these comments.

We will today present the high-level review and have feedback from the Health IT Standards Committee as Paul has mentioned and then following this meeting, this is just to give folks kind of the overview of all the comments that we received, we will be bringing this back to the Workgroup to kind of go through the deeper dive of all the public comments and the feedback we get from Standards Committee so that you all can get the wisdom of the Workgroups in making recommendations to the Policy Committee and then ultimately to HHS.

So, I will turn it over to Michelle to start going through the comments, but really want to just highlight how much work went into making it here today with this level of detail. So, thank you all.

**Michelle Consolazio Nelson – Office of the National Coordinator**

Good morning and I too want to thank all my colleagues that helped us summarize, just keep in mind this is a very high-level summary. We will be taking a much deeper dive at the Workgroup level, but a lot of work from my colleagues went into getting this together so I just want to thank them personally.

I also just want to quickly remind everybody of the setup of the RFC. So, the RFC had a measures and objective section which included work from the Meaningful Use Workgroup and the IE Workgroup and then were some overarching Meaningful Use questions that we asked. We then had questions from the Quality Measures Workgroup and the Privacy and Security Tiger Team. So, Kory will go through the IE Workgroup section, Jesse will go through Quality Measures and Kathryn will go through the Privacy and Security section.

So, we got 606 comments altogether from various types of organizations, allied professional organizations, EHR consultants, hospitals, EPs, federal agencies, payers, provider organizations, vendors and vendor trade groups. So, a very diverse set of comments and we thank the public for all the comments that we did receive, because there was a lot of work on their part as well to get us those comments.

So, I'm first going to review some high-level themes that we saw within all of the comments related to Meaningful Use and where things are headed and where we should be going and then I'll take a deeper dive in the Meaningful Use specific objectives.

So, from a high-level perspective there were a lot of comments that there should be a greater focus on outcomes come Stage 3 and rather than having prescriptive processes which seem to appear, this is coming from the public, they were hoping for more flexibility that could possibly foster innovation from vendors and we heard a lot in the comments that they were overly prescriptive.

Some other things that we heard were concerns about timing, that perhaps we should consider pushing Stage 3 out little bit longer so that we can learn from the experience of Stage 2 before we start to think about increasing thresholds, accelerating measures or moving them from menu to core. We also heard that any new item should always be in the menu set and there also were some concerns about the readiness of standards in time for Stage 3.

Another concern that we heard quite a bit was that we need to start to address the interoperability limitations that are out there and if we address those we'll be able to facilitate sharing of information. And then we also heard that providers are feeling a little bit of pressure. So, Meaningful Use is just one component of the many things that they have to worry about. You know there are a lot of other incentive programs that they are also working towards PQRS, ACOs and providers are starting to feel pressure.

And lastly, we need to ensure that patient safety remains a high priority and need to make sure that we synchronize that with Meaningful Use. So I apologize I have a little bit of a cold, so I'm straining with my voice. One more item that we heard a lot is that there were a few items where we asked for a specific certification criteria, I think those items confused the public a bit; they weren't really sure what we were asking of them. Some thought they were actual Meaningful Use use cases and didn't quite understand that it was really just a certification only item. So, those themes you'll see throughout as we go through the high-level summary, but just to iterate overall those are some of the things that we heard.

So, diving into the Meaningful Use objectives, so I'm going to quickly go over most of these and just highlight the areas of concern. There is a lot to get through for Meaningful Use and as we've talked about we're really going to take the deeper dive at the Meaningful Use Workgroup level.

So, for SGRP 101, which is medications, labs, rads, which are recorded using CPOE, overall there was support for this objective and then there were various opinions about increasing or decreasing the threshold.

For CPOE used for referrals or transitions of care there was general support but there were some concerns for this one about the lack of interoperability standards.

For 103, generate and transmit permissible prescriptions, commenters were not in agreement with this proposal and they asked for some clarification and they had a number of concerns. And they thought that standards for preauthorization and formularies...I'm sorry, they suggested standards for preauthorization and formularies.

The demographics objectives 104. We received the most comments related to this objective, 337 comments around 100 of them were duplicate comments. It was a letter that we received multiple times pushing towards occupation and industry codes. So just keep that in mind as we go through the numbers. There were 606 comments but 100 or so of those were all the same comment.

So commenters were fairly evenly split on retiring this objective. The retirement...there were three items that we suggested to retire that also confused the public I believe. They wanted to understand what we meant by topping out and it was fairly evenly split for all 3 of the items that we suggested to retire. And there were concerns that if we did retire something that a provider would no longer collect the data which would then lead to disparities and quality loss.

There also were a lot of additional elements that people suggested that be required for demographics. And additional specificity for race and ethnicity. So, again the certification criteria related to occupation and industry codes, this is where we got the most comments. And there was overall support to add this in and then certification criteria related to sexual orientation and gender identity, most commenters also asked for inclusion on this but wanted greater specificity related to data standards and definition.

So, moving onto 105. The next three were all certification criteria only items and again these confused people a little bit. So for this one, overall commenters were concerned that this item as written was too vague and suggested that this would be included within the CDS item.

The certification criteria for up-to-date medication lists, many commenters expressed support for this functionality while there was also an equal amount of concern and they were also concerned about the vagueness related to the certification criteria.

For medication allergies, 107, commenters were actually in support of this one but they asked for clear and precise certification standards.

Moving onto 108, which is the vitals measure, again we asked if we should retire this one and comments were evenly split about whether we should retire it or not.

109, is another item that we suggested retiring related to recording smoking status and many commenters expressed support for this...I think, the wrong...I apologize, what you're looking at the wrong data is on the printed copy and up here, I apologize, but again this one there was concern about retiring smoking status.

For advance directives I know for sure the wrong comment is printed on the slides so bear with me and the correct thing is up on the slide. So, commenters suggested revisions to the percentage.

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

Sorry, Michelle, you're saying what's showing on the slide is correct, what's printed is out of date?

**Michelle Consolazio Nelson – Office of the National Coordinator**

Yes.

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

Thank you.

**Michelle Consolazio Nelson – Office of the National Coordinator**

Thank you. So, commenters suggested revisions to the percentage and they questioned whether this should be menu or core and they asked to enhance this objective by lowering the age threshold and they asked to include an actual advance directive document, and they also asked to establish standards for transmitting the advance directive.

On 113, the critical decision support objective, if you all recall we included a lot in this proposed recommendation and there was a common theme when there was a lot of information in an objective we got varied comments, lessons learned for the future where we may want to pull things out a little bit more so we get better comments.

But so, overall, people were evenly split on whether to push this a little bit further by increasing to 15 interventions. There were concerns about alert fatigue and lack of CDS interventions relevant to specialty practices. And they asked for clarification regarding whether the 15 interventions were to be at the practice or group level as it would be much more work for it to be done at the provider level.

And comments were very varied about the tie to CQMs and focus areas. Some opposed viewing it as too burdensome and a few felt that the links in focus areas were too arbitrary and detracted from the overall targeted quality improvement. And a few suggested that ONC focus on outcomes and let providers pick what CDS they need to improve for clinical quality measures.

There was a majority of opposition to the drug-drug interaction requirement and that was due to a source of alert fatigue. There was also concern that standards would not be available for structured SIG and few commenters were in favor of tracking provider responses to CDS.

There was also clarification suggested related to preference sensitive conditions and the criteria to be able to consume CDS interventions was generally met with support. And there were only a couple of comments related to the food and drug allergy interactions and those who commented were concerned about the specificity of information that would be available in the EHR.

So moving onto 114, incorporating clinical lab tests, most agreed with increasing the threshold to 80% and asked for clarification of whether this would be menu or core.

And 115, generating patient lists, most commenters agreed with the intent of this measure but asked for additional specificity.

On 116, reminders per patient preference, most agreed with increasing the threshold, but disagreed with decreasing the time period.

For 117, the eMAR objective, commenters agreed with increasing this threshold and the addition of tracking mismatches.

For 118, imaging results, commenters did not agree with moving this to core and they identified a number of barriers that would be encountered. They also asked for experience from Stage 2, which we don't yet have.

For 119, family history, commenters generally disagreed with moving this to core and a number of commenters asked that this be included in the CDS objective.

For 120, electronic notes, two thirds of the commenters wanted additional specificity before supporting while the remaining agreed with the proposed changes.

For 121, structured lab results, most commenters disagreed with moving this to core and increasing the threshold.

And 122, there was a new test tracking objective and commenters were equally divided on whether to include this or not. And many requested clarification, they felt that the wording that was used was a little bit unclear.

So moving on to engaging patients and families...

**MacKenzie Robertson – Office of the National Coordinator**

Michelle, can I just stop you for a minute, I just want to point out to the committee members that if you're looking for specifics of what was included in the RFC you have the large handout on the table if you want to read that as she's going through. Thanks.

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

Michelle, you're a really quick reader.

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

Another pause for Michelle so she can catch her breath and take a sip of water. It is important, I think, to sort of know that majority of comments that the majority comments said...but I think we need to be very careful about judging this on the numbers, because consumers submit comments but we're always, always not high in the numbers department, right? So, if there's a provision for example that the industry doesn't support but the consumers do, I can promise you that the weight of the numbers will show that most people don't like it, but we should just keep that in mind as we hear all of this.

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

And if I could just build on that and observe that...I mean we had at least...I know of at least 25 consumer organizations who did submit comments and about 18 employer organizations who submitted comments and those stakeholder categories aren't listed on the first page. So, I don't know if the letter like didn't go through because there are definitely some areas where comments did not...aren't reflected in the summary, probably for the reason that Deven described. But if we're not paying attention to what consumers are saying, I'm just worried about that. So, I want to make sure that if those letters are received, you know, we understand where those views are reflected and not. Thanks.

**Michelle Consolazio Nelson – Office of the National Coordinator**

Just on that note, I will say that this is a high-level summary, we did push for everyone at ONC to put together, you know, at a high-level and, you know, we were counting comments as Deven pointed out. When we get to the Workgroup level we'll get to see who made the comment, where they came from and really get a better understanding of making sure that all of the comments are seen and heard.

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

That would be great, I just...I'm really also calling your attention to that first slide.

**Michelle Consolazio Nelson – Office of the National Coordinator**

The first slide, yes.

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

Which has been absolutely conspicuously absent in a couple of categories.

**Michelle Consolazio Nelson – Office of the National Coordinator**

So, I will take full blame for that, that is me just going through just quickly summarizing this is who I saw.

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

No problem.

**Michelle Consolazio Nelson – Office of the National Coordinator**

I apologize Christine. And we are presenting again to the Standards Committee so I'll make sure I update that.

**Carol Bean – Director, Certification & Testing – Office of the National Coordinator for Health Information Technology**

Great.

**Michelle Consolazio Nelson – Office of the National Coordinator**

So 204, for engaging patients and families, view, download and transmit, and there was also a new recommendation for Automated Blue Button. So, a few commenters were concerned about increasing the threshold while there were others that asked for it to be pushed even higher, especially in this portion you definitely see the disparity between the consumer organizations and some of the other organizations. So, as we go through with Christine in the Meaningful Use Workgroup we'll just compare all of that.

So, there were a large number of commenters who were concerned about the providers being accountable for patient actions. And they were also concerned about the timing being increased or sorry decreased to 24 hours and 4 days for labs, but there were also a number of comments that they thought the timing was too long.

For the ABBI objective, overall commenters supported this but there were a number of areas of concern, some related to privacy and security, provider liability and some thought that this was something that would be better suited to a proposed future stage.

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

I'm seeing Michelle...I'm seeing some puzzled looks, ABBI is Automated Blue Button Initiative, so the set it and forget it.

**Michelle Consolazio Nelson – Office of the National Coordinator**

Thank you. And there was also a question of whether imaging and radiation dosing should be added and most commenters were supportive but there were a few caveats that patients would need education for radiation dosing. There were concerns about how we would include imaging and there could be some bandwidth issues that we could encounter if it's not integrated through a link.

Moving onto 204, submitting patient generated health data. The majority supported this but, again, there were some clarifications suggested to better define what is a high priority health condition. Some were confused as to whether this is both an EP and an EH measure. Again, there were concerns about providers being accountable for patient's action and some were concerned about the availability of standards to differentiate between provider information and patient information.

And there was a wide disparity and comments related to the timing of this measure, some wanted it pushed to core while others thought menu was appropriate and even others thought it really should be pushed out to a future stage. Most commenters were concerned about the readiness of standards for medical device data.

Moving onto 204D, requesting amendments to the record. The majority supported this item, but clarifications were suggested. They wanted to define what it means in an obvious manner, documentation requirements, whether or not the provider must accept amendments and what parts of the record could have amendments submitted.

They also noted a need to differentiate between patient and provider data and notify patients if there was an amendment that was not accepted into the record. And many sought clarification on what the measure and threshold would actually be.

Moving onto clinical summaries, commenters were overall supportive of evaluating this measure to ensure that the clinical summary is pertinent to the office visit. There was a robust list of items that we had asked for what items should be included so we got a robust list of things that should be included. But some common themes were to provide information to the patient that facilitates concise and clear access to information about their most recent health and care and understand what they can or should do next.

Commenters were concerned about the current format of many vendors summaries and some of those concerns were summaries are too long, not in plain language and there are some language limitations. So, they were asking for some standard support possibly. And quite a few commenters were confused and wanted clarification on what pertinent to the office visit actually meant.

Moving onto 206, patient education many supported this recommendation, but suggested changing from the Non-English language from the top five national to the top five local. And some of the other comments included many Non-English speaking patients may not have the ability to read the material and the materials may be printed at too high of a reading level. And they also encouraged adding visual or pictorial materials and Braille.

Secure messaging, 207; most commenters did not support increasing this until we learn from Stage 2 experience. And many commenters recommended including family and caregivers in the measure. And there were, again, concerns about providers being held accountable for patient actions.

For 208, recording communication preference, most commenters supported this requirement to document communication preferences and agreed that it was necessary in order to ensure patients receive information in a medium that engages them, but some suggested constraints around being too prescriptive.

For, 209, query for clinical trials. So, most supported this, but there were some concerns related to implementation challenges including the complexity of the functionality that would be required to query. They were also concerned about the lack of specificity related to standards.

Moving onto care coordination, reconciliation of medications, medication allergies and problems, 302, overall commenters were supportive of this measure, but there were some concerns about the ability to measure outcomes, differences of opinion on the percentage needed to be obtained to move with the objective and they also requested for clarification on whether...I'm sorry...they also had some areas of clarification.

So, most commenters asked for a higher threshold for reconciliation items. And they also asked for additional items to be reconciled such as caregiver names and numbers while some others were not supportive of adding additional items to be reconciled. And others were also concerned about how this would actually be measured and the readiness of standards that are available.

For 303, the summary of care objective, there was strong support for the intent of this objective; however commenters were concerned about the burden imposed by the objective and the lack of standards and experience from Stage 2.

For 304, the care plan objective, there were a few commenters that suggested we combine 303 and 304 and make it one objective, but for 303 people generally noted that it was too broad as written and suggested it be more focused and define an approach and the need to define terms a little bit more clearly. And there were concerns regarding over specification, lack of standards and lack of experience.

Moving onto 305, referral tracking, overall commenters were supportive of this measure, 127, interdisciplinary problem lists, again they were supportive of this measure.

And 125, medication history reconciliation and prescription drug monitoring programs, PDMP, the majority of commenters supported the additional requirement to create the ability to accept data feeds from PBMs, but some caveats included data sources must be highly accurate and up-to-date, measures should have a low threshold and be a menu item and there were concerns about the additional burden on providers. Related to PDMP there was a majority of support for the recommendation to include it within the certification criteria.

For 308, notification of health events, there was a great deal of concern for this one, many felt that the 10% threshold was too low and some thought that the 2 hour window was much too short. And they were also concerned with privacy implications and the role of consent for the patient. They also asked for further clarification about what significant actually means. And some thought that inefficient technological infrastructure was available to support this measure.

Population and public health, 401A, receiving immunization history, most commenters supported this but they did have some concerns about readiness of standards. And they sought clarification on the wording and intent of this objective.

For 401B, recommendations for immunization intervention, commenters were fairly evenly split on whether this should be included but there were some concerns about yet another CDS requirement and perhaps this could cause an overburden for providers or possibly be included in the CDS objective.

For 402A, electronic lab reporting, most commenters agreed with keeping this measure unchanged, although they did say that the standards and implementation guide for this measure should be updated to reflect current health of requirements.

Case reporting, 402B, the majority of commenters supported the inclusion of this in either Stage 3 or a future stage of Meaningful Use. There were some concerns about the readiness of public health agencies to receive this data electronically and the maturity of standards available. Commenters were also confused as to why this wasn't an EH measure as well.

For 403, syndromic surveillance data, most commenters agreed that this measure should remain unchanged. As many states are not ready and need additional funding to be able to implement.

For 404, submitting ongoing reports to a jurisdictional registry. Commenters disagreed with the expansion of the scope of this.

For 405, commenters were supportive, but asked for additional specificity whether it would remain in the menu or move to core.

And 407 for HAI reports, commenters were in favor of this and cited that this function was already in place and operating within some EHRs. And also noted the alignment with federal goals of decreasing health associated infections. There were some that were concerned about the federal funding available and that this is not a simple functionality within EHRs currently.

For 408, sending adverse event reports, comments were fairly mixed on this measure. Some were in favor of this but cited that the functionality was already in place...I'm sorry, this is the wrong text, the rest of it and I don't remember what...but we will do a deeper dive at the Workgroup level. I apologize.

Okay, we're done with the Meaningful Use measures and objectives. So, some of the overarching Meaningful Use questions that we asked, the first was about whether there was a way to provide additional flexibility if providers came close but didn't achieve 100% on all of the objectives. So, most commenters agreed with allowing additional flexibility and they suggested that it would be especially important if they were required to do full year reporting.

For MU02, what is the best balance between ease of clinical documentation and the ease of practice management efficiencies? This question is a great lead-in to our clinical documentation hearing next week and most commenters favored improvements in overall usability, but there were some concerns about whether this really fit into the scope of Meaningful Use.

MU03, improving safety for EHRs, the question was if a safety risk assessment should be included. The Certification and Adoption Workgroup will cover this in more detail later on today. But there was overwhelming opposition to making this a Meaningful Use requirement as they thought it was premature, but support is needed for EHR users to do a safety assessment.

MU04 will be covered by Kathryn in her section and MU05 will be covered by Kory in his section. So moving onto MU06, what can be included in the EHR technology to give providers evidence that a capability was included for the entire reporting period? So this is kind of getting away from a provider

Having to click like "yes I did this" for some of the objectives. And commenters generally agreed that EHRs should be able to track usage for yes/no measures and many suggested that this could be done through an audit log. But commenters equally noted the difficulty in tracking these activities in EHR technology and those that occur outside of EHR technology.

And that is the end of the Meaningful Use measures and objectives I'm now going to pass it onto Kory who is going to discuss Information Exchange and the one overarching Meaningful Use question about API.

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

Thank you, Michelle.

**Kory Mertz – Challenge Grant Director - Office of the National Coordinator**

All right, so I'm going to start with MU05 and this one was really focused in on innovation within EHRs and how to really move information out of EHRs and into other systems and whether APIs or other, you know, innovative approaches would be more helpful in this area.

So, in general commenters were very supportive of this kind of innovative approach in APIs to really push things forward. You know, one of the questions in this area was around whether the Consolidated CDA and some of the existing interoperability standards would good for communications from EHRs to other devices and commenters generally felt like those standards were not the right ones to move from EHRs to other devices.

Some were supportive and had suggestions on additional areas to add for instance to the Consolidated CDA to make that more amendable. And, you know, again I think there was broad support from the commenters around APIs or other ways to really make it easier to move information from EHRs to other Health IT systems.

So, IE Workgroup 01, this was focused in on querying from EHRs. And, you know, in general there was a lot of support for inclusion of this objective in Stage 3. There was some confusion about the focus and scope of it though. A number of commenters seemed to feel it required providers to participate in a health information organization and there were concerns about whether there was a kind of broad availability of such infrastructure across the country. But, you know, in the IE Workgroup's deliberation that was, you know, the focus wasn't necessarily on it had to be an HIO-type infrastructure providing this, you know, different ways to achieve this. So, I think that's one thing that needs to be clarified.

You know, there were a number of comments and questions around the privacy and security implications of this objective. And I know the Tiger Team is looking at this now, but there were questions around, you know, what needs to be included in the authorization form, you know, questions about standards for consent management and if those would be ready in time for Stage 3. You know, a number of commenters thought HIEs or HIOs should be able to support providers in achieving this objective.

And then there were to call out questions within the objective, one around measures asking if it should be focused on the number of patients or if it should be a percentage-based. The majority of commenters suggested this should be focused on percentage. And there were some requests for clarification, so for instance how does a failed query, how does that get counted in this. So, there were just some requests for additional detail there.

And then there was also a call a question around patient matching and, you know, there were a handful of comments in this area asking ONC to establish explicit standards around this and there were also a few calls for a national patient identifier.

Moving onto IE Workgroup 02, this was focused on provider directories, so this was kind of an interesting dichotomy here. You know, it's fairly evenly split as far as whether this criteria should be kept for Stage 3, which, you know, a slight majority of folks said this we would be good to keep, but on the other hand the majority of commenters felt the standard readiness was not there for this objective. So, but a number of those...

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

Kory, maybe it would be helpful as you go through to just give a brief, the brief title of that measure.

**Kory Mertz – Challenge Grant Director - Office of the National Coordinator**

Yeah, so this was a certification criteria only for provider directories, for querying a provider directory. So, you know, I think one of the other points of confusion on this one was one of Michelle's overall high-level points was that for the certification only there was confusion. I think a lot of people felt like this was also tied to an objective and they weren't quite clear how they would meet that and there were concerns then about the availability of provider directories across the country to query.

For IE Workgroup 03, this was really focused on data portability out of EHRs, so for providers when they switch EHRs to be able to get the information on their patients out and import it to their new EHR. So the majority of commenters were supportive of this and felt further progress needed to be achieved around data portability.

And one of the questions was around what additional data elements would be important in this? So, there are a number of kinds of various points of view on this. I think the common theme was really around any new data elements included in Stage 3 should be added to this and then also any historical data required for quality measures should be included in the core set that needs to be able to be exported out of EHRs.

And then, you know, there were a few commenters who felt this criteria was somewhat duplicative of the care summary criteria earlier and a few who weren't sure that this, you know, without substantially more data included as part of this export that it added that much value. So, that is it for us and moving onto Jesse.

**Jesse C. James, MD, MBA – Office of the National Coordinator**

Thanks. I dare not start without thanking Michelle for all of her hard work in corralling both the comments and the reviewers and we really could not have gotten done how much we got done over these last few weeks without her work and her attentiveness.

So I'll start the review of the Quality Measures Workgroup, our RFC for Stage 2 actually was released as a separate document and the majority of the document was focused on NQS domains and sub-domains, and actual quality measures, specific quality measures that would be in the program. And the Quality Measures Workgroup for Stage 3 decided to step back and push forward so to speak. So, if you can do both at the same time, that was the goal.

And we wanted to think about the environment in which quality measures are developed and the environment in which they're used and the extent to which they drive quality improvement which of course should be their goal. So, to describe that framework the RFC is really split into four sections, first section being questions focused on the purpose of the quality measures in particular and on patient centeredness and how we get a broader input on our measures.

And then the next section focuses on how we achieve the goals we have with the measures. The third section is focused on what we described as an innovation pathway, which measures should be part of the program. And finally the last part is to drive quality improvement how we insert measures into some quality improvement population management dashboard or flexible architecture and we've had discussions both at the Health IT Policy Committee level and the Quality Measures Workgroup level on each of the sections.

So diving right in, this is a view of the high-level of those four major areas of how the questions split up. The section with the largest amount of comments was patient centeredness, but in general we had 30-50 comments for each question and there were 30 questions. I'm not going to go question by question I've chosen a question or two from each of these major buckets that were indicative of the comments and the themes that we received.

So, for the patient engagement section we asked how we can get more input from patients and from a broader number of stakeholders, a greater variety of stakeholders and the majority of commenters stressed the fact that we've had a good start with the tools we use currently, but they really want to push us to get more input from patients and more input from a variety of stakeholders and some in particular or some

tools we could use, tools that were suggested, were webinar, social media and blogs, in particular and also greater outreach to professional societies. And that was a consistent theme throughout the comments both to engage with physician groups more to give physicians more flexibility and to have more outreach to the societies.

The next set of questions focused on the types of measures that we used and the Workgroup in particular wanted to get input on process measures versus outcome measures or combinations of process measures and outcome measures as our developers reported back to the Workgroup there has been a push towards bundling the process measures with outcomes measures that they are associated with.

Comments on that age old process versus outcome debate there is still a majority of comments supported outcomes or a combination of process measures and outcomes measures, I think for this question in particular there were 48 comments that were directly related to this, many of the comments were at a higher level than they could be...that allowed them to be split up into these discrete categories.

Another question about whether we should bundle the outcomes measures with process measures, the majority of responders supported bundling outcomes and process measure suites. A smaller segment of 15% stayed focused on outcomes only. And an even smaller segment of the commenters suggested that we should only make process measures.

A few of the comments that stood out from the group or that were indicative of other comments in the group noted that there would be some challenge to creating a process and outcome suites, but that they're also an opportunity to build measures that are more alike than they are different. If the denominator along this bundle of measures stays the same that from a development stand-point, a software development stand-point that's an easier lift for EHR vendors and for implementers and also for physicians, it makes the measures make a little bit more sense as opposed to having so many measures that are so similar but also so incredibly different. And, I understand that my role is not to interpret as much as it is to report, so forgive me for moments of interpretation.

So, moving right along, staying within this theme of the types of measures that should be part of the program measure developers have also reported back to the Quality Measures Workgroup that there is some difficulty if not dissatisfaction with retooling or re-engineering paper abstracted measures and we've been interested or the group has been interested in how we can have a greater push towards creating de novo measures, measures that from our Vendor Tiger Team in particular the vendor said there are many things that the EHRs do better that Health IT does better than claims abstracted measures and we could leverage the technology better if we design our measures for EHRs and not simply design paper measures to be used inside of EHRs.

So, with that charge from the Vendor Tiger Team and in the interest of the Quality Measures Workgroup we asked the question to the public, should our development continue with de novo measures or retooled measures and their comments, as you can see, there was strong support for having more de novo measures. There were a few commenters that mentioned that they had not had enough experience with both to prefer either/or, but many of the large IDNs who have been developing their own measures and using their own measures in particular reported that de novo measures were likely the better way to go in building measures for EHRs.

The last two segments of the RFC were devoted one to the idea of an innovation track and to population management dashboards. So the American College of Surgeons in response to the NPRM for Stage 2 and the Partnerships for Patients in response to the same suggested that we find a way, inside of the program, to allow physicians to choose their own measure or measures, measures that were especially important to them and their practice and the Quality Measures Workgroup noodled on this in the fall of last year and we also added a few questions, they were questions 18 through 24 in our RFC on this subject.

There is very strong support for an innovation track, very strong support for allowing clinicians to choose some measures themselves or even design some measures themselves to be part of the program. I won't read this entire paragraph, but this is the lead up that we had inside the RFC to guide our comments.

Two important questions that are in this segment, one question asks whether this seems like a reasonable way to proceed, whether it's feasible to have clinicians to some of their own measures or a portion of their own measures for the program and the next questions continue to ask how it might be organized or how we might constrain development. So, there was strong support, as you can see.

There was a split between those that supported strongly either clinicians or large groups of clinicians being able to choose measures. There were some reservations about either fraud, waste and abuse or the measures not being meaningful from a national perspective or from an HHS perspective. Actually this question had one of my favorite comments, it was the strongest comment received and it was actually not in support and it used the words experimentation should not be a part of this program, but that was not indicative of the majority of comments on this, but it did catch my eye.

Twenty-eight of the, it was 41, comments in the section supported an innovation track and Boston Medical Center in particular said they found that their QI Departments...really this is happening. QI departments across the country are building measures, they're putting them into EHRs, they're using the data and they're doing it on a lifecycle that's a whole lot shorter than the one that we're currently constrained by. So, there was some support saying this will be difficult to do, but should be considered and then many of the larger vendors had some reservations about opening the process to any or all clinicians.

Finally, we asked whether we should be conservative in types of groups that can build their measures and conservative being large IDNs or ACOs, or health plans and an alternative being whether we should liberate or be entirely democratized in our approach to quality measures and allow any clinician with reasonable constraints to find measures that are meaningful for their practice. Again, overwhelming majority, almost 2 to 1, was in favor of EPs, at the EP level being able to design and use measures.

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

The colors were correct, but I think the numbers were switched on the previous slide.

**Jesse C. James, MD, MBA – Office of the National Coordinator**

Oh, touché my apologies. And for the conservative approach for having large organizations perhaps being certified to create their own measures we posed a certified quality measure development organizations being responsible for the measure development.

Many of the commenters said this is a way to go that will allow organizations who already have the ability in this space to continue to move forward in it while on the opposite end of the spectrum there is very strong support for individual clinicians being able to use measures that they're already using in practice and for this being as flexible as is reasonable. The VA in particular said the same, clinicians should be able to use the measures and they are a part of the program, however, when they cannot find a measure that especially suits their patient population we should find a way to give them the ability to use those measures as a part of Meaningful Use.

We also asked, how should we constrain, there must be some constraints. You could imagine without constraints clinicians or an organization might make a measure saying which patients visited me in the last year and left on time or enjoyed their visit, or paid, or did not pay.

So, we wanted to consider which constraints...what constraints that are in place might be useful for this innovation track and the majority of the commenters mentioned some of the tools and standards that we have in place now, the QDM, use of the MAT making sure that the measures conform to HQMF, XML and being confident that the measures use data elements that are part of the data element catalog for Stage 2.

So, to move right along and to keep up with time, the final section we asked what is the readiness, so to speak, of the market for population management dashboards or which by another name called business intelligence tools, or clinical dashboards, or population health management tools, what's the readiness and interest of the clinicians, and what's the readiness and interest of the market.

Is there a business case and whether the Workgroup or the Health IT Policy Committee should play a role in this space is a question we had asked previously to our Vendor Tiger Team and the report back was essentially that the technology is developed and being developed, but the market is a bit immature and we opened the question to the general public in particular to get wider comments and a greater variety of comments than we could within our Tiger Team, but also because there is a certain knee-jerk reaction and instinctive understanding to what these tools should do from the clinicians stand-point.

And clinicians have said "I would like to not only know who is my numerator and denominator, I really want to know who is in my denominator not in the numerator so that I can act upon them and improve my care going forward." There is support for some population management platforms to be a part of Meaningful Use and a part of the tools that clinicians use.

When we move onto comments that were typical of the ones we received for this section really the comment from Tom Yackel from Oregon, make clear population management tools should be a part of CEHRT and the market itself should be lead towards the development and there may be room for the Policy Committee to set some baseline functionality. On the opposite end of the spectrum there is a comment from CHIME saying that there is additional time needed to allow this market to evolve.

So, finally just from a high-level some of the themes that appeared in several of the questions, there were 30 questions, we went through all of them and created a summary for them, but in this presentation we decided to focus on a few of the questions and go deeply on them. But there is a push for us to...or for the committee in particular to listen more and engage with the specialty societies and with patients, and to listen in a way that's perhaps is more flexible that includes blogs or web tools or social media.

For measured development there is a push to go de novo and to go broad, we had a question about whether our goals for the next stage should be to include more measures or to spend time refining our measure set and there is strong support for us to refine the measures that we have in place.

And finally, for many questions even ones where we were not necessarily focusing or expecting comments to include flexibility for providers, one question in particular that comes to mind we asked about the NQS domains and which domains in particular we should focus on and many of the commenters said we should let the clinicians decide which domains are important to them and if their measures fall outside of those domains they should be able to choose measures in that way. So there is strong support for expanding the flexibility of the providers.

And finally, when it comes to the National Quality Strategy domains there is support for the areas that appear to have gaps from a quality measurement point-of-view care coordination, patient engagement and safety were consistently mentioned as the areas that should have more attention in the next stage of the EHR incentive program. So, on that thought, thanks again to the Quality Measures Workgroup and leadership of David Lansky for putting together the RFC especially. Thanks to Michelle Nelson for keeping us rallied over the last 2 weeks to get the work done.

#### **Kathryn Marchesini – Office of the National Coordinator**

Good morning, I'm Kathryn Marchesini with ONC's Office of the Chief Privacy Officer and I'll now briefly touch on the nine questions that were focused on privacy and security and then discuss some of the common themes we heard in response to the specific question.

The first question focused on how the recent HIT Policy Committee's provider authentication recommendations could be reconciled with NSTIC approach to authentication and identification. Of the 41 comments many of the comments stated that the NSTIC model could be adopted in healthcare and strong identity proofing and multi-factor authentication should be required for MU Stage 3 and leveraging existing standards. You can see some of the examples of the existing standard sources listed on this slide.

Other commenters do not want multi-factor authentication to be required for MU Stage 3 citing references regarding unrealistic deadline, burden and costs, and it not being a core competency of an EHR.

The RFC asked a related question about how the two factor authentication recommendations could be tested in the MU certification criteria. Of the 26 comments received, some suggested approach to testing included developing a checklist to verify the system set up, requiring attestation to having the architectural support for third-party authentication and requiring a demonstration of that. A third approach that was recommended was developing a model protocol for self testing and an iterative and phased testing program.

Commenters noted that existing standards and guidance could be the basis for the testing procedures. The slide highlights some of these that were mentioned. One commenter did note that in general that the domain is not mature enough for the certification criteria for testing authentication.

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

Kathryn did anyone comment on the DEA requirements for ePrescribing of controlled substances interaction?

#### **Kathryn Marchesini – Office of the National Coordinator**

Just in that they could be used for a basis for the testing procedure, but they didn't go into specific detail.

The last question dealing with authentication focused on whether there should be certification of the EHR as a stand-alone entity and/or the EHR with a third-party authentication service provider. Many of the 30 commenters suggested supporting both approaches to certification, while several suggested permitting the certification of the EHR and the third-party vendor independently of each other.

Commenters also provided suggestions around certification in this area including handling third-party dependencies in a way similar to those in other industries, implementing NSTIC in lieu of requiring certification, leveraging NSTIC accreditation authority could also assist with the certification and using external labs with the capability and experience in testing in this area.

In looking at building on the existing privacy and security MU requirements the RFC requested the identification of security risk issues and also feedback on requiring the attestation to implement the HIPAA Security Rule provisions regarding workforce, outreach and training, and sending periodic security reminders.

In regarding to the actual attestation for workforce security outreach and training some commenters supported requiring attestation regarding the workforce and outreach citing the importance of the workforce in keeping patient information secure. Many commenters are against requiring attestation, commenters most frequently noted that it would be burdensome or duplicative of the HIPAA Security Rule.

Other commenters were neutral towards the attestation requirement but they did mention support for the current HIPAA Rules Security provisions. Commenters identified other security areas to be emphasized in MU Stage 3 of those which you see listed on the slide, some of these included access controls, emphasis on encryption and backup and recovery of storage of protected health information. Also, some commenters requested the need for more HIPAA Security Rule guidance and education for providers.

In PSTT5 the RFC requested feedback on a prescribed certification standard for audit logs. The majority of commenters noted that the prescribed ASTM standard is feasible to use to certify the compliance of EHRs. Other commenters questioned whether or not there should be even be a certification standard in this area some of the reasons you can see, excuse me, some of the reasons that were cited include waiting until the promulgation of the HIPAA Accounting of Disclosures Final Rule.

They suggested conducting additional feasibility studies and research before an audit log access before mandating a standard. Some also noted that the question in general seemed to conflate the audit log, the actual electronic capture of the data with the accounting of disclosures which deals with more report production.

In response to the question about is it appropriate to require attestation that audit logs are created and maintained for a specific period of time, many commenters suggested waiting until the HIPAA Accounting of Disclosures Rule is finalized before specifying any attestation for an audit log requirement.

Many of commenters supported adding this audit log attestation requirement, they identified other points of consideration when this requirement would be noted, you can see some of these listed on the slide, some of these include relying on existing NIST standards or federal and state regulations, request to specify the period of time and identifying a minimum data set, while other commenters suggested expanding the attestation requirements to all the requirements of the HIPAA Privacy and Security Rule.

A majority of commenters are neutral toward attestation in this area, various reasons were cited including as mentioned earlier waiting for the final Accounting of Disclosures Rules, completing feasibility studies. Others disagree with adding this attestation requirement in general citing reasons including administrative burden, it's not improving security and the audit log is only a functionality of the EHR and not provider attestation.

Many commenters generally noted that there is no dominant or mature existing standards to meet the stated need for the audit log files of EHRs that was posed in question PST07, most commenters supported a need for a standard format requirement in this area, others noted that they were neutral toward a standard format requirement or they stated that the adoption of such a standard would need to overcome the challenge of the variability and details that are captured by existing EHR systems.

Some commenters disagree with the need for standard format citing that it would be a burden on healthcare organizations and vendors, and others noted that only a minimum data set or elements should be defined. Also some commenters say that there is no need for an MU-based standard related to the Accounting of Disclosures Rule.

A related question about audit log file format specifications received 37 comments in which respondents mentioned many existing specifications that could be considered for audit log purposes including some of these listed on the slide. Some comments noted that while there may be existing specifications or standards, none of these are widely adopted, although there have been multiple attempts to develop a standard for audit log format. Other commenters are opposed that the addition of any new Meaningful Use requirements based on the proposed HIPAA Accounting of Disclosure Rule.

The last privacy and security related question focused on patient consent and consent management which was included in the MU questions. The RFC put forth three questions of the 74 comments received in

regard to the EHRs and HIEs and whether they can manage information that requires patient consent many commenters indicated support for metadata tagging approach to enable this type of consent and several noted that data segmentation capability currently exist and have been demonstrated. However other commenters stressed that segmentation capabilities required to enable this type of consent management are not currently existent in the vendor market.

Commenters provided alternatives including focusing on identifying and punishing inappropriate use of the data while others commented on that there are easier ways to accomplish consent management is to give patients control of their information via the personal health record.

In response to the questions around the capacity of the EHR infrastructure and consent a number of commenters support the idea of creating and promoting standards. Also a number of comments specifically support a creating standardized fields for specifically...excuse me for specially protected health information.

Several commenters recommended that all certified EHRs be able to manage patient consent and control redisclosure. Some comments recommend that the system also be able to modify the consent choice over time.

In response to whether there are existing standards that are mature enough to facilitate the exchange of this type of consent information in today's EHR and HIEs responders noted that the S&I Framework's Data Segmentation for Privacy Initiative is looking into this area, HL7 confidentiality and sensitivity code sets, the SAMSHA VA pilot, and work is being developed by eHI and being done for some states and HIEs.

Regarding the specific question about the data segmentation for privacy pilot as a model many commenters noted that the pilot is a good start and provides a good framework while several felt that the pilot is too granular and not proven or should address the rules regarding what data would be tagged.

So that concludes a snapshot of some of the comment themes regarding the privacy and security questions in the RFC.

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

Well, I want to thank this group for an amazing job. So, first I want to thank the public for the amount of effort. So, this was a high-level summary and was so detailed even at the high-level that that just reflects how much time was spent by each organization and individuals who submitted comments over the holidays.

So, and I want to thank the ONC staff, so the public had 60 days to write things and you had two weeks to digest them and summarize them and really did an extraordinary job in doing that. And special thanks to the lead shepherd, Michelle, for having this come together in a timely way because, as you know, we're on a timeline to try to get feedback from this group, from the Meaningful Use and other Workgroups and then come back to this group with our draft response to get approved on the way to final recommendations to ONC and CMS. So thank you so much.

I want to start out with maybe a couple of framing comments. We have an hour to talk about this so we have plenty of time. But, let me piggyback on what Farzad talked about both the last time and this time in terms of sort of areas of responsibility that govern human behavior and humans, and it starts out with individual responsibility and accountability to one's self, whether that's an individual or to an organization that you work for.

The second is the social mores that govern sort of behavior in corporate citizenship in a sense, societal citizenship and the third is the regulatory arm which is you could either look at it as a last resort when the other two aren't working sufficiently well. Another way to look at it is sometimes it's useful to set a level playing field. So nobody will do X until everybody has do X and sometimes that's a real help.

The other times is when there are things where we do have some outliers and things that sort of rock the system in ways that are detrimental to the overall population or society. So, that's one of the balances. We don't want to go to the regulation when we don't have to and yet we want to create a level playing field when there is certain public good that needs to be enacted.

The other concept I want to sort of layout before we open it up for discussion is sort of to remind ourselves of the context of both HITECH and Meaningful Use and how this group got started. So, HITECH even though it preceded the ACA by a year still I think at least HITECH within that era was intended to support health reform. So, I think that really was its need even though it predated the legislative act, but it was clearly of interest to both Congress and the administration.

So, it was always preparatory for health reform and the goal was to be put into the provider hands and patient's hands the tools needed to execute a different way of managing health and healthcare. The second is that this group chose to work on the exemplar approach meaning it was not to over specify every little piece of the system, it's really what are the critical few, in a relative sense, things that a system has to do that it wasn't already doing that would help us to get to the new way of doing business in healthcare in the United States.

We'd always from that ark talked about doing it in phases remembering that before HITECH it was estimated that only 3% of physician groups and less than 10% of hospitals had anywhere near a comprehensive EHR and probably none of them had what would be in Stage even 1 of Meaningful Use now.

So we went from zero and we're trying to get to 60, so we did it in phases, one is to get information in a standardized way or structured way as possible. The second stage where we're at is to spread it around where it can be used in patient care decision, so that's the HIE part, but also supporting advanced clinical process.

And the third stage, which is what we're discussing now, was, at least our original intent, and I think it's still true, was to move us towards measuring and improving outcomes and getting the tools in the provider's hands to do that.

We have to remind ourselves that people who are now going to qualify or in the future are going to qualify for Stage 3 have already been through Stage 1 and Stage 2. So, if we look at Stage 3 as sort of being more...well Stage 1 and 2 as being more process oriented or functionally oriented then Stage 3 maybe can sort of lift that sort of burden of executing improving process compliance and move more towards what we intended, which is sort of measuring outcomes.

So, a couple of thoughts in terms of other analogies to this kind of certification in a sense or accreditation is you know that many of the accreditation programs focused a lot on process, and sometimes there is an alternative path for outcomes. So, even if you're...as you're licensed there are ways or go through board certification you have the sort of the learning, the book learning and training proving you've earned this and that degree, and then you have the experience base as an alternative pathway and once you're already a professor of something and you've created something, well by golly you probably know the stuff in a sense.

So, I wonder if this is a time, and we've talked about this even at Stage 1, a time to reflect and say without replacing the current way we're going, you know, the trajectory we're going with these stages of Meaningful Use there's an alternative pathway to say, by golly if you've gone through Stage 1, you've gone through Stage 2 you still in fact have a certified EHR then...and you're getting good results, you probably know how to...I mean, we've also said it's probably impossible to get good results on paper.

So, in some sense once you're getting good results you probably using an effective EHR and you're probably doing so effectively. So, maybe that is an alternative pathway by Stage 3, once we've gone through two process stages to consider as a way of gaming people in qualifying for Meaningful Use.

The other corollary is by Stage 3 the dollar amount is actually smaller in terms of incentive and we're moving towards the penalty phase. So, this may be a really good inflection point for us as a committee and in particular the Workgroups to reassess, really go back to the first principles we talked about way back when and say, it's not a rip and replace but is there an alternative pathway to gain qualification for this program which was always intended to support health reform.

Another idea I had is we've always been linking and there's a reason why we link the certification criteria with the functional objectives. So, a Meaningful User is a provider who uses this tool meaningfully. We

realize that in order to make Meaningful Use there has to be a certain set of functionality in the tool you're using, it's not necessarily clear that the timeline for what gets issued as a requirement for certification has to be completely aligned with its instant use, because we have gotten into that fine we'll take X amount of time to develop and test, and deploy, and then it takes X amount of time to get your whole organization to use the new functionality, why does it have to be completely coincidence, which puts us in some of this timeline quandary, and we knew we had to actually switch out, add that extra year for the very early adopters for Stage 1 because of this.

I'm not sure that's prescribed in the statute of why that timeline has to be coincident. The certification is driven by the needs in Meaningful Use but doesn't have to be coincident and cause all of this pile up of the lead time required. So, that's another way perhaps that there's certain cadence with which developers need to make tools that we think are important to providers dealing with the new way of delivering care and managing health along with their patients, but maybe the cadence of the human calendar time needed to take this functionality up, use it effectively and measure what happens, maybe that needs to be separate.

So, there's lots...I think it's time to look at some of the dimensions of the program that we have at our disposal, because most of this is not in statutes, there are some things that are, but most of it...we've sort of concocted this and I really think a lot of good things have happened. I mean, I believe most people think that.

A lot of things...there's been challenges and pain, but even when we ask the folks who've been through the pain and do talk about the challenges what can we take out in the past people have never been up to come up with anything we should actually take out, because they say, well that would be wasteful, we don't need to do that in order to get good care.

So, we've...the program's been doing a good job at coming up with good functionality and good kinds of Meaningful Use objectives it's just that it takes a fair amount of time and effort to get there.

So, trying to think of ways, alternative ways of giving people a way to do the things that were fully intended and on a time and in an area, talking about specialists or rural area, that is most important to them in delivering local care which is what happens everywhere.

So, I just want to open up sort of the thinking instead of only concentrating on individual details and probably not concentrating on individual details, we have some Workgroups to worry about that, but maybe look at the overall framework and as I said, I don't think this is...it would be counterproductive to do a rip and replace, but it may be very helpful to think of alternative pathways. So, with that I'll open it up. And Gayle is the first card up.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislator**

Thank you so very much Paul. This is Gayle Harrell. You know, this opens up a whole new conversation and one that we started out with perhaps way back 3 years ago in the direction we take and I couldn't agree with you more with your framework of individual responsibility being the number one premise and then moving onto social norms and then regulations, and laws. As a lawmaker, I understand that and certainly we write laws and regulations for outliers, you know, for people who are not performing. There has to be some rules and regulations there.

But as a...you know, in the political arena I think I would lean more towards the individual responsibility and social mores as being controlling entities that achieve goals much more rapidly and succinctly than to rules and regulations and laws.

So, I absolutely agree with the direction and the thinking and starting the whole thinking process perhaps in a little different direction, because as you say, we've gotten through Stage 1, Stage 2 you have an infrastructure in place. You have requirements and certification requirements; you have requirements on providers that people have been meeting all along. You have to say what is the ultimate outcome this program wants to achieve? And that is improved outcomes in health care. And also being a tool for really changing how things happen in health care.

So, to me the key component of what we do and where we want to go in Stage 3 is quality measures and that should be where we concentrate is how do you...what do we need to measure? And we want to be as open to specific groups and especially the specialty groups who have kind of been left out of the conversation in where we've gone with core measures and requirements and things of that sort.

I think this gives us time to perhaps step back and say what improves outcomes? How do you measure the quality that you really want at the end of the day? Yes, there are some technical things and requirements you have to put in place to allow that to be achieved, but at the end goal it's the measurement of quality, and we need to give flexibility to those providers and groups, and specialty groups, and different types of organizations to develop those that really use the technology things that we have at hand now, because we've gone through Stage 1, we've gone through Stage 2.

So, gearing up and really looking at that, but, as I always have to say, remembering those privacy and security requirements that have to be there to make sure you maintain the public trust in this whole process as we move forward. But to me the key component in this is making sure you have those de novo quality measures that really define what we want to accomplish care coordination, improved outcomes, better public understanding and awareness, and participation in their own healthcare. So, you come back to that individual responsibility once again. So, less is more in this endeavor as we go into Stage 3.

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

Thanks, Gayle. David?

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

Thank you, Paul, I appreciated your framing very much, I think it was really helpful and I do want to start by thanking Jesse and the staff for doing a phenomenal job both developing the RFC and then figuring out what the responses meant.

I had a couple of reactions to how we're starting this off and, again, Paul, I think you really framed it well. And one is, and very much, I think consistent with Gayle's point, we all want to feel and show that the investment in the technology and the investment of dollars is producing an improvement in health outcomes. And what we envisioned in Stage 3, if that's still feasible, maybe it's 4, is to be able to show that health is improving as a result of this transformation and the care infrastructure and we're not so far able to do that.

In fact, we're not even close because the measurement environment we're in is not producing reports of actual outcome changes tied to the introduction of the technology. We're still at a point of reporting use of the technology and the capability of generating measures but we're not actually looking at the results yet. So, I think that's....I want to come back to that as one way to I think address the comments Gayle made as we go to the next phase.

Secondly, I'm nervous, maybe in a good way, about the word flexibility as we've used it already today. Flexibility can be a device to allow people to persist in current behavior and patterns of care and just say check the box that I've done something rather than say I've used that flexibility to achieve an improvement in health and an improvement in outcomes.

So, I hope as we...I am very supportive of flexibility and I was very supportive of the approach we took in the RFC to invite that and I think it has to be bound closely to outcomes reporting, that as we give people the flexibility to innovate in the processes of care and the functionalities they deploy they have to show that it improves health and that their own creative use of the technology and other care processes produces a health benefit, which takes us I think to Gayle's last point about toughening up on the outcome measures as we loosen up on the requirements either on the functionality or the process measurement side of things.

So, the last point I want to suggest is one thing we could just begin to think about for the next phase is to introduce actual performance on outcome measures as the mechanism by which you escape further specificity on the process on functionality requirements.

So, as you say, Paul, people have already jumped through Stages 1 and 2 hurdles so we know they're on a strong foundation, maybe, and I'm not sure, but maybe we're at the point and perhaps in some domains or some specialties, as Gayle suggested, that we could say, okay if you're outcomes are improving for asthma care, hip replacement care whatever it is you're working on, then we're no longer going to be specifying the certification requirements, functionalities, etcetera, because you've shown you can actually improve health with this capability. So, I hope we'll entertain that as a pathway.

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

Thanks, David. Marc?

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

Thanks, and I couldn't agree more with the comments that have already made. And I'm really humbled by the brilliance that exists in the public who have provided these comments and the great work you guys have done so quickly. I mean, it's helpful to have all of this knowledge come together so quickly and I would just add probably two things.

One, as I went through this report I was kind of just underlining words, now we all focus on things that are important to us, but boy the word standard showed up over and over, and over again, and I think we have an opportunity, as a Policy Committee, to help define those as we look forward. Where do we need them and how can we facilitate those getting put in place? Because with those in place a lot of the things we're trying to do would be facilitated. So standards was the one point.

The second is sustainability. I think we are putting in a lot of infrastructure, we're putting a lot of demands on organizations and people, and we need to...we have been, I'm not saying it's been ignored, but we might want to put a greater focus on sustainability and how that infrastructure remains sustainable, how security and the other privacy, and other things that we're demanding on people remains sustainable, but excellent work, thank you.

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

Christine?

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

Thanks, Paul. First of all, thank you guys and we probably have aged your eyeballs at least a decade reading all of these comments.

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

Thank goodness they're young.

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

Be thankful you're on that side.

**W**

They are all so young.

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

Hey, some of us could be on that side, I'm just saying. So, you guys gave a really great overall summary, thank you very much. As we go into the, you know, deeper work, particularly in the Workgroups whether it's Quality Measurement or Meaningful Use, you know, I think one of the biggest benefits of public input is that there are a lot of people who have fabulous ideas. I think the downside of the public input process is it's really hard to, you know, sift through 600 comments and then find the gems, right, because maybe one person came up with some gem of an idea that you guys read and you go, you know, that's not a bad idea.

So, as we go through the process, I think, if you guys are keeping your eye out for those...you know, maybe one person said it, but wow it's a good idea, that was really, I think, a big piece of what we were looking forward was some help, you know, kind of getting to the yes, we can do this if, you know, piece. So, that would be great.

The second thing is, you know, I agree, Paul, and great framing, I think as I look at the program and as I talk to many individuals, you know, we do want to avoid the Christmas tree syndrome where Stage 3 just is...we just keep hanging stuff off of it, right? So, and I think we all share that goal I think, but to David's point, the devil is, you know, like in the details, right? And how we really incent health outcomes and I think it's...and I would add, by the way, patient and family engagement which people don't always necessarily connect to better health outcomes even though the evidence is there that it is.

So, I think we have to be thoughtful in our approach. I think you're right that we should go back and look at some of our overarching principles and think about them specific to Stage 3 when there are some assumptions or facts we can take into account like people have been using an EHR for a minimum of 4 years, right? But, we know that there are...so maybe we have some principles that govern Stage 3.

You know, we know for example that they're hopefully going to continue, as you always say, to use the features and processes that are useful to them, by this point, but we also know that there are some gaps in functionality particularly around quality measurement, around a population health management dashboard, I think Jesse kind of described that idea very well.

There are probably some gaps in the program's structure I think itself with respect to specialists. So, if we think about using Stage 3 as a tool to address some of those areas, but keep in mind, I think David's framing of how we show improvement connected to the technology, I think demonstrating the value of the technology is really important. We can't do that by itself we know that. We know, you know, our HIE hearing was really great in pointing out that a lot of the accelerated information exchange that's happening today is a result of a business model. We have an ACO, we're trying to develop, so we have a business need.

And, I think we can't be exclusive, right? Those two pieces are very connected. But on the other hand we have all made arguments for decades that electronic health records when implemented well will drive cost savings, will drive patient and family engagement, will drive better health outcomes even in and of itself.

And, so I think we have to think through the lens about how we balance those two and what's reasonable. Maybe we simply use the certification process for example to address some of the gaps in functionality, but there may be some elements that we actually do really want to drive use, right?

We want to say, you know you need to actually be using it in these ways and to that extent, I think the one warning that...I have two warnings actually, one, is when we potentially propose ideas that are more transformational and harder it invites an enormous amount of opposition, right? Because, you know, our reaction to change is its hard and we want to find the ways we can't do it instead of finding the ways that we can. So, we need to be aware of that and realistic.

I think the second caution is it will take time for us, as a group, to really think through some of these details and what a different structure might look like. So, I'd just encourage us on a practical level to have a conversation about the timeline that we need to operate on to give CMS and ONC what they need so that we can really do it in a thoughtful way and really be open to a new approach in Stage 3 that really does end up in improved health outcomes. Thanks.

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

Connie?

**Connie White-Delaney, PhD, RN, FAAN, FACMI – Professor & Dean – University of Minnesota/School of Nursing**

Thank you, Paul. Connie Delaney, University of Minnesota, I want to thank you for your comments, Paul, and reflecting where we started and where we're at, and yours Marc for commenting on the steady thread and stronger thread of the importance of standards.

When we reflect on where we started, the importance of getting the best of the care and the science to the people fast was a key driver. So it seems to me that in addition to our emphasis on quality measures and the outcome work it perhaps is time congruent with your comments of pausing and looking at overall programming, Paul, that we specifically take a look at the role of the researcher and the research enterprise, if you will.

And I would suggest that perhaps there are parallel complementary and maybe in some cases some overlap investment areas going on related to infrastructure. And perhaps we have time now to take that pause, study this space, and then have that inform our next steps.

The additional reason I'm suggesting that is it ties back to the importance of standards. When one relies, as our society does, on the role of the researchers and that investment for the new discoveries in science the role of standards is absolutely critical, particularly as we move into the eScience and big data world. Thank you.

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

Thanks, Connie. Judy?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

As we look at the need for population health, the improvement in population health to help us reduce costs and for the healthcare society I think we have to look very carefully at where healthcare is going and it's going more to the ambulatory care side than it is to the acute-care side, and it's particularly going to be weighing heavily on the primary care physicians, yet we have a shortage of primary care physicians, we're predicting a shortage.

And, so, I think that as you look at your responses you have to weight most heavily the physician's responses who represent that group that's going to be so critical to the improved care and I thought of it like a car. I was thinking of Steve Jobs saying he doesn't use focus groups and I'm not saying not to use focus groups I'm saying to be careful how you weight them, because suppose you had a car and you were going to say how should we build this car?

Well, if you go to the passengers they're going to say make the back seats really roomy and soft and make sure there's a really big truck. If you go to the highway police they're going to say create in there capabilities to alert us anytime anybody is speeding and send us their name. If you go to the car builder's they're going to tell you some of things may be impossible. If you go to the efficiency standards folks they're going to say make the car really small. If you go to the safety folks they're going to say make it big enough and heavy enough so that if you do have a crash you're not hurt.

So, we have all these competing things and that's why I am saying that as you look at those competing things, think really carefully about how you weigh them. They don't all weight the same and the most

Important weighting, in my opinion, is how is it doing for the productivity in particular for the primary care physicians?

So, no matter all the data we collect, if we're going to slow down those physicians so they can't see the people they need to see, remember there's not enough of them probably, that's going to hurt our health care a lot and I've said a number of times that we see the systems as they go overseas being simplified, they take away stuff they don't add to it and they ask us why do you have that in there? And so, as we look at that we have to keep in mind that all the multiple purposes, every one of which is good, has to be balanced.

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

Thanks, Judy. Neil?

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

So, not to be outdone by Judy, I was going to talk about dogsleds actually, because, you know, to reflect on what you said, Paul, I think there's something huge that's happened since we started and that is that the environment has changed dramatically. You know, I think when we were talking about looking at outcomes four or five years ago and we were just thinking about, you know, so how long was it going to take until we could get to Stage 3 that would really look at outcomes and we were trying to figure out so what was going to drive that and, you know, there were a few insurance companies we thought maybe there would be some increase in public reporting, but now the whole environment is changed.

And the reason I said dogsleds, there was an article in today's Times about the Iditarod Race and how the people are basically...who are training for it have completely changed because of global warming, they're now breeding a new kind of sled dog that has shorter hair that can survive in warmer temperatures while they're running because the dogs that used to run get overheated now and they can't run and they're teaching them to sleep in mud overnight because they're used to sleeping in snow and they didn't get good night's sleep when they were sleeping in mud.

And, I'm thinking, so, you know, are we still designing for what the world was four years ago and how would we design it differently today if we were starting today knowing that, you know, whether you're forming an ACO or not, or whether you're advanced in the way your systems are negotiating contracts with insurers, we all...every single conversation we're having now with any payer has to do with looking at outcomes and looking at rewarding performance based on outcomes.

We no longer have to be the force to sort of move the outcome vision because every conversation I have with anybody is about outcomes. Every hospital meeting I have is about outcomes, it's about looking at safety, looking at numbers, looking at numbers of infections, looking at all of the things. You don't go to meetings now in your specialty societies without people talking all about how you look at outcomes. So, I don't think we need to drive that.

I think actually HIT, if you think about it, and I reflect also on something that Farzad said a few years ago, which was that, you know, our responsibility is being an accelerant and I'm feeling more and more like that because if we did nothing this evolution would continue to take place. So, what is our role to sort of stimulate this thing happening faster?

And, so I worry about the regulations and I worry about growing too many things on our Christmas tree, and I worry about sort of creating a model that's still trying to get people to do things, because I think all of that stuff is going to happen and what I really am troubled with is something that we used to sort of credit only to the vendors which is like when we put in a lot of requirements the vendors are going to have to spend all their time doing that instead of innovating.

Well, I can tell you that exact same thing is happening in the provider community that our entire IT staff and everybody are completely consumed now with meeting requirements many of which are reporting on things that we don't have the capability of sort of following up on, so we're continuing to stare at some of the same sort of outcomes that aren't as great as we'd like to see them, but they're not high priorities because we've identified other things in our system that are really hurting people that are high priorities and we're trying to balance all of those things that we're reporting on against the things that we have identified that one we have the resources to fix, so if we could get the data and get the systems in our HIT programs we could actually fix things and we could actually do a better job.

So, I'll just end with a quick example. So, we're, you know, we have an enormous number of diabetic patients, over 8000 in our system, and because of that we ran a report to see how many people had early mid-stage and end-stage renal failure and we're looking at over 400 people who are sort of headed towards end-stage renal disease and we've done nothing in that regard to try to identify best practices in that area, figure out what the requirements are, what would we want everyone of those patients to have?

And that's not something that's going to get built into Meaningful Use, but it's something that's incredibly important to our patient population, it requires an enormous amount of work now that we're doing between our own department, which is a primary care department, and two specialty departments in the hospital that are helping us to derive those standards and now we have to program...we're going to program decision-supports around that. We're going to start reporting on it. We're going to develop methods of communicating data back and forth.

All of that is to the side of Meaningful Use and I can give you five other examples of things like that we're doing. So, I would like to see us in this next iteration not just allow innovation but figure out a way to reward it. These kinds of things that we're doing and that are happening all over the country when problems are arising that people are responding to in developing systems around, if we want to accelerate this process I think we need to figure out a way to reward people for doing what we're doing around individual projects and what every other hospital and medical group that has IT is doing.

They're taking the natural curiosity of their providers, the things that they're identifying as important problems, they're putting IT to work at those problems, they're putting decision support to work at those problems. We need to find a way to support that through this incentive program so that...and then to sort of consolidate that information in a way that it becomes available to people.

And, so if I think of what the next iteration would be it would be to not just sort of allow innovation in this space, but to back off on a lot of the requirements and then to figure out how we drive innovation in this space and also to sort of consolidate the information that's coming from people, because the environment's changed and this stuff is moving and I think our role has to change in it.

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

Thanks, Neil. Gayle?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislator**

I would like to make one more comment. In hearing what everybody had to say, I think this is probably one of the most productive conversations we have had in really looking back at what we did over Stage 1 and 2, but really looking to Stage 3 as a jumping off point to Stage 4 and I would say Stage 4 really does what both Connie and Neil have suggested is linking that innovation and research component and capabilities that we are building within the system. Add to that the cost savings that is going to be realized as the coordination of care truly starts to take place.

So I think the linkage between research and we have to really look at that holistically and the capabilities we're putting in place that allows us to do even more in innovation as Neil is describing it and empowering providers with the flexible tools that we need to really come up with the new indicators, the new quality measures, the new ability to really drive outcomes and improving outcomes.

So, I think we're really...this is the most productive conversation we have had and linking those things together and throwing into the pot some usability for those providers out there who I hear from on a daily basis who have wonderful ideas and I would love to see some kind of a public hearing of linking innovation and research together so that you could bring the best researchers here and say, you know, what do I need? What are some things I need? Bring some of those innovative thinkers, bring people like Neil's folks in and look and see how do you take us now to Stage 4 and make that the innovation stage?

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

We refer to Stage 4 as the learning health system which would tie this together really well. Christine had her card up?

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

Yeah, thanks, so I just wanted to follow-up everybody is in a really glass half full mood and I think that's fabulous, yeah, I know...

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

What are you doing pouring it out?

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

Yeah, Debbie Downer.

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

Hold on I'm going to fill up your glass before you go on.

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

Yeah, I saw that coming, thanks Neil. So, I just want to say, and I agree and I hope that's where we're at, but, I also want to acknowledge that, at least from a consumer perspective, the reality that we still have fee-for-service and while we have been part of...the National Partnership and many of our consumer colleagues have been part of driving the system toward a transformation for decades now, and we are incredibly hopeful when we hear you talk, Neil, and the progressive providers like you who are really doing right, and we see the pockets of change and hope in the environment, but we're also not seeing, you know, accelerated unbelievable trends in patient and family experience for example. We're not seeing people developing a deeper understanding of how to partner with patients and families in doing the delivery system redesign on a widespread basis, you know, we see pockets of it.

And, I think the challenge for us is Meaningful Use is that it applies to such a broad spectrum of providers, right? And, so we end up sometimes designing like a pretty minimal floor and we end up with a whole lot of process requirements and so, you know, and here we are. So, I think we are ready and I want to encourage us to, you know, keep checking and looking at the external environment and help to design Stage 3 in a way that does, I agree with you Neil, reward innovation, but at the same time make sure that we are protecting patients and families from, you know, the status quo, right.

And what we're seeing today, which is people...story after story of patients and families going to a so-called patient centered medical home and saying "gee, I hear that you guys are this medical home model and tell me about it, how is it going to be different?" And the provider "goes, oh, you know, what the insurance person said something about that" and its vaporware, right? So, we have to just be realistic and at the same time hopeful and so I just...from a consumer perspective want to not forget that there are some kind of fundamental protections that we need to also be mindful of. Thank you for the water, Neil.

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

Thank you. Terry?

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

I had a few comments one of them I wanted to go back with was what Jesse said liberate the data that providers kind of to follow-up with you just said, Christine, the patients, the family, the communities. So, I think we need to remind ourselves of that routinely as we look at these, especially as we look at quality.

There are a couple of things that I wanted to just mention. We talked about quality standards, research, I actually thought, Connie, where you were going to go to the next step was the advances in computer science. There are huge advances in technology and I think we need to be attentive to them and leverage them as we move forward in terms of where we want to go.

And I actually don't want to go to Meaningful Use Stage 4 yet, I really want to be at Meaningful Use Stage 3 and I want to go with what Neil said, because I think that this is really important, and I don't know the answer to this, but how do we embed in the process this sense of discovery, which I believe is predominantly at the local level, with the patient perhaps in a medical home, perhaps not, then to innovation, then to sharing and then to integration?

And, I think that that is a step that we somehow have to embody in certification, not that I know how to do it, but we don't want to be an obstacle to that and I would just say Neil this whole issue of chronic

kidney disease, the impact of potential incredible resources saved from a CMS perspective and how does that get a hearing? How do we get that there I think is really important.

And finally, I think that there is this whole sense of, Christine, once again what you said is why does that provider only know that somebody told him he is part of a patient medical home and I would argue it goes back to what Judy said, the providers are stressed, they're busy, all they want is a little more time. They want efficiency and they want that relationship with the patient and with the family. I don't know any providers that do not want that.

What do we create to help engender that and I think we have an opportunity here. I wish I knew the answer to it, but I don't, but I think we should wrap...the framework should be improving care, improving outcomes but really also this recognition of what can be put in here to facilitate that?

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

Good, thanks. Judy, Deven and then David?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

I like what you said, Terry, about we should think about this about Stage 3 and not delay it until Stage 4 I agree with that and I was listening to a great TED talk by a guy named Barry Schwartz I think it was and he was talking about innovation and discovery, and he was calling it wisdom but I think it's also innovation discovery. And he was talking about the two things that kill it, which I thought might be relevant to what we're talking about here.

The first thing he said that kills it is rules and he said that...he gave an example of a professor with his 11-year-old son in a ballpark going to get lemonade when the kid asked him for lemonade. He went to the concession stand and it said hard lemonade and he was an academic and didn't know what it meant so he took it to his kid, got arrested, got put in jail, wasn't allowed to go home, had to live in a hotel and everyone said "I'm so sorry these are the rules we have to do it."

And so he's not saying that rules are bad, he said rules are essential but rules should be like a GPS that get us to the city and finding the house within the city should be the wisdom, the innovation, the discovery that each individual is allowed. I thought that was a good analogy.

The second thing that he said was a killer of innovation, and I absolutely agree with this, is incentives. Incentives say we don't trust you to want to do it inherently, we don't want to trust you to do it because it is the right thing to do, the only thing that's going to make you motivated is to pay you something extra for it. So I think we have to be careful. There is a difference between an incentive and the freedom to do something else that might be put into our rules here and so I would recommend that talk.

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

Could I actually ask Neil to say a little bit more? Neil Calman? Dr. Calman?

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

I was telling Judy that we showed that talk to our entire faculty because it's really profound in the way it thinks innovation.

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

Neil, I was wondering if you could say a little bit more about there is the taking away, right, that gives more time, more time for innovation. But how can setting that floor, setting the standards, setting the basic framework help accelerate? You mentioned Health IT can accelerate this. In particular, for those who are struggling with getting their arms around population health management for the first time who are not those who've been innovating in it for 10 years?

So, how do we not...how do we use the innovation of those on the leading edge and not hold them back, but slingshot that back around to bring admittedly the vast majority of the practices in this country who may or may not know that they're moving towards a new delivery system but certainly don't know exactly how to do it? So, if you could speak a little more about not just what we should not do but what can we do to help?

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

So, I think we're doing it. I mean, we have created a huge financial incentive for people to get the basic tool in their offices that they're going to need to do anything creative or innovative or to be able to meet a lot of the kind of outcomes that we are seeking including lots of things around patient engagement and care coordination. So, we've done a tremendous amount, you know, and we're continuing to do that by continuing to offer incentives for people to get the tool.

I think we're doing a lot because we have also gotten a lot of standards kind of put in place already so that the tools have many increased uses than they did 2 or 3 years ago and I don't think we should stop that process.

I guess what I really am reflecting on is trying to figure out how we can't take 10 or 20 academic labs and a few big providers like Kaiser and Geisinger and expect that all of their innovations are going to be relevant to every place in the country or that they're going to develop all of the innovations and things that are relevant.

And when I talk to my colleagues people are doing amazing things and we need to figure out how to bring that into the system. So, I think the way you do it and let me just say one other thing, I don't think that we're responsible for through IT for making sure that every last outcome that we're trying to deliver in healthcare gets driven through our work.

I mean, our work as you pointed out early on is to get the tool developed and to get people using it and to make sure by having some functionalities in patient engagement, some functionalities in quality measurement, some function that they have experimented, that we've forced them almost to experiment in using the tool in these different ways, but now to let them go, and this speaks directly to what Gayle is talking about in terms of specialist, let them go so that the tools can be used in ways that are relevant to their practices and give them the capacity and time, and the resources that they can energize around those and I don't know how we capture that stuff, you know, as a country, but I think that we should do some good thinking about that issue.

How do we capture some of these things? I know that, you know, through our system the tools that we developed are democratized in a user web and are made available to all the other people that use our system, that use the same kind of system. I think that's one way of doing that. We all have come to depend upon bringing tools from other places into our system and sharing tools that we have with others. If there was a way to do that in sort of a cross vendor capacity I think that would be even more important to do.

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

But, can I just say, I think part of it...

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

Wait, one more...

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

Yes.

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

I just wanted to respond to something you said before. I think the innovation goes right to the issue of patient engagement and again something that I just was reading on the train on the way down, you know, the number one hospital that sort of got the highest scores in terms of patient service and they were interviewing the person who did that and said, so how did you do it and he said we started a process where every half-hour around the clock a nurse goes to every single room on the floor and the if patient is awake asks them if they need anything and all we did was we...that one innovation, you know, and a way for them to get those services to the patients and I thought wow I can't believe it took until 2013 for us to figure out that we actually had to stop waiting for people to hit the buzzer and actually ask them if they needed something.

But that's, you know, if that thing alone got driven across the country, you know, to every, you know, inpatient facility imagine what that would mean for people to actually be able to take an innovation like that and that has nothing to do with IT but it's just...you know, those are kinds of innovations I think that we need to be able to sort of bring out in public.

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

So, I agree. I think part of the challenge though to your question, Farzad, in the Meaningful Use Program in particular is when most people think about Stage 3 the penalty phase is not far behind, right? And I think that's a big part of why we designed for, you know, kind of a floor so that everyone can meet it because no one wants to be penalized.

If we had a better sense of what the options might be for Stage 3, we have to understand the, I think the sort of legal and regulatory option and here's what I mean. Is there a way to give partial credit? Is there a way to say, you know, partial payment therefore? Is there a way to say okay, not everybody is actually going to be able to succeed in Stage 3 because we're going to orient it around advanced stuff and innovation and that's going to drive a market of available tools for anybody to use once they do have the business case, so not everybody's going to get to do it, but we're not going to tie the penalties to your ability to meet Stage 3, we're going to tie it really to 1 and 2. Do you see what I'm saying?

So, I mean, I'm throwing these out, but I think having a sense of how we think about some of the fundamentals of the program structure that are not already laid out in the law, because we can't go change the law, would be helpful to understand innovation will be difficult when every provider has to meet it in order to avoid the penalty.

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

Deven?

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

Yeah, I feel like Gayle you said this was the most important conversation we've had, I actually feel like we've had this conversation before. And, I feel like the next step really has to be the sort of opening up of these criteria and thinking through what exactly could we, should we take our foot off the gas on and instead be reorienting towards things that are going to drive us toward the health care system that we always intended to drive toward, right?

It's we got a set of comments back that were specific to criteria, each individual criteria that said, oh, you know, this is really burdensome for us, can we not do this? This is going to be hard for us to do, right? I don't get the sense, and I could be wrong when we do our deeper dive, that anybody was really able to take the time and say here's another way to think about this, to drive this forward, right?

Because that's the hard work, that's the hard stuff, that's the most important conversation that we have to have, because it is very hard when you look at all of this individual criteria to say, well, you know, we can sacrifice this and one and we can sacrifice this one, right, because they all were leading to something.

So, it's almost as though we have to almost take it off the table and not exactly rebuild...I'm not even an expert at doing this, but I feel like we're stuck groove that we all...that I think most of us, if not all of us recognize we've got to try to get out of but we haven't yet found the way to do that that rewards innovation, that rewards providers for being...to thinking about what their particular patients need and how to get there and how to improve outcomes, and how to use the tools of patient engagement to actually help achieve those outcomes.

And so, this is not meant to be a criticism...I would include myself in that bucket; I'm on this committee, right? Like, we have to figure this out in a way that the important conversation is the one where we start really figuring out what it's going to mean to get to the Stages 3 and 4 that make a difference without sort of making people dance in lockstep and do 80% instead of 60% on CPOE. I don't know how to do it, but that's I think what it takes.

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

David?

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

Everybody's thoughtfulness it's the hard stuff. I'm thinking about both Neil and Judy's comments and obviously the physician orientation that was talked about at that end of the table and I'm thinking about what both purchasers are thinking and concerned about and what the payers are thinking and concerned about and Neil sort of postulated that the payers have been creating an environment and now negotiating with providers in an environment that will drive towards some of those values and National Quality Strategy and so on.

And I think that's partly true, but it's to the purchaser's view not very substantial, it's symbolic more than it is real at this point much as Christine was saying about the patient experience not having changed generally across the country that's also true for purchasers and payers. So, while the signs are there I'm not sure we're there yet and part of what that takes me to is really two things.

If we believe that the signals from the payers that Neil described is accurate, are accurate and that incentives will be big part of what shapes behavior and change, and that we've put in place some of the capabilities that will be responsive to that one thing we might do is kind of a Gap Assessment of in what areas is the technology that is so far being deployed and certified not adequate to address the emerging needs of those payer expectations? And, I mean, especially the public payers because we are representing in part public programs, but also the private payers and whatever we know about them.

And that to me suggests a different kind of partnership maybe with the payers in this process in which we have a closer conversation with them about where they're going and when they're going there and what capabilities are needed to meet the things they want to incent, and obviously, again CMS would be a principal partner in that conversation but there may be others. And so having that conversation and working back to what are the gaps in current capabilities and how do we fill those gaps with our program might be one pathway to do some things.

And then the second thing I think goes back to Marc's point, which I also have heard a lot of, and understand it not very well but I'm sympathetic to, that part of that is in a sense we need to be both at the top at the outcomes we're looking for and in some sense the payers in the community is looking for, and also down at the bottom of whether the foundational standards and interfaces are in place to support the evolution of the system.

And it's not an area that I have any competence in, but I think we need to do an audit again of where those...and I think John will help us this afternoon, where those standards not sufficiently articulated without getting over stringent and too many rules, which we've all talked about, but enough standards to ensure that true interoperability and data aggregation and so on is possible. Those are the two kinds of ends of the spectrum I hope we give more attention to.

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

Thank you, very, very good comments. So some of the sentiments I think that were raised are one we've been in the Stage 1/Stage 2 sort of establishing both the floor and perhaps a lot of that was regulating and essentially certifying vendors, but also guardrails for the providers and maybe we're trying to ask over towards...moving towards the recognition of success and in fact that would help us align with the other federal programs much better like CMS and the new delivery system initiatives.

Going back to what Marc was saying and David just emphasized, we're going to hear from John and I don't know that he's on yet, but we're going to hear from John about the HIT Standard's Committee response and we see in our paperwork a lot of responses...well they aren't there yet.

But maybe what we need to do, just like we pushed vendors and providers to do certain things, maybe they need to in addition to saying it isn't there yet is find some way of making it happen faster and I know there is certainly S&I work going on, but maybe we also have to turn up the fire there because that seems to be not only an enabler but it's also an Achilles' heel for a lot of the things we have to do, so, that maybe another kind of a different push.

But, at any rate, I think this has been very useful to have this conversation, it's been extraordinarily useful to have the public summit and ONC to digest this information and now the work that remains to be done is to answer some of Deven's questions that we don't know the answer to yet, but I think we're starting to go on a path of saying there are other ways we can take this ship and leave the guardrails in place and continue those but also give another way for us to recognize excellence, particularly recognizing improvement and maybe that's the way out of saying instead of setting thresholds which isn't our role and performance, but saying the only way to improve is to use this tool adequately and we don't have to watch over you while you do it, but if you're doing it that's good enough for one of the pathways. So, we will take a look at this. Farzad?

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

A couple of things that I think have come out of the conversation but hasn't been made explicit and I was wondering if folks would be interested in talking about it, one is the concept that incentives aren't necessarily the best way to drive change and there is a lot of I think good literature about that, about how you change the way people think about something when it becomes about money versus when it becomes about, you know, the right thing to do or professionals and a moral truism.

But we may be able to, and to Christine's point about different ways of formulating the program in the future, so there's a minimum level to avoid penalty, but could we create almost...like your responses...and this is not a well-thought-out plan, so this is just for discussion purposes, if there were a way to almost have a star rating for Meaningful Use where you avoid the penalty if you meet the minimum, but there's a way to demonstrate that I'm just a kickass Health IT user, right? That, you know, we do things way over and above and to be able to be recognized for that.

So, right now you're either a Meaningful User or you're not that's it, you know, everyone if you pass you pass, but there isn't a way to say, you know, I'm over here on this side of the distribution and to reward and recognize that and I think people do care about recognition among their peers for their, you know, excellent use of technology. So, that's one idea I'd like us to think about in terms of new framing of this.

The other is, one thing that I don't think has been quite explicitly articulated as a value of the regulatory approach, although it was alluded to, when we talk about standards implicitly and when we talk about making sure there's a floor, is there's a value for some measures that goes beyond, it's not linear to the number of users, there are network effects, that when there's an assurance that everybody is going to have this function, this capability, this standard that the benefits to society are more than the sum of each individual's user's use of that function.

And those are things that maybe makes particular sense for us to emphasize, because if we let anybody go their way in innovating we will get much great innovations in individual pockets but won't get the network effect until we get...and the network doesn't pertain for everything that we're talking about, certainly not all the functional measures do, but things like, you know, sharing tools and protocols, the standards for being able to do those, sharing that information and that knowledge, certainly interoperability standards, but also things like Blue Button.

So, if providers are...there's a difference in the benefit that we...societal benefit that we can get in terms of an ecosystem emerging where patients can have a reasonable expectation that wherever they go they can download a copy of their records versus if that were left to the priorities of each individual practice.

So that to me makes a difference and we should consider whether they're among the criteria we look at, certainly we look at, you know, population health impact and the benefits, and, you know, people are already doing it, but let's particularly seek out those examples and be kind of hard-nosed about it, about whether...are they really network effective or are we just saying this? But, where you can actually by having everyone doing it you get more.

And then finally, one way that I think we can, as the technology advances we can simplify. So, Judy mentioned cars, you know, I remember a time when, you know, my dad had to be able to be a pretty good mechanic right? He knew, you know, a lot about the belts and the carburetor, and you had to, right? But nowadays their sealed, the whole engine is sealed, right, because the tools advanced to the part where you don't need to do a lot of the detail stuff about your car.

And I think, similarly, you know, looking at things like automating Blue Button, set it and forget it, make it seamless, then, you know, maybe we don't need to have providers printing out a copy and giving it to the patients every time and all the...right? So, we can replace maybe the patient education and the clinical summary, and the copy, and the online access, and the...right? You can simplify through advancement also it's not always you take something away, you take something away.

So, those are, I guess three thoughts in terms of this new conversation we're having, which I think is tremendously helpful.

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

Very good. Judy is that another comment?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Yes. Farzad you were talking about how do we show the best use of IT and I wanted to ask you right now there are things such as the Davies Awards and HIMSS Stage 7, do they meet your needs in that?

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

I think it's terrific to have recognition of individual, you know, people who have done amazing things. What I guess I was thinking was something more like PCMH maybe or the star ratings for plans, something that pretty much every person could put themselves on the scale and measure themselves and say how am I doing, you know, in the words of Mayor Koch, how am I doing? And be able to answer that question for themselves.

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

Terry?

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

I had one comment and I really want to push on this simplicity, you know, the least amount of code you have to write the better off you are, especially in older systems. So what I wonder, and Farzad, I really do think this is true, and not to do ABBI, but Blue Button download, if we can find certain things that embody standards, interoperability and that by asking people to do them that kind of stuff for the providers in the backend they don't need to know about it because they don't want to look at the lines of code, but yet it meets the ability to accelerate the patient experience and the quality of care. I think we should take the time to do that.

And I really am intrigued by what Judy said happens overseas, that people simplify and I think they simplify for many reasons, but in that simplification I would assume the core stuff of what you need doesn't get lost and to go back to what you said, are we on this path and we're just, you know, the mule is pulling us along and we're digging a deeper trough and should we just step back a little, but I'm intrigued by this concept of finding a few things that when they exist and are utilized actually embody where we want to go.

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

To lump one of the things I'm taking away from this conversation and Farzad's posing a question, maybe there's a value to this regulatory arm of the floor for necessary but not sufficient and there's an additional increment where there's guardrails to protect the interests of patients because you can't have people not opting out and to gain the advantages of network effects and a level playing field.

So, maybe that is...but then there's a threshold and saying all those things we just talked about must be there because everybody has to play then there's a penalty for people to not to play. So, maybe after you cross that threshold and maybe Meaningful Use Stage 3 is a threshold it becomes recognition and all of a sudden not only the network effects but the market rewards and pressures start kicking in. And we don't need any push there and so there are ways to move...we still potentially can be wanting to create floors, enabler floors in the systems so that providers can continue to excel, but maybe there's a penalty like I think you suggested 1 and 2 are moving, Christine, 1 and 2 are the penalty because opting out creates harm to the whole society.

So, anyway this is really good food for thought. Any other last comments because I think we're really right on time? Great discussion prompted by the public input and ONC staff digestion and thanks for the participation of the committee members in coming up with these great ideas.

So, the Meaningful Use and Information Exchange, and Privacy and Security Workgroups are all going to work on their respective...and Quality Measure Workgroup, work on their respective parts and come back to this committee in April with an update reflecting some of the thoughts that advanced today. Why don't we open up for public comment, please?

## **Public Comment**

### **MacKenzie Robertson – Office of the National Coordinator**

Operator, can you please open up the lines for public comment? And as that's being prepped I'll ask if there is anyone in the room that would like to give a public comment if you could please come up to the presenter table and the panelists in the first one you're free to step back to the audience.

### **Alan Merritt – Altarum Institute**

If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press \*1 or if you're listening via your telephone you may press \*1 at this time to be entered into the queue.

### **MacKenzie Robertson – Office of the National Coordinator**

And seeing someone at the table I'll just remind everyone that public comments are limited to 3 minutes, so I will be stopping your presentation in 3 minutes.

### **Paul Tang, MD, MS – Internist, VP & CMIO – Palo Alto Medical Foundation**

And thanks again, Michelle, Kory, Jesse and Kathryn, wonderful presentations.

### **Sean Cahill, PhD – Director Health Policy Research – Fenway Institute**

Good morning. Is this on?

### **MacKenzie Robertson – Office of the National Coordinator**

Yes.

### **Sean Cahill, PhD – Director Health Policy Research – Fenway Institute**

I'm Sean Cahill and I'm with the Fenway Institute at Fenway Health in Boston. We're the world's largest health care organization focusing on lesbian, gay, bisexual, and transgender people. Last month Fenway Health joined with the Center for American Progress and 143 other organizations including the National Gay and Lesbian Taskforce, the Gay and Lesbian Medical Association, the American Psychological Association and others in submitting public comment and strong support of asking sexual orientation and gender identity questions in clinical settings and I have a copy of the comment here.

Specifically we urge you to include sexual orientation and gender identity in the Stage 3 Meaningful Use guidelines in the core demographic objectives and we urge that such data collection be required of all eligible hospitals and professionals. The status quo is that LGBT people are largely invisible in the health care system now.

The Obama Administration sought to end this invisibility by promoting data collection through the Affordable Care Act, committing to eliminating LGBT health disparities in Health People 2020 for the first time, publishing the 2011 Institute of Medicine Report on LGBT health which calls for data collection in clinical settings, and holding the IOM Workshop that many of you attended in the fall looking at data collection on these demographic variables in EHR.

The Joint Commission has also called for data collection on sexual orientation and gender identity in clinical settings. We know that lesbians are less likely to get preventative care including Pap smears and mammograms. Some indications, some research indicates that lesbians may be at higher risk for breast and ovarian cancer related to nulliparity, but we don't have enough data and good enough data to really know for sure, so we need more data.

Yet, most providers don't discuss sexual orientation or behavior with their patients and they don't gather data in a systematic way that will allow us to better understand disparities to look at regional or age cohort differences to look at how LGBT disparities intersect with racial disparities.

The American Hospital Association has said that hospitals must take the lead in eliminating disparities in care, but if we don't gather LGBT data in clinical settings how can we know if we're making progress toward this Healthy People 2020 objective of eliminating LGBT health disparities?

We know that some have spoken against doing this saying that providers must be trained in how to ask these questions in a culturally competent way, that we need to train clinical staff, that we need to educate LGBT patients about why these questions are being asked, address privacy and confidentiality concerns. We agree that these are important implementation steps, but they're not insurmountable barriers and they're not a reason not to do this. The LGBT and HIV advocacy groups are supportive of this, healthcare groups like the Joint Commission are supportive, researchers and public health professionals are supportive.

According to the Health Research and Educational Trust and the American Hospital Association disparities in healthcare can be addressed if data are available and they talk about data collection being central to the quality assurance process and that it also helps ensure nondiscrimination and access to care.

**MacKenzie Robertson – Office of the National Coordinator**

Mr. Cahill that's your 3 minutes.

**Sean Cahill, PhD – Director Health Policy Research – Fenway Institute**

Okay, final thing is just that I realize this is a burden for providers but not having these data is a burden for researchers, for those of us trying to reduce these disparities. Thank you.

**MacKenzie Robertson – Office of the National Coordinator**

Thank you; are there any more public comments in the room, if you could please step to the table? And if you could identify yourself? Thank you.

**Chantal Worzala – American Hospital Association**

Good afternoon, Chantal Worzala from the American Hospital Association. Really appreciate this very, very thoughtful conversation and the opportunity to provide public comment both in response to the RFC and also today. And I'm encouraged by your thoughtful conversation and really want to urge this committee to ground your conversation in fact and to that end the HITECH Act was passed 4 years ago, we have 2 years of Meaningful Use incentive dollars have passed, 2 years of the window have closed, any critical access hospital or eligible professional that has not already attested will not benefit fully from the incentives that's in the law.

So, I would urge you to ask HHS to fund a comprehensive external evaluation of the program to date. What's working? What's been successful and where do we need to make improvements? And, importantly in that evaluation we would ask that you make no final recommendations about Stage 3 until you have the results and you know who has not met Meaningful Use. Why haven't they met Meaningful Use? What resources have been required to get to Meaningful Use? Is that spent both in human capital and financial capital sustainable over time?

How many state departments of public health can actually receive the data in the public health measures, which ones? Do they have the capacity to work with all of the providers in their communities who currently want to send the data? The answer to that is no, and those that should come online as Meaningful Use rolls out.

So, I would really encourage fact-based work and just as an anecdote, I received an e-mail on February the 1<sup>st</sup> of this year, a small hospital in the Mid-Atlantic was saying, you know, I really don't know what to do here I've contacted a vendor to get on board with Meaningful Use, they've said they can get to me within 12 or 18 months from February 1, 2013, but to get in my queue you have to put 60% down.

So, please, I ask you to look at the environment. What's really happening on the ground and how do we first make Stage 1 possible? Two, get Stage 2 off the ground, no one has met Stage 2, there isn't a certified product on the market today for anybody who wants to go to Stage 2 and learn from that before we design Stage 3. Thank you very much.

**MacKenzie Robertson – Office of the National Coordinator**

Thank you. Are there any more public comments in the room? If you could please come to the table and identify yourself before speaking, thanks.

**Kellan Baker – Health Policy Analyst – Center for American Progress**

That was a very bracing comment, so I'm going to go back to the glass half full discussion of Stage 3 itself. I'm Kellan Baker from the Center for American Progress. We are a longtime supporter, as many of you know of the collection of data on sexual orientation and gender identity. We worked with Fenway Health on the letter or participated in the Institute of Medicine Workshop that Sean Cahill referenced and have followed many of the resources that various organizations have been putting out about the importance of ending the invisibility of lesbian, gay, bisexual, and transgender people in healthcare settings.

And I just want to emphasize that this is not about vanity. The Christmas tree is very pretty, it's not just though our desire to add many more things to it, it's about the importance of recognizing the diversity of patient populations and the reality of where people are coming from and from our perspective of demographic data as a whole the connection between these data and high-quality care and good outcomes for patients and families.

Sexual orientation and gender identity are demographic measures. They are about much more than sexual health, they are about how we form and support families, they're about mental and behavioral health, they're about disparities such as smoking and obesity. They're also specifically about clinical considerations for transgender people. As such we're particularly concerned about some of the discussion around the demographics objective which we believe has both substantive and symbolic importance.

We can't take the collection of this data whether it's about race, ethnicity, gender, sexual orientation, disability for granted. We believe that we need a toehold in Stage 3 to ensure a sustained focus on demographic data. Moreover, if the objective is retired where will sexual orientation, gender identity, occupational codes, disability fit in?

So, we overall believe that sexual orientation and gender identity, as well as the other demographic measures under consideration should be included in Stage 3. And we believe that the certification requirement proposed in the initial Stage 3 recommendations, on which we commented, is vital.

But, we also believe that we need to do more to retain the focus on demographic data collection overall. This may mean the retainment of the demographics objective and inclusion of sexual orientation and gender identity, as well as disability, and the occupation codes within it. It may also mean a new objective or a new way following on the discussion this morning, a new way of thinking about what is the purpose of collecting these data and how are they going to be used?

Some possibilities listing race, ethnicity, language, sexual orientation, etcetera and other demographic data and asking for a condition list by demographic factor or ensuring that providers are able to generate reports on patient populations by these different demographic factors. This is something that we know that community health centers are already interested in doing as their understanding of the diversity of their patient populations, where they're coming from, how far they're traveling, what their needs are both clinically and in terms of cultural competence as that understanding develops.

The bottom line is we believe we cannot miss the opportunity in Stage 3 to emphasize that robust demographic data collection must be part of any truly patient centered system. Thank you for your time.

**MacKenzie Robertson – Office of the National Coordinator**

Are there any more public comments in the room? Are there any public comments on the phone?

**Alan Merritt – Altarum Institute**

No.

**MacKenzie Robertson – Office of the National Coordinator**

Okay, we have no comments on the phone so with that I'll turn it back to Paul.

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

Good, thank you and thanks to the members of the committee. Did you have something?

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

Yeah, I just wanted to thank the committee. I'm sure there are folks out there who are going to say, wait a minute I thought there was this groove, right? And, you know, there's a groove and...

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

I was in it and I was...

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

I was in it and I was upbeat. I was in it and, you know, gosh what's going to happen?

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

Right.

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

And I want to make two points about that. The first is Chantal is right we've got to focus on implementation of Stage 2 this year, in 2013, right? We've got to execute the heck out of this. I think we ended up with the right policies in Stage 2. I think we ended up in the right place with the right balance and no one has said here that anything we've done hasn't been necessary. The question is, if you've been doing Stage 1, if you've been using Stage 2 where does Stage 3 evolve into? Where are you going to be if you're that person who we haven't seen yet, right, that unicorn who achieved Stage 2 two years ago, right? What would Stage 3 look like for you?

So, this committee is doing their job they're looking towards the future of saying what should Stage 3 look like not in any way saying, you know, Stage 1, Stage 2 aren't the right steps and not saying that we shouldn't, as a community, focus and as a Policy Committee, make sure we damn well nail Stage 2 in implementation, because we've got to do that and we've got to be fact-based and we've got to be evidence-based and we've got to understand the challenges that are emerging and find policy and other levers to address them. So, that's one.

None of this takes away from the need to implement Stage 2 and to do it well and to know what...you know, make that happen, because until we do that it is way too early to talk about moving beyond process and interoperability to outcomes if we haven't gotten the process and interoperability in place first. So, that's point one.

Point two is when we started this, as Paul said, the very first presentation to the Policy Committee from the Meaningful Use Workgroup, I know because I was there, we showed a smooch, right, that said Stage 1 data capture, Stage 2 advanced care processes, Stage 3 outcomes. This is exactly the conversation that we need to be having if we're going to be staying true to the original vision of what Meaningful Use was set out to be and we have to be responsive to the changes in environment, but this is, I think, very much a continuation and an evolution in the direction that we hoped we would be in a position to do back when we started this.

So, I want to reassure folks who have gotten used to, in a sense, the Stage 1, Stage 2 groove stay tuned, but this is the right conversation for us to be having now even as we're going to focus like heck to make sure that Stage 2 implementation is successful.

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

Good, thanks, Farzad. Okay, so we will take a break for lunch and reconvene at 1:15 where we're going to hear from John Halamka about the HIT Standards Committee's response to the RFC. Thank you.

**MacKenzie Robertson – Office of the National Coordinator**

If everyone can take their seats we'll get start in a minute and operator can you please prepare to open the lines?

**Operator**

The lines are open.

**MacKenzie Robertson – Office of the National Coordinator**

Thank you, if everyone can please take their seats I will turn the agenda back over to Dr. Paul Tang.

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

Okay, thank you, MacKenzie. And John, you're on the line?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

I am indeed.

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

Thank you, so much. So we're open to hear your response on behalf of HIT Standards Committee. We did hear a lot about standards coming up in the RFC comments on the policy end. As you go through, and I know a lot of your comments will have the lack of standards, if you can also annotate that with well what could be done to change that situation, how can it be accelerated, what are the levers that ONC might have that would be helpful.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Very good, well thanks so much and Paul I wish I could be there in person. So, I will tell you that overall the Standards Committee applauds the aspirational direction of everything in the RFC. I don't think there's any member who would argue about the appropriateness, the notion of improving quality, safety, care coordination, patient and family engagement.

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

Okay, John, we've heard that before though.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

The question that we ask...pardon?

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

We've heard that before.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

The questions that we asked were a reflection of standards maturity and implementation and so, although, again, everyone read through every comment and said "hmm, you know, would like to get to this" as I reflect on the comments that we've provided in our spreadsheet back to you they...into five major themes.

One, this should be a menu set rather than a core criteria because of the somewhat immature nature of the standards or lack of implementation experience, lack of workflow or product. It should be a certification requirement rather than a Meaningful Use requirement, meaning that we think it's a wonderful idea and the products should be enabled to do this, it just may very be that the work flow of eligible professionals and hospitals isn't yet itself evolved enough to perform the function.

Then, as you point out, standards don't exist and of course there are gradations of standards not existing. There are those that have never even been considered, those that have been considered but aren't yet brought to fruition, those that have been brought to fruition but aren't yet implemented, and those that are implemented but not yet widely adopted. And so there are gradations of standards comments.

Workflow doesn't exist. I mean, maybe there's a standard but what is suggested for example in certain health information exchange workflows may mere existent paper processes but there's actually no evidence that such an electronic process has ever existed or could easily exist and then some...I mean, don't worry, Paul, we just agree with you, in fact we say, wonderful and take it from 80% to 95%. I mean, we think that it's absolutely something we should do in Stage 3.

So, of course you have this spreadsheet and you can go through every comment, but what I'd like to do, Paul, given our limited time is take the SGRPs and actually just very briefly go through a one sentence summary of the general tone of comments on many of them and then reflect on what ONC can do and the Standards Committee can do to ensure a positive trajectory forward.

So, for example, on SGRP 101, which is interested in drug-drug interaction and advanced medication decision-support our comment there is we love drug-drug interaction checking and of course we want that embedded in all EHRs as it has been in Stage 1. Alas, there are no standards for representing knowledge like drug-drug interaction rules that would be authored by some expert and easily incorporated into an EHR such that never events would have a set of what I'll call externally authored triggers or knowledge consumed from the cloud.

Now, admittedly, we have ONC on the Health eDecisions Initiative working quite hard on both knowledge representation and calling cloud-based knowledge functions. So, there is a trajectory there it's just at the moment there is no standard that exists and nothing in pilot that any of us are aware of that would allow external rules to be consumed.

Similarly, SGRP 130, using CPOE for referral, love the idea of care coordination and automated referrals and closed loop processing. At the moment there is not a product that we are aware of available in the marketplace that has this fully integrated CPOE referral management close the loop capability. Now, there are pilots, it's true, Atrius Health Care in Boston has worked hard with EPIC to actually develop a lot of the functionality you describe in SGRP 130 it's just not a widely available electronic workflow at this time.

SGRP 103, formularies...

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

So, John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Yes?

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

When you say there is some pilot work going on do you consider any possibility of it maturing by 2016?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

So, just a very quick digression for you, Paul, the Harvard Hospitals have a technology taskforce where all the CIOs meet on a quarterly basis for breakfast. We've actually looked at SGRP 130 as a group and agreed that it's really a laudatory goal. We actually came up with 11 steps that are necessary in a workflow in order to enable SGRP 130 and we actually looked at gaps and we are doing pilots over the course of the next year and a half to use the state healthcare information exchange between Children's and Atrius to illustrate how SGRP 130 could actually be done in the field.

So, I guess one challenge is, is that the pace of Meaningful Use is such that it is a bit hard to say that we will have ready for Stage 3 products and workflows that would be mature enough to mandate. So, in a sense, maybe that's a Stage 4 item rather than a Stage 3 item just the fact that we're in pilot in one location in Boston with CIOs working hard on it now suggests, you know, Stage 3 as currently timed might be a bit aggressive.

And, you know, again we don't want to ever at the Standards Committee level be a wet blanket for any of the stuff you suggest. Liz Johnson and Cris Ross on the implementation side just want to keep me honest to the state of implementation and the burden that we have placed on providers, IT vendors and the various specialist trying to roll this out to be realistic about what we can do and how fast.

So, on the formulary side what Jamie Ferguson concluded in SGRP 103 is that there are actually formulary standards. So, the standards are actually good enough, you've got some NCPDP formulary standards, but there are some really interesting workflow challenges like generic substitution. And so, strict adherence to an externally provided formulary actually may not work in many settings. And so, the suggestion is we think the standards are good, we think formulary from external sources is good, but we would probably want the language on that one to suggest that there are obviously, at times, workflow requirements to not strictly adhere to say what an external formulary might dictate.

Interestingly enough, lots of debate on whether or not we should retire certain measures where we have achieved an 80% top out. And the language was something like this, you know you've just run a marathon, congratulations; you've accomplished the marathon, move onto the next great thing. You know, that in some ways we depress people who've worked so hard to get something done by taking it out of the Meaningful Use requirements list, that was sort of one bit of logic.

The second was, you know, demographics. If we're truly interested in disparity of care and measuring quality across different race, ethnicity, age, primary language it's so important that maybe the right thing to do for demographics is raise it to 95% and leave it in for one more round, as well as it will keep people feeling good that they've accomplished it.

SGRP 105, smart problem lists, the thing we all agree to was, boy, you know, it's very true that problem lists are sometimes incomplete, you have a hemoglobin A1c of 9, you've had glucoses elevated for years, you've got eye exams, foot exams and no one has called you a diabetic. The challenge again is very similar to SGRP 101, at the moment, there are no ways to represent rules that would help us decide, for example, what a diabetic is, that would be consumable by an EHR from an external source.

So, we thought in SGRP 105, 106, 107 and a few others that this is a technology that should definitely be developed. We think we would love to see helpful guidance, suggestions offered by the EHR that maybe you should think about putting in a problem for this patient of diabetes, but the state of the standards and workflow is immature to mandate implementation of such a function in Meaningful Use.

So, 106 with smart medication lists, same sort of issue, the standards and rules just aren't at the level of maturity we felt that could be mandated.

And 107, so, admittedly this is on our work plan for FY13. And you have some slides that I sent from the last Standards Committee where we look at five categories of work and five themes within each category. We believe very much that better standards for adverse reaction and contraindication recording should be developed and we are committed to work on that over the next year to two.

The challenge with allergies at the moment is that there is not a controlled vocabulary for the nature of reactions, for some of the aspects of allergies that are non-medication, for contraindications or just general adverse reactions. So, therefore, with 107 like 105, 106 might there be a way of saying we absolutely believe that the product should have functionality that can offer advice, but at the moment the standards aren't quite there to make this a mandatory function.

Now, here's where we agree with you completely, 108, 109, okay to retire vital signs and smoking, we feel like the trajectory is good and there is not a lot of additional functionality to add there.

SGRP 112, on advance directives, we believe it is possible in Meaningful Use Stage 3 timeframe to create CDA standards that will allow structured advance directives to be recorded. The standards aren't quite there yet, but as you pointed out, sometimes you just have to have faith that by 2016 they will be. And we think that advance directive falls into that category.

SGRP 113, where its clinical decision support from external repositories, you know, at the moment such centralized repositories of CDS don't yet exist. There are a couple of web service examples. I've done one of them with radiology ordering, but that's one where again we're just a bit cagey because standards, workflow, products don't yet exist.

SGRP 114 with further incorporation of labs, completely agreed on that one, no argument.

SGRP 115, dashboards, real-time and actionable data fed back to clinicians in near real-time. Sometimes some of the things in the RFC raise questions as to the meaning of the requirement. So, we weren't quite certain what near real-time or actionable meant. So, I guess the interesting thing we did on 115 was push it back to you for clarification on more definition and then we are happy to provide additional comments back to you.

On reminders we agreed to ramp that up to 95%. On eMAR agreed to ramp that up to 95% and you know, some of these we just think are so good just keep going. Go from 80 to 95.

SGRP 118, now one interesting comment on this one is that it described images including EKGs. Now, this does get a bit in the weeds, but EKGs aren't an image. EKGs are a set of timed series data, so the comments from the Standards Committee is you really can't intermix EKGs as a modality with DICOM images like a chest x-ray or an MRI. So, totally different standards, totally different technology, totally different data.

So, beyond that on images one interesting question is what is going to be the workflow of image sharing in the future? EHRs may not be the rational place by which images are deposited. In fact, we may end up with cloud hosted image exchange, there are many products that do this. So the wording of SGRP 118 and how we're going to go in the future with image sharing just should allow a lot of flexibility on the technology architectures that may evolve just recognizing that at the moment EHRs and hospital information systems are not image repositories.

SGRP 119...

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

John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Family history...

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

John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

We agreed that this should be retained as a menu set item.

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

John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Yes?

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

It's Farzad, before we move off of the image and EKG. So, in terms of the policy intent to have images be able to be shared.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Yes.

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

And separately, I guess, to have EKGs be able to shared, I'm not quite clear on whether the recommendation of the Standards Committee is sure separately we should do this because we can provide for a number of different ways of accomplishing this or, you know, however much your policy intent is that images to be shared, we don't think, you know, we should move forward.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Well, that's an excellent question with an easy answer. We all believe that image sharing is critical. Redundancy and waste in image duplication is a huge issue, safety, huge issue. All we were simply saying is that it's not as just saying, you know, every EHR should be able to send and receive DICOM you're done.

That this one, the policy intent is right, it's just we want to recognize that there are many technical logical approaches to facilitate image sharing and that you should allow innovation to occur, require it but don't be overly specific on how it should be done.

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

So, MU yes. Standard no?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right.

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

Okay.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

And people might argue, oh, well DICOM is a mature standard and you should use DICOM. The two answers that I give to that are, well at the moment DICOM has been extended significantly by vendors so that Siemens, GE, Philips, AGFA, Kodak, etcetera all have slightly different flavors of metadata around their DICOM images and that the EHRs themselves really aren't the right vehicle in which to say hold that data and display that data.

So, hey, if novel products and services evolve that are cloud hosted image exchanges that are callable by EHRs in some fashion, great, so let's get the policy goal accomplished at a time when the technology is rapidly in evolution. Does that answer your question?

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

Yes.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Good. So, yeah, I in particular am very passionate about image sharing and many of the hospitals in Boston have acquired certain cloud hosted products that enable it to happen.

Family history, we suggested on that one that family history is structured data, standards still evolving in that space, that, you know, it's a very good goal, should be done, but suggest menu set because the standards are still so much in evolution and notes, we just completely agree with that one as a menu set item. So, no argument at all on SGRP 120.

On SGRP 121 where lab results are required, we specifically recommend that LOINC be required. So, again, the standard there, highly mature, think it's good enough, should specifically enumerate LOINC.

SGRP 122 was one where we get...sought a bit of clarification there. The challenge of test results tracking and having a specific three day timeframe for test acknowledgment we thought, you know, three working days. What do you do on the weekend? That one just maybe a little bit...the policy intent good but it may need a little bit of clarification recognizing workflows on 72 hour turnaround maybe a bit challenging, but intent is good.

SGRP 204, patient data access. We just wanted to emphasize we need to allow a lot of innovation there that just as with image exchange, the marketplace now with Automated Blue Button pilots and Fitbits, and iPhone Apps is so rapidly evolving that we completely concur with the need to be very transparent about all data types getting to patients, but that the technology stack is moving pretty rapidly.

Image exchange functionality for patients is one of those whose future is not totally clear. An example, Farzad, when you were sitting next to me at the Standards Committee I actually showed my chest x-ray pushed in an HTML5 standard to Microsoft Health Vault as a good enough way to share images with patients and their families and the families could show it to a primary caregiver and it's good enough.

That thing I showed you was developed about two hours before I showed it to you. So, just be careful with this one because the image side of patient and family engagement is very much a work in process.

There was also a comment in SRGP 204 about a web content accessibility guidelines and that moving to a AA web content accessibility guideline may pose some implementation challenges.

And 204B, patient generated data. So, the challenge, and there was a fair amount of agreement with policy intent, but concern about data integrity and the reason for that is, at the moment, we do not have completed device standards with a universal device identifier that is something very much that the FDA is continuing to work hard on. So, kind of a necessary foundation for data source from patients from devices as a universal device identifier. We need to wait for that would to mature.

We also probably need some patient friendly vocabulary standards to evolve a bit more. Patients probably don't think in SNOMED. So, how do we use Kaiser's converged medical terminology, some unique services from the National Library of Medicine and if we are going to incorporate patient source data directly into the EHR that we can ensure vocabulary standards that are comparable to provider implemented vocabulary standards and data integrity across all data, patient or provider sourced, is equally good? So, just some additional standards work needed.

SGRP 205, the concern with this one is it said basically provide a summary that is specific to an encounter and we're not really sure how you decide what data is truly specific to an encounter, because, you know, ultimately medicine is longitudinal across your life. So, we thought 205 was just operationally very challenging metadata doesn't really exist thing. Oh, this piece of datum is just purely for this visit.

Okay, 207, on the electronic messaging. Just recognize that electronic messaging is early between patients and providers, you know, Beth Israel Deaconess already has exceeded the 10% threshold several other organizations have, but, you know, we certainly envision a future where the Direct protocol and new products and services in the marketplace facilitate easier patient /doctor communications, because at the moment, it's largely through portals and the adoption of electronic messaging through those portals is somewhat limited. So, allow flexibility and evolution of technology.

And 208, patient communication preferences, completely agree, absolutely, we will want to continue getting that recorded and we should move forward.

And 209, clinical trials, the comments there basically where, you know, this is one that hasn't been widely deployed. Standards are certainly being developed by CDISC. In talking to Becky Kush and other experts thought that maybe requiring a link to clinicaltrials.gov might be a more constrained way to describe how the EHR might offer easy access to clinical trials, because this was one that since the products in the marketplace are continuing to evolve was something that we felt needed to be a little bit more constrained in scope.

When then get into SGRP 302...

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

Sorry, John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Allergy and problem list reconciliation.

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

John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Yes?

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

So, hey, John, it's Christine Bechtel, I just I think I'm confused because I'm not sure if you skipped over the language requirement piece, it seemed that you were talking actually about secure messaging and that's kind of how the document also represents. So, 206 is actually around additional language support and the comments are around electronic messaging. I'm not sure if that's a mistake or if it is something that I just do not understand.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Okay, let's see, so you're correct, I skipped over 206. Let's see, I'm just looking at the comments that were made, you know, let me go back and chat with some folks in the Standards Committee about 206 because there was only one comment made there and it isn't really that helpful to you. So, you are correct I had skipped it and I will make sure the Standards Committee offers additional commentary.

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

Thanks, John and I did have a question but if we need to hold this we can, but going back to, you know, the numbers are very confusing, but this idea of patient contributed...

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

Why don't we just hold it just we so...otherwise we'll get into...

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

Okay, so...

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

Thanks.

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

Keep going, John.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

What was that, Paul?

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

Keep going.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Okay, yeah, believe me I only have a few more to go, it'll be okay. SGRP 302, the concern is that that the workflow for allergy and problem list reconciliation does not really exist yet. I know that in my own institution getting medication reconciliation right actually took us five iterations of software and several years of process change to ensure we didn't put the patient on a whole lot of unnecessary medications just because we were trying so hard to reconcile everything.

And so our worry with 302 is because the workflows are so immature we could end up with problem lists that contain vast numbers of problems that are no longer active or allergies that are not verified. So, only push back on 302 was workflow doesn't exist.

And 303, the transitions of care requirements, generally the thought was that at the moment upping the measure to 30% would be challenging given the state of healthcare information exchange and production, the amount of connections we have today. So, really the intent policy-wise completely agree with, standards pretty good just thought the threshold was a little too high on 303 given the state of the marketplace.

And 304, we recognize that there are very good standards for problems, medications, allergies and labs. Other items that were suggested in terms of transition of care documents are immature and so there is some, you know, work that would need to be done on expanding the consolidated CDA to provide such things as care plans, care teams those sorts of things, because, at the moment they exist purely as free text. So, it's a standards gap for some of the other items you've suggested.

And 305, closed loop referrals, I mentioned that we're piloting some of this over the next year to two in Boston. The concern was that the workflow that was specified doesn't widely exist and depends upon a fair amount of infrastructure that will allow the physician or clinician doing the referral and those receiving the referrals to have bidirectional communication.

SGRP 125, PBM medication reconciliation, there was concern there about the standards not being mature enough to allow PBM or externally sourced data to be incorporated into the EHR at a granularity enough to allow medication reconciliation.

An example of what we do today at Beth Israel Deaconess is that I take data from Surescripts and I display it to the clinician using the format that Surescripts provides, which is actually quite different than a format that we store our data in natively for medications, SIG and all the rest and so the physician has the benefit of seeing it and then can reconcile, but we don't really have, in effect, the standards of the way we record data internally and the standards the way Surescripts supports data are disparate enough that easy incorporation and reconciliation in an automated fashion is not really possible yet.

And 308, event notification, this is one where they were just asking for a little bit more use case specificity. So, for example, if you told us it was an inpatient admission notification we would come back and say, oh, yes there's a standard for that and we believe we can do it. So, just if you give us some use cases we'll respond.

Immunization contraindication and immunization rules. We love immunizations. There is a wonderful and robust standard for transmitting and querying immunizations. There are no standards for immunization contraindications. As I said, we actually believe that contraindications, adverse reactions in general are a body of work we as the Standards Committee will take on and we'll try to get done in the next year to two, it's just the standards don't exist.

SGRP 401 with immunization rules is the same sort of issue as drug-drug interactions, at the moment although, although Health eDecisions is working hard, there are no rules by which we could transmit from an external entity, you know, your DPT vaccine should be given here there and there and have an EHR incorporate such externally source rules. So, just don't exist.

The same thing with 402, case reports via external rules, there are no mechanisms to represent externally sourced rules so having an EHR fire a trigger based on externally support rules, standards don't exist.

On 404 and 405, registry reporting, one issue there is we're not clear what a mandated registry really is, mandated by whom and the standards that would be necessary to support submission to a registry, well certainly some things like the continuity of care document are used for registries, but depending on the exact nature of the registry in question it may not be sufficient.

So, this is one where specific cases delineate what a mandatory registry is, enumerate the registries and then we can tell you what standards exist to support them, because we don't have one-size-fits-all standards for registry reporting and especially if it is what I'll call a non-mandated registry, you know, a niche registry, a specialist registry it may be very hard to mandate in a certification rule the exact standards to go to a non-mandated registry because in fact you don't what data you're reporting.

Although new standards do exist for hospital acquired infections, CDC has issued those, on SGRP 407; those standards are really not deployed in the field yet. So, just the head's up that 407 is very immature.

SGRP 408, yes, there are some standards for PSO adverse event reporting, the challenge with that is they've never been implemented in an EHR and it's just not clear that an EHR would naturally be the thing that one uses to report adverse events. I mean, in general we have things like adverse event reporting systems that capture the appropriate data and send it off to our PSO. So, 408, basically no EHR has ever done what it is that is suggested there.

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

John?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Yes?

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

I only interrupt because this was something that Commissioner Hamburg specifically in the letter that FDA wrote to us mentioned this as being something that the FDA cares about. So, I want to be sure we afford this, you know, all due consideration and, you know, maybe a dialogue with the FDA in terms of any experiences they may have had or pilots and potentially the interaction between this and the common format reporting of adverse events more broadly through electronic health records maybe something we can ask the Standards Committee to take another look at.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Oh, absolutely, happy to do that and again, the spirit of the comments is we think adverse event reporting to PSOs is a very good thing to do it's just when I look at, for example, I use a product called RL Solutions which is a specific application structured for capturing all the data and metadata around adverse events and transporting it via common format to PSOs, probably 80% of the fields aren't recorded in an EHR and that's really the issue is just purely PSO exist, common format exists, transactions between adverse events reporting systems and PSOs exist it's just bringing the EHR into that we'll be happy to take another look at.

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

Thanks.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

And then, you know, I want to enumerate all the issues with the IE Workgroup and you can take a look at some of those. There was some concern on some of the IE items that the workflow described for example in IE 101 was actually a replication of the paper-based workflows we have today and actually not necessarily a reflection of the way healthcare information exchange is being deployed by states that are actually handing consents and so that we felt, in general, that the workflow enumerated, which was a three-step workflow, didn't necessarily make sense in an electronic world.

So, as I said, general again the tone of our comments I hope you see as positive and supportive. We are just trying to make sure that where we move forward with Stage 3 we are balancing standards maturity and hopefully focus on a few key domains where we can make progress and we're very happy to see thresholds on existing workflow transactions raised and selected domains being added to Meaningful Use Stage 3. We just worry about adding so many domains with standards at not perfect maturity and work flow in the pilot phase.

So, hopefully, Farzad, that since you've been in many these meetings gives you the collective sense of the Standards Committee and where there are gaps. To fulfill those gaps or fill those gaps, because you asked, Paul, what we might be able to do, Doug Fridsma and others at ONC working with Jon Perlin and I will over the course of next two weeks be trying to turn what we believe are the "to do items" that you have suggested in your RFC plus some "to do item" the Standards Committee has brought up plus S&I Framework "to do" items into a structured work plan very akin to the one that you have done, your 4 quarters of work. MacKenzie, do they have actually my slides available to them?

**MacKenzie Robertson – Office of the National Coordinator**

They do, they have your presentation from the 16<sup>th</sup> last month.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right, so if you go to slide 3, 4 and 5 what you'll see is we believe that we need to work on flexible platforms for quality reporting. We need to figure out how to measure usability of EHRs. We need to do content gap, for example lab ordering, formulary downloads to make sure that those exceptions that I mentioned like generic substitutions are somehow going to be supported, canceled transactions for hospital sourced discharge medication ePrescribing, genomic data.

And, Farzad, to the point you just made, how do we ensure that the EHR can collect and transmit the data elements using the common format to PSOs. How do we deal with the fact that as we have more data exchanged, especially patient sourced data that we avoid having redundant data that is going to be replicated over and over, and over across different health exchanges.

How do we support the expanded use of such things as the clinical document architecture to deal with record sharing within an encounter, across an encounter, bulk record sharing, across multiple patients? How do we support additional image exchange?

On the consumer side, I mentioned the consumer friendly terminology necessary to ensure good data integrity of consumer source data and ensure that we have all of the transport standards in place to get data to and from consumers and record advance directives in the clinical document architecture, and include such structured data elements as the care plans and the care team.

And so, you'll see again for category 4 and 5 there are just a series of items we think are essential to help you and we will be, at the next Standards Committee meeting, showing how we believe we can work on a subset of these over FY13, because what you see laid out on these slides is probably at least two years of work. So, I turn it back to you, Paul, for any questions, anything I can clarify.

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

Thank you so much, John, and for joining us and for giving us these comments from the committee. Comments and questions from the Policy Committee? David?

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

John, it's David Lansky, I'm looking over that last set slides as you say it's a lot of work a couple of years work or more. We talked a little bit this morning about our own views on Stage 3 and how to set priorities for what that program might look like going forward and I'm wondering whether there is a dialogue to be had here looking at this long list and is there a way to take the policy environment, and the market environment, and the pressures on providers for example, from payers and others around reporting, and quality improvement, and quality measurement, and so, and use that as a filter to prioritize the schedule of which of these standards get pushed more aggressively and which are on a secondary path?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Well, absolutely and now, Farzad, is Doug at the meeting today?

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

No.

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

No.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Okay, so we said, hey Doug, you are wise and you can gather input across the ONC Empire and help us with exactly the question that you have just asked and I believe that it is beyond Doug. He will do a first pass, John and I will help and then it is very reasonable for us to vet what we think is a first pass by you for additional filter and prioritization feedback.

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

Christine?

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

Hey, John, it's Christine Bechtel, thank you for this. I just had a couple of questions. In a couple of areas you mentioned the workflow being immature and I wanted to know what was meant by that if it's sort of the clinical process or if it is a process related to standards?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right, I meant the clinical process. So, when we look today, because remember not only is the Standards Committee charged with the data standards for interoperability, but we're also charged with the certification of the products and our Implementation Workgroup looks at how products are used and where we said, you know, this is a really noble goal but there is no place we could find where a product is used in this way. And so the concern would be we but be introducing new electronic workflows where there just is no experience with them today that was all. It had nothing to do with the standards per se; it was the function of the EHR technology in the field.

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

Okay, I mean, I think my question...so that makes sense and that helps a lot, but one of the areas in which you said that the workflow was immature was around medication reconciliation, medication allergies and problems.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Oh, no, not medication reconciliation that one we believe is mature.

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

Okay.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

It's across organizational allergy and problem list reconciliation is something that we haven't seen done outside of an organization's four walls.

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

Okay, okay, so my next question was about the information exchanged threshold. You know, we spent a good part of the morning talking about how the environment has really changed. Of course you played a leadership role at the terrific information exchange hearing last week as well. So, what I heard you say was that the group or maybe it was an individual, I don't recall, said that the threshold, you know, increasing the threshold was premature because of the state of the marketplace today and I'm wondering how much the group was really considering the trajectory of where we're going since Stage 3 is not active today and we need to think forward about what we expect the environment to be.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right, so, I think part of this was, we aren't quite certain what a transition of care is and what I mean by that is, if I am at Beth Israel Deaconess Medical Center and I send a patient to a facility that is part of our affiliated organized health care arrangement, is that a transition or not? Well, the answer is, I think as intended, it is not because they have access to the full electronic record as Beth Israel Deaconess.

Where really a transition means those data elements sent from one organized healthcare arrangement to another healthcare arrangement using a different EHR and a different geographic location and if that's the strict definition do we believe we have the health information exchange infrastructure in production that will allow 30% of such very tightly defined transitions to actually flow electronically.

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

A couple of years from now?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Yeah, and the worry was...I mean, I'm New England, maybe see that's our problem I've got Rhode Island, Connecticut, Vermont, New Hampshire, and Maine and although we may have robust functionality within states at the moment we don't really have robust functionality across borders and my borders are only 30 miles in each direction. That was the concern is that we weren't sure that that level of robustness of broad information exchange would exist to a 30% criteria, 10 sure, 30% maybe not.

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

Okay and then my last question is coming back to the patient generated or patient contributed data element and I understand the device identified piece. A big part of this was this idea that maybe we could have a structured...we could create the capacity for the record to accept and digest, and help the provider really act on some kind of structured or semi-structured survey data and that could be adaptable based on the practice type, for example, what's relevant to their patient population, etcetera. Frankly, it could also be quality measurement.

So, there's a lot in here that is of real skepticism of information contributed by patients. And I just sort of have a fundamental issue with that. And I think the issue relates to, we spend a lot of time thinking, for example, in the data exchange world about...well we do these things today but we just do them by fax and so this is really no different we just need to enable it electronically.

And I feel like in my view-point that is a big part of how I view patient contributed data that while we're doing it electronically we're also doing it on paper a lot, right? So, there's a lot my new provider doesn't except what I write down on the clip board or what I tell him or her in the office visit that then gets documented into the EHR, but that doesn't get treated, necessarily differently or flagged, or held out, or described as, you know, maybe there is a lack of evidence of the usefulness of the information, for example.

So, I'm struggling I think with these characterizations unless I could maybe understand from you, and hence my question, what are the examples where you really have to know that this is patient contributed as opposed to, you know, electronically, I should say, if it was something the patient told you in the office but you recorded it and therefore you have faith in it.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right, so no one in the Standards Committee for a moment doubted the importance of patient generated data, so don't worry, please don't take any of the comments as this is skeptical. What we were concerned about is that if one is to incorporate inside the EHR, in the same data field elements as data which is input inside the EHR natively, the challenges ensuring vocabularies are mapped, that the nature of the data and the various fields, the various, you know, sub-elements of the data like an allergy is a type of substance, the nature of the reaction, the level of certainty of the reaction, the observer of the reaction that you have a detailed clinical model that is going to ensure that you've got the same data integrity of data coming from the outside world as you do inside the EHR.

And so an example for you, what I've done for years at Beth Israel Deaconess is I show the doctors in a window all the patient source data so it is fully viewable at all times and considered very important,

but it tends to be less vocabulary controlled and less structured as that which is put in through the EHR so there's just a difference between viewing it and incorporating it. Those were the concerns.

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

Well, I get the difference in maybe how it could be represented and maybe this is a conversation that you could help me understand off-line, but I'm still struggling to understand how data is natively in an EHR when I think a lot of how it gets natively in there, you know, does get sourced ultimately back to a patient. But, I think my concern is, well, if I tell you I'm allergic to penicillin I'm trusting more...you know, myself or my family caregiver to tell you that rather than whatever data feed you've got externally when we know the state of data exchange is a little bit immature, everybody knows, you know, Dave deBronkart's experience with, you know, incorporating an external data feed that was riddled with problems into a personal health record.

So, I just want to encourage us maybe we could think about some solutions in this area that might, you know, focus on semi-structured questionnaires that I think would be represented pretty differently in an EHR compared to the kinds of data elements that you're talking about. So, maybe we can think about some ways to focus on that piece as an entrée and help us get ready to do the rest of those pieces.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

So, that is an excellent, excellent point. There is a very good difference between, you know, I actually want to ask you about your functional status. I want to ask you about your activities in daily living and it's a structured questionnaire that goes into the EHR as patient's sourced data from a structured questionnaire, no one would argue about the appropriateness of such data. It's where we are asking, say, a patient to put in a SNOMED encoded problem list for reconciliation it's just purely because at the moment patients aren't thinking in SNOMED and therefore it's going to be a little bit like comparing apples and oranges to use the thing that was entered by a group of clinicians after going through a doctor's brain being translated into SNOMED and entered into a structured EHR that was all they were saying.

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

John, in terms of what could be ready in light of all the work that has been going on in the 10 or so standards and interoperability initiatives, which touch on many of, and in fact it would be good to map

them to these...the S&I activities that are already underway everything from the long-term care work with the LCC, the data segmentation, the Healthy eDecisions, which you mentioned, Query Health and so forth, is there a sense of which of those in response to these that those that touch on these might be more ready than others or might be ready if prioritized?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Sure. So, when you look at the S&I Framework slides that Doug always updates us with, lab is something that's moved across very, very nicely, you know, the lab compendium that Clem McDonald has at the NLM has worked on. So, it's very likely that lab ordering will be mature, it's very likely that transfer of care content will be mature, as you point out, the goal of long-term work, excellent, and clinical document architecture with 450 some elements for transitions of care and our only question there was, is the transport going to be sufficiently deployed to require that 30% threshold? But the content is good.

Query Health, there's a little bit more work to be done and there are pilots that are going on now on making sure that say the QRDA standard and HQMF standard are expanded a bit, but there may very well be elements of Query Health that are going to be good enough and certainly, as you saw, in our work plan that polishing up those standards is something that we would like to do. Healthy eDecisions, still very, very early. So, the work is essential, not quite sure it's going to be ready yet.

And, so, you know, again, at the next Standards Committee as we discuss our work plan, probably something we can also do is take Doug's S&I map and actually in a formal fashion give you that feedback of yes, yes, yes, no, maybe.

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

And structured data capture, which just launched, would address several of the standards gaps you mentioned. What's your sense of optimism? I know that's its maybe a little bit unfair since we haven't really started the storming and norming there, but what's your sense?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right, so in the past, the folks of the Standards Committee have used SNOMED and LOINC as standards that could be used to specify questions and specify answers, and so I am optimistic that we can leverage standards that already exist to represent questions and answers in questionnaires.

Again, my role here was to try to communicate what would be an operational reality based on where we currently have experience. So, although I'm extraordinarily optimistic the standards will be ready, I'm not quite certain that they will be broadly deployed or adopted sufficiently to necessitate a core item in Meaningful Use Stage 3. So maybe that's one where we get to a menu set item.

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

Thanks.

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

I have one, hopefully, quick question, John. When we talked about essentially sharing up-to-date problem, medications and medication allergy and the problem you said that we weren't there yet, the logic. So, one example is like hypertension, which is, as you know, under diagnosed yet it's in their coded form under vital signs. What would be in the way of using that information to help prompt a clinician to say, should this person...should hypertension be on this person's problem list?

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Right. So, I guess there are two questions that with the proper reconciliation, which the concern was the notion of coming up with advice or, you know, we think that this has been reported from some external system you should consider incorporating it, you know, as advice as opposed to actual automated incorporation for problem, medication reconciliation is something that we would say is reasonable, because the workflow of actually doing the incorporation of externally sourced data wasn't quite there.

With regard to the idea of a rule that could be created, let's say as a country we decide the definition of hypertension is 140/90 or greater and we are going to transmit those rules so EHRs can come up with alerts and reminders based on externally sourced rules that alas just isn't a universal format by which we can represent that knowledge or rule so an EHR could digestive.

So, we have no problem with an EHR being able to offer some advice to a doctor saying, oh, you should really consider this, it was the notion of representation of rules that we thought was immature.

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

Right, so I don't think the Meaningful Use Workgroup was specifically saying that it had to be something...a standard, that a standard had to exist.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Okay.

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

It just had to have the capability within an EHR.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Okay, so yes, if an EHR incorporates such things that would provide advice and guidance to clinicians. We thought that that was actually a very reasonable thing.

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

Good, okay, once again, thank you John. Thanks for taking the time to go over it and then to present it to us.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Well, great, well thanks so much I wish you the best and I will review all of the transcripts so

I can hear what happened this morning. I'm sure there was fascinating discussion.

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

It was actually.

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

More than you would guess.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

You guys have a great day.

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

Thanks, John.

**John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center**

Thank you.

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

Okay, so Rob Anthony is going to update us on the latest information on the Meaningful Use Program from CMS.

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

Good afternoon, so I'm actually going to give just a short update regarding numbers. However, at the end of this presentation there is our typical attestation information, it hasn't changed significantly. We will begin as we started getting in January, February more the people returning for a full-year of Stage 1 and start comparing some of that data, but of course we're not at that point yet.

So, this is the basic registration and payment data. We are currently at a little over 350,000 providers registered for the program. Almost 15,000 registered in December alone that is fairly consistent with what we've seen obviously in August, September, October we had a pretty large bump with eligible professionals coming in and registering on the Medicare side. That is generally people who are coming into the system in preparation for end of the year.

Most of what you're going to see here does not represent most of the end of the year EPs, it certainly doesn't represent any of the returning EPs, people who are coming back for a full-year of Meaningful Use, all of those folks are going to be in January February, but of course we have our sort of sneak preview of January here at the end.

So, sorry, I'm following along on my iPad here, data over there, Farzad and Paul are blocking the numbers from the screen so excuse me. No, no that's okay. So, we paid under Medicare a little over 100,000 providers so far that's both eligible professionals and hospitals.

In December, we had a large number of payments processed for hospitals still from fiscal year 2012. A number of hospitals have two months after the end of the fiscal year so they had until November, a lot of those payments ended up here, so we did have a sizable payment in December through Medicare, a little over \$1 billion alone and we previewed some of that in our last meeting.

We are at a total of, once you include some of the Medicare Advantage, over 100,000 Medicare providers at this point in time. And this chart hasn't changed a whole lot. We have that 58% figure that represents the 58% of Medicare EPs who are paid are their specialty, their non-primary care providers, that seems to have stabilized at this point in time we haven't seen much fluctuation in a little while on it.

Again, we had a pretty sizable month in December, but the payments for the EP side are rising a little bit slowly, you're going to see a much bigger jump in January as we see a large number of eligible professionals come in.

On the Medicaid side the thing that I really want to highlight here, obviously, a large number of providers also, but I want to highlight, and we talked a little bit about this last month, we are measuring that adopt, implement, upgrade payment versus the Meaningful Use payments on a month to month and then showing a program to date.

We are starting to see a migration of providers, even though at this point in time it is a smaller figure, relative to the overall whole of almost 72,000 providers paid. We do have about a little over 5000 providers who have hit Meaningful Use and almost about 4800 of those are actually eligible professionals. So, we're starting to see people come in.

A thousand of those people came in on the Medicaid side as Meaningful Users in December alone. So, we are starting to see that migration and we were asking how quickly we're going to see that happen since they have a longer timeline on the Medicaid side and at least we're starting to see some of that now. Again, we see a bump here on the hospital side for December because we're still processing through some of those October, November attestations.

So, overall we have pretty significant program totals. We are at...and I think when we talked last time we had an estimated figure of about \$10.2 billion it's at about \$10.7 billion, but, I think the more important figure here or the more impressive figure is that we are at a little over 190,000 unique providers paid as of the end of December.

These are the percentages and because I got tired of the percentage that would never correct itself, I've now broken eligible hospitals into a registered and a paid slide. We do have a little over 84% of all hospitals registered at this point in time and we do have 70% of all hospitals paid under either Medicare or Medicaid or both, a significant figure.

I have been asked when you see the unique number that have been paid, and I'm going to go back here, you see that unique number of a little over 3500 hospital paid, that actually is a unique number from both 2011 and 2012. So, we're actually seeing over 3500 hospitals out of the total of 5011 have received a payment at this point in time.

On the eligible professional side, a little bit slower but still a significant number, two thirds of all eligible professionals have registered for the program. We have not seen as many paid, but we are still seeing a percentage increase, which as we are getting more people who are returning for the program we'll see whether that continues to climb as well, but we did go, you will see, from about 25% of Medicare EPs who were paid to 28%, we're still about one out of every four. There were 33%, a little less than 33% of all EP paid were at 35% so that's going up and as I said, the 58 % for non-primary care is holding steady.

So, the good news is, and the interesting news is that we have people who are coming in droves in January and February. I'm going to show you a little chart about folks coming in, in a second, but it looks like we're going to have about 21,000 unique providers paid in the month of January, that is going to bring us very close to 200,000 providers paid under this program as of the end of last month. I do think that once we get through and actually look at real numbers here we will probably surpass that. The reason the 21,000 doesn't necessarily add up when you add 190,000 to more than that is because we're looking at unique providers paid here.

So, we do think we're going to hit that 200,000 mark as of the end of January and that will put us at, again we'll see a significant amount of payments because we're also seeing some hospital payments still from the end of the year that are going through, a little over \$1 billion paid out in January for about \$11.3 billion for the total for the program.

I eluded when last here to, I think it was January 6<sup>th</sup> or 7<sup>th</sup>, we had seen a few days of activity in the attestation module. Now we've got about one month to look back on. This chart represents the number of attestations that are coming in daily. The peaks represent the actual business week, the valleys are the weekends, everybody is not doing it on the weekend, but you can see that from November there has been a steady increase to the point where we are now where we're averaging over 2500 attestations a day through the system.

Now, obviously we've got a lot of people who our returning from 2011, but we are thinking we're going to see very much the same trend as we saw last year where there were a lot of people who were still first 90 days of the program who were coming in there, as well and that trend, as I said, is going up and continuing. So, we expect February to also be a very large month for attestation as well.

And, again, I don't want to go through any of the attestation data, but I will say that what we have here represents, again, it's just Medicare but we've got over 161,000 EPs represented in this attestation data and a little over 2600 hospitals are represented in this. So, this is a pretty good slice of what a 90 day attestation looks like. We'll begin to take a look at in future months what Stage 1 90 day versus a full calendar year looks like.

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

Good, thanks very much Rob. Any questions for Rob? Terry?

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

Hey, Rob, thanks, I want to hearken back to the comment we got this morning from the American Hospital Association. What do we know about the people or the hospitals that are on slide 16 that aren't engaging, like so we know a lot about who's engaging, well we don't know, well we know enough, but what do we know about that group that isn't engaging, hospitals and providers?

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

So, I think some of what we know is what we know through the Regional Extension Centers. We have a number of rural hospitals; we have a number of smaller hospitals. There is much more of a hurdle implementing those systems in a smaller framework. So, that's what we're looking at as far as what the challenges there are.

I do know, and this is more anecdotally than it is survey result, there are certainly hospitals in that 15% who are facing the challenge of interoperability within their own systems as well. So, they are upgrading to an EHR or they're implementing an EHR for the first time, but they're trying to make those legacy systems play with that EHR. So, I know that is another hurdle what we see in that 15%.

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

And how about the providers?

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

We have a lot of information about providers and it depends on what area you're...what type of a practice you're in. If you are a one, two, three person practice that has its own particular challenges. Sometimes it's a question of ROI for them. Sometimes it is a question of actual implementation. They don't have the resources to dedicate to an IT person who can come in and take care of all of that for them so they are implementing on their own.

If it is a larger practice, a multi-specialty practice very often it's a challenge to implementing workflow across the practice as a whole. So, I think...and we saw some of this in some previous months with some REC data, we can revisit that again if we want to at a future...

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

Well, I just want to...I think what Christine said this morning about patient and patient centered care and kind of the dialogue this morning was really about why are we doing this and how are we moving it and if we only have one out of four Medicare EPs Meaningful Users and we actually have a pretty high...it seems like we have a higher percentage of specialists than we have primary care, that might not be true, but it is hard for me...

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

Slightly higher, it's about a 58%.

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

Yeah, so that's really intriguing because I think it behooves us too try to figure out what are the barriers and perhaps they are all so individual that we can't aggregate them, but as we move to Stage 3 we just want to make sure we're not creating more barriers for them.

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

No, no, no it's an absolutely valid point and maybe this would be a good time perhaps in the next presentation to bring back some of that REC data, because there are a set of challenges that we can break down by practice type, but they all fall into the same general areas. I mean, there are financial challenges whether it's a matter of return on investment or whether it's being able to make that investment in the first place.

There are specific workflow challenges and we can identify what those particular areas are, we've talked about this in some of the attestation data when we look at exchange of data, when we looked at areas like transitions of care. There's a reason people aren't choosing those objectives in Stage 1 because they are a much higher lift for them to do.

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

The other thing, Terry, every time we hear from Rob it's another snapshot of where we are today.

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

Right.

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

And, in fact this is a stochastic process where there's constantly new people coming in, there are new people registering. It's astounding to me the registrations are absolutely a leading indicator of what ends up later being people attesting and then paid and the registration numbers keep going strong particularly as we're nearing the, you know, the end of this period. So, I think we should...it would be interesting to look at the trends and say, if current trends continue by, you know, say the October 2014, you know, are we...would we see...where would we see the issues remaining, because it's hard for me too look at these numbers and be disappointed.

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

No and I don't mean to be disappointed but I think it's really important that we don't have an unintended consequence that we're creating a very unintentional gap out there because there is something that we could address.

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

Yeah and that's as Rob pointed out, that's why we have the Regional Extension Center Program, among other tools, to make sure that we don't leave critical access hospitals behind, rural health clinics behind, small practices behind, primary care providers behind and we have a great deal of information from 150,000 providers who are, you know, working towards Meaningful Use that we can bring to bear, but I think the big picture of saying, let's look at the data, and let's look to see how progress is being made and I agree, it would be good to both look at trends and also look at some of the subpopulations for those critical access hospitals or rural providers and so forth.

But, it's pretty...Stage 1 at least seems to not only...you know, we have 84% of hospitals and counting who have engaged with the program, 70% paid. When you compare that to some other programs that, in some cases, are much simpler to implement than Meaningful Use, that in some cases have just as much money on the line, it's very good progress.

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

Good, thank you very much Rob for the continuing good news. Next up is going to be the Certification Adoption Workgroup comment on the ONC HIT Safety Plan that was put out in response to the IOM recommendations and Marc Probst and I don't know whether, is Larry on the phone?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

I'm on the phone, Paul.

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

Thank you.

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

Well, thank you and as we look at the whole...well this isn't the right slide, oh, yeah it is the right slide, we were asked to talk and provide comment on the safety plan. So, over the next 16 hours we're going to go ahead and make comments about safety and HIT and hopefully you're all prepared for that.

Actually, there's no interest about HIT, also, you know, if I pick up the Wall Street Journal I'm not seeing articles about HIT safety or the New York Times, I think that bodes to the success of some of the things that have been happening in this room in getting the adoption of EHR out there and it's garnering a lot more attention and certainly the concept of safety is a big issue and one we were asked to focus on, but we weren't asked just to talk about HIT safety. We were actually given some very specific questions to answer.

When I was texting Larry to make sure we actually had content in this conversation and that he would be on the phone, he texted back to me and said, Marc, given this morning, we are so yesterday. So yes, Deven, we are back in the rut of recommendations and providing that specific information. This is the committee that we had lots of information right now about safety. Amy had just put out an article on it. I know the Bipartisan Policy Center has put a piece together on it. We're seeing a lot more interest in it.

Joan Ash participated a lot in what we put together and has been working on something called the SAFER guides standards, no not standards but guide, tremendous work and so part of this process has been very educational and helpful.

So, let me just set it up really quickly. Jodi, I think it was last month, talked to us about the plan that was put together the safety and surveillance action plan. Again, very good information, but specific questions were given to the Certification and Adoption Group to look at.

And these three, well there's more than three questions, there's four bullets, but these were the three categories and questions we were asked to provide recommendation and comment on and so rather than spend a lot more time setting it up, I'm going to ask Larry to go ahead and go through the recommendations and the discussion that we had and then if there are questions at the end, we can go to that. All right, Larry are you there?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

I'm here, let's take it. So, these are the questions we were asked. They were about risk safety assessments. They were about reporting and they were about standards. So, let's back up one more slide, nope the other direction.

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

Which direction, other direction? You want questions?

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

No, no, no, no I want to go reverse of the slides, thank you, one more, back to the background and principles. Okay, so this is sort of a reminder of where we're going, right? The goal is a learning health system and a culture of safety. Those things are, in some ways, classic healthcare that's been with us really from the beginning and has been with us since our journey with all the Meaningful Use efforts and that Health IT in part is in this story, because it offers a vehicle to improve safety and quality, but there are also risks, particularly any new technology and it may be the process workflow changes that actually create the most risk rather than something just inherent in the technology.

And there is a lot of work happening in this area. I mean, Marc mentioned sort of the stuff that's been in the press; there has been a continuing background story of asking the question about how safe is the electronic record? And, in many ways, we don't know. There isn't a lot of good large volume of reporting although there have been some studies looking at what we do know.

What we do know is that there certainly are some examples of where there are issues. This morning's discussion was all about sort of timing. Where are we with respect to the next round of regulations? And, so I'll let that continue into the discussion with the committee.

I think with this whole area was resurfacing a sense of the discussions we had when we were looking at quality measures a couple of months ago with this need for agile development, rapid standards development that this isn't in some ways new territory, it's territory that may already be in place.

So, John Halamka when he was talking about existing event reporting systems and that the logic around a health acquired infection is more than just, hey the patient has an infection and it's the day after they were admitted so we're going to assume we acquired it in house, as opposed to, you know, they came in with it, we only just found it now where the bug finally grew enough in them to be a problem now.

So, there's a lot I think that we can do and I think there's a lot that we need to understand what's actually capable and a reminder of not adding burden to our users. Okay, so, I think we're actually...I'm not sure what direction we just went in. So, we got some feedback from ONC on things that they heard in the comment period most of which has already been raised about is this premature as a requirement? But, on the other hand, a sense that safety assessment actually would be a really good thing. Let's move onto the next slide.

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

Well, and also, Larry, I think what we discovered through the process is there are some, like we said would Joan Ash and the work they're doing around SAFER, there are some good guides that are coming, these may be...I think they mentioned that this would probably be available later this summer. But, a lot of good focus in this area that will give us a lot more to work with than the recommendations you're actually going to get today.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

Yes, that's true, thanks, Marc. Let's go onto the next slide. Okay, so in terms of actually doing a risk assessment and so given this morning's discussion framing these as recommendations maybe too strong, they're certainly items for discussion and this was the sense of the Workgroup, that this should be a menu item, it's something new, that providers should attest to performing a safety risk assessment and that they should have a plan. And that this could be done in the context of the existing HIPAA requirements with respect to downtime and other issues. And also that, as Marc mentioned, the SAFER guides are coming and they're on the next slide, but hold on a second.

So, this was seen in many ways as an educational issue. How do we get people to understand that there are safety risks with lots of things and incorporate Health IT in their planning around patient safety as well as part of their general quality planning, it's back to how do we actually inspire people, help people facilitate their having a learning health system. Safety is one piece of the things to be learning about. So, next slide.

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

And, so again, part of this recommendation is raising an awareness that the guidelines even exist and that people are making proactive steps relative to doing a safety assessment. Again, prior to this process, I didn't know what SAFER was and much of the public is not going to know, but so part of this recommendation is, you know, let's raise that awareness so that people are actually looking at them and working toward it.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

So, here we have, for those who aren't familiar with SAFER, the nine areas that they feel are important that based on the work they've already done these are recurring themes of areas where there is risk and things need to be addressed and I think you'll see from the range of things here that these are everything from embedded things completely in the computer systems like the systems interfaces, to planning for downtime and managing downtime, to human skills needed to be safe, provide safe care using these tools. Let's go on.

So, reporting. So, I almost thought about flipping the order here, so hang onto some questions in your mind for things that come up next. So, we suggested voluntary reporting of safety events to PSOs similar to other event reporting and that this is really a two-part thing, there is a capture step that happens inside the EHR system, which I really think we should be looking at the EHRs to do and do better, but then there is a reporting function that needs additional information and it was great to have John Halamka perceive this because he pointed out, you know, 80% of the data that's needed for completing the common format isn't in the EHR and isn't known to the person who's initially logging the event and we don't want to get in the way of capturing that initial event, that really I think would be the breakthrough capability we're talking about adding, is let's get better data by having the users of the system be able to say, something doesn't look right with this patient or with this data, or with this display, I'm going to click something, minimally interrupt my flow, get a note off too someone so we can fix the...you know, do the root cause analysis and I'm going to work on trying to figure out what's actually happening at this moment with this patient. Let's go onto the next slide.

So, this is a pretty rough diagram that was put together over the phone during one of our calls trying to highlight the separation of systems and functions of what we were talking about, because it sounds like from what we've heard in the comments what was even embedded in the questions was that all of this is being lumped together into one thing and I think we need to separate out some of its pieces.

So, in the EHR we want to be able to capture that something happened, it could be a technology-related something that's being reported. It could be a patient related something that's happening that's being reported and that there should be initial data capture that happens and we understand that there is a surveillance subset of the common format, and that might be the right standard to use. So, this is suggestive here we're not trying to enter into the standards realm only to make a suggestion that we understand that this is in the works.

And that standard could then be passed off to event reporting systems that would then do some kind of root cause analysis of what actually happened and based on that analysis there might be information that went to the PSO to say, hey we had an event here or we had a near event, or we had an unsafe condition and we want you to know about this to do some large scale analysis.

We also want to make sure that the EHR vendors are getting good information and, you know, there's an implied feedback loop here. So, we didn't draw it in, but the EHR vendors and the EHR users are actually in a tight relationship in that they talk to each other and that there is a partnership here to find where there are safety risks in the systems and to improve their reporting around that and that both the vendors and the PSOs could report to ONC and other agencies. So, this was sort of the framework that we thought was implicit in the questions and wanted to make it explicit. So, let's go on.

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

Again, at the risk of being a crowd sourced on-the-fly design this isn't meant to be a design for anyone just conceptually the fact that we want to be able to capture that information and get it to the right people that can actually then do something with it. So, that's why that model got pull together.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

So, that then leads into certification criteria that we think there should be a mechanism to capture the risk and incidents, that you automatically capture EHR context and it was pointed out that that could be, you know, a huge data dump and we weren't looking to do a complete data dump we were looking to do something that might be practical like a screenshot, like the user and patient context, and allow for some simple user text to say what happened and to make this as low overhead as possible for the EHR user, because we want to encourage that this happens and then there should be partnering and reporting out of this so that the vendors get informed and that the PSO gets informed. Do we have one more?

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

That's it.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

Yeah, and so what we heard about the common format is that the surveillance subset is in the works and expected relatively soon and I might even have the timing wrong on that, it might be sooner than Q3, and that we heard discussion about that the common format seems to have had a lot of uptake in the last year and we should build on that and continue with that momentum. And we should look to have links between the EHRs and event reporting systems.

And, I guess it's worth pointing out that ONC did do some application challenges around this and there are some pretty clever applications that...as continuing sort of discussing that separation of what is in the EHR and what isn't, these are free standing Apps that are not part of EHR but are able to query the EHR using existing protocols, using XDS protocols to say okay, I know something about a patient, can you give me their care summary, their CCD so I can bring that information into this and then the event reporting system users can have that as a basis to actually describe what's happening. So, interesting notions here about pulling information in electronically and some pretty interesting Apps.

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

So, these were three specific areas we were asked as the Certification and Adoption Workgroup to look at and obviously, when you get on a call like this you're talking about the gamut everything from training, implementation to really the environment that this needs to occur in. We believe it has to happen in an environment that allows for people to respond to provide this information without a huge penalty sitting over their head or it's going to slow down the flow of that information.

It was also clear from some of the providers on the call, don't make me do another step, you know, even one more click is problematic. I'm not sure how you're going to do this without at least one more click, but I think the focus is right and we appreciate the opportunity to address these.

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

Good, thanks, Marc and Larry. I think these recommendations do address one of the deficits we have which is lack of data and we won't either know what we're doing. I think there is some pent-up demand to try to express users concerns and this is just making a way to start gathering data so we can better understand what's going on and mitigate any risks.

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

And we really hope the focus the safety doesn't distract from the benefit coming from EHR. I mean, we talked about it earlier, but there's so much benefit coming from it and now that it's so exposed, I mean, obviously we're going to get questions around safety.

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

Farzad?

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

Marc, in our surveillance national plan there was reference made to certification in the context of surveillance. So, this is the way I understand it is, you know, you may do a testing in a laboratory of a lead level in a doll, right, that the manufacturer hands you and you say “yep, this is good” but then you may go to the store and pull some of those dolls from the store and test them to see if they’re the same thing or what the lead level is when it’s in vivo on the shelf there.

And so, part of what’s encompassed within our current regulatory framework for certification is this kind of post, I guess post marketing, right, surveillance of systems in the wild and we could potentially have the certification bodies include some component of assessment of the systems after they’ve been already installed. Is that something that your committee that your Workgroup thought about in the context of safety?

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

We did not discuss that specifically in the context of safety and clearly the fact that you can get the information, right, the screenshot, the associated information to the PSO, to the vendors, I mean, you can certainly start to provide that data but we didn’t discuss about that process.

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

The reference you made to JCAHO and using existing mechanisms like JCAHO does get at kind of where people are actually in practice and in use, but the certification angle is a different one. Thank you.

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

Thanks. Judy?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

You mentioned a couple of times to be able to report these without fear of severe penalties and I’ve seen that happen sometimes that there is reporting and then there are some significant penalties. Any ideas of how not to have that happen?

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

No. I mean, I know how to do it within my own environment of the organization.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Oh, okay.

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

And how we can deal with and how...

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

So not severe penalties of the organization against its employee.

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

Well, but the same issue is going to exist, right?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Yeah.

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

If we want it to go to PSOs and others, even back to vendors or to a national, to ONC was ultimately. There we’re going to have to figure out processes that facilitate that so that we actually...there’s an active reason...there is always an active reason to give the information but there isn’t this huge penalty that if I do give this information then I’m suddenly going to get, you know, slapped because of that.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Yeah, that’s important, I think.

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

Well, it's great for the environment that actually gets it reported. I mean, it will get reported anyway because it's law but maybe not as easily facilitated or as free-flowing as we want it to happen if we're going to learn as quickly as we need to and provide some of the prevention that could be there.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

I think it's probably worth pointing out that the PSO process does provide some legal coverage for folks, but to Judy's point sometimes this is, you know, if it gets public it could be damaging, even if you're trying to address a problem and get ahead of a problem.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Because as you think about it you've got it from different angles, you have the organization and the employees who might have made the safety error, you have the media who may build that up, you've got civil lawsuits, and you've got multiple state and federal governments all who...and our whole look to just society. So, it seems like there are all those different levels that have to be addressed.

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

Yeah, and I just suppose how we're trying to facilitate it happen, we do it today around privacy.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Yeah.

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

I mean, if there's a breach you report that breach and there are severe penalties if you don't and that seems to be functioning as a process.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Well, sometimes there are penalties if you do too and that's where it hurts.

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

I think, speaking from another provider organization I think there's a lot of interest...there's a lot of folks who...well, the amount of incidents that get reported is probably two orders of magnitude less than actually occur. We know that from adverse drug events and actually work done at LDS was a big part of that. I would say the same thing is happening in the EHR related incidents.

Most people are worried about the risk and just want to get it out there so that it can be improved upon and once we make it more convenient I think we will see a big uptake and everybody will benefit. The products will benefit, the way we implement will benefit and it will just be safer place. So, I think the big bias is towards people wanting to see things get better and that this would facilitate that happening.

Other comments? Questions? Good. I guess, do we need to approve this or these are just the Workgroup's feedback back to ONC?

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

I'd ask ONC that question. We were just giving feedback back to ONC through the Workgroup.

**MacKenzie Robertson – Office of the National Coordinator**

So, this is MacKenzie, I would recommend to do a transmittal letter for the ONC that we do have committee agreement.

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

Good. I'll entertain a motion then to adopt their recommendations.

**W**

So moved.

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

Okay and second?

**W**

Second.

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

And other further discussion? And all in favor?

**M/W**

Aye.

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

And any opposed or abstained? Okay, thank you very much Marc and Larry.

**Larry Wolf – Senior Consulting Architect – Kindred Healthcare**

You're welcome.

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

Okay, we'll move to the final committee action, which is an ONC update and we have a party of Jodi, Kevin, and Lauren who are going to talk to us about different kinds of activities going on in ONC, updating us with different activities in ONC.

**Jodi Daniel, J.D., MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

So, I'll get started, I'm going to be very brief while they're assembling over there. I'm just going to give the brief overview and leave most of the time for the other folks to give their updates and do a little bit more of a deeper dive on some issues.

So, just wanted to give a couple of updates some focused primarily on the workings of the Policy Committee. I wanted to let folks know, remind you about our call for nominations for one position on the Policy Committee and 12 positions on the Standards Committee back in June, we did receive 153 nominations for the committees, we completed a thorough review of those nominations, and the new members will be announced later this month. So, keep a lookout for that. We hope to have the new members start serving at the March committee meetings. So, not too much impact here it's only one slot, but more so on the Standards Committee side.

With respect to the Consumer Workgroups, we have talked about having a Consumer Empowerment Workgroup for this committee, as well as for the Standards Committee. In December 2012 ONC announced a call for applications to serve on these Workgroups. We're currently wrapping up our review of the applicants and we did seek input from Christine Bechtel on this side and from Leslie Kelly Hall on the Standards side into that process and so we hope to have that wrapped up and announce the committee members later in February as well.

We also did an announcement for a new Workgroup on Accountable Care for the Policy Committee, we made that announcement just last week on February 1<sup>st</sup> or earlier this week, no that was last Friday. And the applications are due to ONC by February 15<sup>th</sup> through our applications database website. So, if folks are interested who are listening in participating on that Workgroup please submit nominations and we'll go through the same process of reviewing and vetting the applicants, and developing a good balance stakeholder group for that committee as well.

Last time we talked about the 2013 work plan and we got some great feedback from members of this committee. We did include a revised version in your materials and I'm not going to go through the details of that now. There are modest modifications. So, if you do have any comments or questions about that feel free to come and talk to me or Paul about it or you can ask questions after we do our updates.

But, just to let folks know some of the changes that were made in there that you'll recognize are the Meaningful Use Workgroup we did add an item to discuss Meaningful Use beyond Stage 3 starting in the third quarter. For the IE Workgroup we added that future discussions will address direct public health emergencies that was something that came up as well.

The Privacy and Security Tiger Team we moved up the discussion on patient generated health data to the second quarter to help inform Meaningful Use recommendations and for the Consumer Workgroup we clarified that the eHealth Equity Roundtable follow-up would include a broader discussion of health disparities which was also raised, with respect to that, I just wanted to let folks know an announcement that we will be having this eHealth Equity Summit, this is a collaborative effort with ONC, The Office of Minority Health and we're also working collaboratively with Zerodivide Inc. and Health2O who are cosponsors of the achieving eHealth Equity Summit.

It will be on February 21<sup>st</sup> from 8:30 to 12:00 at the White House, the purpose is to convene thought leaders from diverse backgrounds to discuss how we can achieve eHealth equity for underserved minority populations through policy and action, and will focus on improved consumer access and utilization in underserved communities. So, we will make sure to have a report back on the status of that to help feed some discussions here and we do hope that we can invite some of the members of the new, to be formed, Consumer Empowerment Workgroup to that as well so that they'll have the benefit of that discussion that they can bring back.

So, I'm going to cede the rest of my time to Kevin Larsen who will be talking about an update on quality measures development, as well as Lauren Thompson who will be giving a standards update and overview of Federal Health Architecture. So, I'll turn it over to Kevin.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

This is Kevin and Kate are you on the phone?

**Kate Goodrich, MD – Acting Director Quality Measurement & Health Assessment Group – Center for Clinical Standards & Quality (CCSQ) – Centers for Medicare & Medicaid Services**

I am.

**Jodi Daniel, J.D., MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Oh, good.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

So, I'll give a brief intro. So, Kevin Larsen from ONC currently also on detail at CMS, we are working together with CMS in a program sponsored by the Secretary called an Innovation Fellows Program to apply innovative practices from the community and this is to innovate around measurement development and so Mindy, who is sitting here at my right, has actually come to us from Intel to help coach us in using lean and agile techniques as we build the clinical quality measures.

So, Mindy has been with us about two months and we just had a big event last week really kicking all of this off and Kate I know you have to go so I'll let you speak a little bit from there and then I'll let Mindy speak.

**Kate Goodrich, MD – Acting Director Quality Measurement & Health Assessment Group – Center for Clinical Standards & Quality (CCSQ) – Centers for Medicare & Medicaid Services**

Actually, you know what if you want to have Mindy give sort of an overview first I think that would be helpful before I speak. I can stay on a bit longer.

**Mindy Hangsleben – Lean Innovation Fellow – Department of Health & Human Services, CMS, ONC**

Okay, so just as some background, the Innovation Fellowship that I was tasked with when I came here was to work with CMS and ONC to really lean out the electronic clinical quality measures and also to actually integrate lean into the culture of ONC and CMS. So, jointly we've been working together and for those of you who aren't familiar with Lean it's really process improvement but it's also a culture change so it's removing the waste out of your system that doesn't provide value to your customers. So, it's really taking a look at your processes and saying, you know, what can we do to shift the way we're thinking and be excited about the horrors of our waste and really improve the processes so that they add value to the customer.

And, so one of our first events that we did to really, you know, start working on the electronic clinical quality measures was to have a Kaizen Event where we brought in multiple stakeholders, everywhere from the EHR vendor down to the contractors, and our federal representatives and I'm going to turn it over to Kevin and Kate to talk a little bit about the details.

**Kate Goodrich, MD – Acting Director Quality Measurement & Health Assessment Group – Center for Clinical Standards & Quality (CCSQ) – Centers for Medicare & Medicaid Services**

So, this is Kate, I'll start. So, this was event that was all of last week, all five days that required quite a commitment from everybody involved. And as Mindy stated, this was not just for feds. I don't know who is in the room there, but I wouldn't be surprised if some of you or people you work with and know were at this event last week, because we had, as Mindy stated, developers, other contractors, people who do our testing, we had the National Quality Forum there.

We had other federal partners such as the Office of Management and Budget there. And we had, at least on the phone for much of it, our contracting shop. So, it was really an unbelievable commitment from a quite large number of people who are just very committed to making this process work so that we become more efficient with a better quality product at the end. And it was a very, very exciting five days there was a lot of very hard work and I have to admit, I was kind of exhausted at the end of it, but it was well worth it.

So, we initially had to define what we thought the scope of what we wanted to lean out was, because the whole eMeasure lifecycle is quite broad, quite long and we basically decided, at least for this first event and the first pieces of the work that we're going to tackle, that the beginning part of our scope would be at the measure concept phase where we're putting together contracts to develop measures and that would go through measure implementation, which for us, we defined as implementing a measure into a rule and everything in between is all about the actual development of the measure.

But, we had to leave out some things in order to not have our scope get too unwieldy that we hope to address with our partners in the future such as the NQF endorsement process, that's something we're very committed to working with all of our partners to also make more efficient, but for this particular purpose it was out of scope.

And so we spent the week dividing that larger scope into about, I don't know, 8 or 9 different smaller scopes sort of chunking it out and then mapping out those processes in a very detailed way for what we do now, so our current state. And then we spent a lot of time mapping out what we want our future state to look like.

And, so for example right now our eMeasure lifecycle time is about 3 to 5 years. And so we decided that for our future state we want that to be 1 year or less. In the ideal world it would be even less than that, but for now that's our goal that gives us something to work towards.

And with the help of Mindy and Lauren, and some of my staff Karen Nakano and Kim Schwartz, and others here at CMS and at ONC I think we had just an unbelievably successful week, lots of excitement generated, lots of new relationships formed where I'm very optimistic about us being able to all work together in a very integral and productive way over the next, at least year, and of course this will sustained beyond that I believe. And, you know, I'd be happy to tell you more, I could probably, at this point, talk about it all day but I'm going to turn it over to Kevin to see what else he has to say.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

Yeah, I'll just say a couple of more comments which are really much of this is the vision that this group has had for a long time which are how do we get the measures that matter into the programs and how do we get them in a timeframe that makes sense so that we don't have to wait 5 years from when there is a goal to have a measure around care coordination to actually having a care coordination measure eSpecified and ready for a program?

We also have heard a lot from the vendors and the community that our measures could use improvement. This was an innovative process from the beginning and we know there was a lot of innovation in the first two stages, but this is a time to really reflect and say what did we learn and how can we do this even better?

So, we're really applying some agile development techniques for those of you that know software, we're using a lot of software frame around our measures which was really exciting and taking some software best practices about early testing, early testing with real EHR vendor partners, early testing in real clinical sites and putting all of that into this commitment to a new way to develop measures so that the measures that we have work and they work quickly in the places that we need them.

Christine actually gave a fantastic talk, one of the precepts of Lean is that we always focus on our customer and we were very clear that our customer is the patient and consumer in this stand, so she helped frame that from the consumer's perspective for our week. I've got Lauren here sitting next to me as well. We have committed at ONC and CMS to staff this internally so that we can really do an internal change management process to ensure that we are achieving these goals that we all share together.

Thank you, oh, if you're interested I'll give plug, Mindy does a Blog as part of being part of the Presidential Innovation Fellowship Program or excuse me not the Presidential Innovation Fellowship the HHS Innovation Fellowship Program, so if any of you are interested in following our work feel free to look at HHS Innovates and you'll see some activity there as well as the Blog from Mindy and a few other innovators across the HHS sister agencies.

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

That's very exciting for someone who has also spent a lot of time in the quality measurement field to see the ability to go from the de novo that we heard about this morning to incite you in a short amount of time that would be very, very exciting. Now, just to be clear, I think Kate said this, so the NQF endorsement process is outside of scope so you would add that to the one year goal?

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

Correct, they're absolutely partners with us in this. Again, another precept of Lean is you work on your own work first and then you engage partners that have their own work and you find out how you have joint opportunities to improve, but really this is, at the beginning to say, what can we control? What do we control? How can we make the things that we know need improvement improved and do that in a big tent way where we include stakeholders and other partners?

**Lauren Richie – Project Manager, Performance Measures – National Quality Forum**

Just one quick comment to that, NQF is having their own Lean event this week, as we speak, to Lean out their consensus development.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

That was Lauren Richie.

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

Now that seems hopeful, it seems like you might be able to get some overlap between the development particularly as it relates to testing, because if you're going through agile and you're doing more iterative testing that might feed into the process that NQF...the endorsement process that NQF has.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

Believe me, many people made that same comment.

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

Okay, because that tends to be one of the hold ups. Terry?

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

I just have one comment and Kevin knows this, we actually have a Lean team at the VA that's in our business part of the VHA, but we would definitely be interested in partnering and lessons learned, and you teaching us and we regret we weren't able to staff last week.

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

Yeah, any other comments or questions? Yes, Christine?

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

So, when are you going to be done, basically?

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

Lean is never done.

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

I knew that was coming, but you know what I mean.

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

Yeah, so we have already started this week in changing some of our processes. So, we have, as we speak, measure developers in discussion with vendors about how they can use vendor data that currently exists to understand feasibility of data elements at the very early stages in measures. So, we anticipate even in the course of this year we will have shaved a lot of cycle time off of measure development and are hoping that measures that we're getting ready for MU3 will be of higher quality delivered more quickly and better tested than the ones we've done before. So, we absolutely plan to have a better product for the MU3 timeframe.

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

So, I'm really excited to hear that because we desperately need it. I think one of the questions that the Quality Measures Workgroup asked in the RFC around Stage 3 was can we use Meaningful Use as an innovation track? Should we...I think Jesse used the word this morning, should we democratize the eCQM development process?

So, I don't know to what extent you guys looked at that, but it would be helpful to feed forward anything of value in figuring out is that a good idea? You know, obviously, we don't want it duplicate the work in the process that you're doing, but we also don't want it centralized so that CMS and ONC are like the only people who are developing measures either, right?

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

We're right there with you, I mean, we're very involved in both of this policy discussion as well as the operations part. We know now that as the standards have developed we've had to develop tools to support measure developers to those standards and in the early stages those tools weren't necessarily easy to use, they had a pretty high learning curve, but as the standards mature we can actually make more user-friendly tools and those user-friendly tools could then potentially be used by lots of different people.

And giving people a sandbox of kind of modular elements that they could potentially rearrange in ways that make most sense for their practices is one of the things we're working hard to try to achieve because that speeds are process. It also actually liberates that process from just a small group of technical experts to a lot of people that could have good tools that they could use.

We do want to be careful as we talk measures. Measures for value-based purchasing programs may be a different animal than a measure that an individual creates for local use, visibility and improvement. So there will...we all want to do this together in a spirit of improvement, but we do...we will still have a place for these measures for achieving the ACA goals of value-based purchasing.

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

Great, that's really...I mean, I just want to congratulate you guys. I mean, for the piece that I was able to attend at the meeting, I mean, it was just to see the excitement in the room, the energy in the room and it really felt like people were willing to move outside of the current mental construct around how we develop measures and how we implement and test them and I just want to say congratulations and really well done and what a worthwhile chunk of time and resources to put into this. So, thank you.

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

When you said you had the customer... Christine representing the patient consumer as the customer I assume there were lots of providers and informatics folks that are...

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator**

Absolutely, we had lots of providers there and it's easy to get providers there. We wanted to be sure we didn't miss the consumer voice and how did we do that without subjecting them to a week's long worth of detailed discussion of QRDA1, which a consumer would not pay much attention to nor should they need too.

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

Thank you, very exciting. I'm glad the activity went on and we look forward to the results.

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Good afternoon, I'm Lauren Thompson, I'm the Director of the Federal Health Architecture Program within the Office of Science and Technology and ONC. What I wanted to do today was to give you a little bit of a standards update on behalf of Doug Fridsma, who was not able to be here today, and then a little bit of an overview of the Federal Health Architecture Program. So, that's our agenda.

So, what I wanted to update you on was a new initiative that Farzad actually mentioned earlier and has been the topic of some discussion here today and that's the Structure Data Capture Initiative that has just kicked off. The focus here is really to address the interoperability challenge around research and patient safety event reporting and the focus of the initiative specifically is to work towards the development for new standards related to the capture and storage of structured data through electronic health records. Specifically, standards for clinical data elements used to fill specified forms and templates, standards for the structure or design of the form or the template, standards on how EHRs interact with the templates, and then standards to auto-populate the form in the template.

As was mentioned, this initiative has just kicked off. What you see on this slide, slide 4, are some extracts of the charter for the group, which again are to identify and harmonize standards that will facilitate the collection of supplemental EHR derived data and to validate a standards-based architecture and a set of structured data. Specifically focusing on the electronic case report form used for clinical research, which includes the patient center outcomes research, the incident report used for patient safety reporting, and surveillance case report form used for public health reporting of infectious disease. So, that's really the focus of this initiative. Again, we've just kicked it off and I think very relevant given the conversation today.

For additional information you can find the charter on the standards and interoperability wiki, the URL you see here, Doug Fridsma and Farrah Darbouze in our organization the Office of Science and Technology are leading this effort. Again, Doug couldn't be here today and gives his apologies, but as we go forward we'll continue to update you on how this initiative progresses.

Shifting over to the Federal Health Architecture Program, I wanted to give you a little bit of a history and then highlight some of the things that we have had ongoing in the last year. Some of you may be familiar with the Federal Health Architecture Program, which we refer to as FHA, some of you may not be. FHA is an OMB E-Government Line of Business that was established in 2003 for the purpose of supporting federal agencies and their activities related to the development and adoption of Health IT standards.

The focus is really to work with federal agencies to ensure exchange of data seamlessly and securely across government agencies and over time, in the time that FHA has been in existence, as you all know, the landscape has shifted tremendously and we have worked hard to align the work of FHA with those shifts in the landscape.

We have had the participation of many federal agencies. What we've illustrated here is just a number of those that do participate. We have a core group of agencies that we work very closely with which include the Department of Veterans Affairs, the Department of Defense, the Social Security Administration, CMS, ONC, the HHS, Office of the CIO, we also have other agencies the CDC, AHRQ and others who participate on a number of our working groups and our advisory committee.

So, one of our goals, as I will talk a little bit about, is really to expand beyond the core group that has been working very intently over the last few years on some specific initiatives and bring a broader array of federal agencies to the table as we go forward with our initiatives. I'd like to describe the evolution of FHA in eras, the early years being the years from 2003 when FHA was initiated to 2008 and the focus here was really on developing a health enterprise architecture across the federal agencies.

In 2004 when ONC was established FHA was moved into ONC and the focus has been during that period of time, very much focused on development of standards, enterprise architecture, a lot of education and coordination among agencies around standards.

The next era is sort of the timeframe of 2009 to 2011 during the period of HITECH and Accountable Care and much of the focus during this period of time was on the Nationwide Health Information Exchange Program and the CONNECT Gateway Program as the software of capability to enable the transport for that exchange.

I'll touch a little bit on the evolution of NwHIN Exchange to eHealth Exchange. I know you're all aware of that evolution that has occurred and we really view this period as sort of the incubation of the exchange and the CONNECT Program.

Last year was very much about strategy, architecture and innovation for us. We took a step back and looked at the organization that we had in place overseeing the program. We put a new governance structure in place that was intended to create a little bit more strategic focus and better align the federal agencies at multiple levels around the goals of interoperability and data exchange.

We tried to instill more transparency in our activities, improve the communications of the program and really made a recommitment to fulfilling the original intent of the Federal Health Architecture Program as an e-Gov Line of Business.

We began a strategic planning process and at the end of the year got approval of our governing board for that plan and I'll share some of the highlights of that. We focused very much on creating the framework for developing an interoperability architecture, shifting from development of a health enterprise architecture to really focusing on where the exchanges of data occur to get a little bit more focused on the value add activities of exchanging data and enabling interoperability across agencies and between the federal agencies and their private partners.

We undertook some innovative activities. We had a pilot program related to RESTful Health Exchange. We worked with the MITRE Corporation in working through this. We had a couple of pilots one with the Telemedicine and Advanced Technology Research Center or TATRC and this was focused on a consult referral use case demonstrating secure person-to-person exchange of information looking at OpenID connect as the mechanism for distributed user authentication.

We had a second pilot working with HealthInfoNet the Maine HIE and this was related to...the HIE and Maine HealthInfoNet has a clinical data repository. So, the focus here was demonstrating secure machine to machine exchange looking at OAuth2 for service-to-service authentication and populating the clinical data repository of the HIE with data from fairly qualified health centers in a rural area of Maine. So, this was really exciting work and I think we demonstrated the utility of a RESTful Health Exchange and we're looking forward to moving this work forward.

Another area that we are moving forward in is with respect to CONNECT. CONNECT, as you know and as I mentioned, is the software mechanism that was developed through the funding of the federal agencies to exchange data among federal agencies participating in the eHealth Exchange. CONNECT is an open-source platform, has not historically been managed as a typical open-source project might be managed, so we're trying to move more in that direction.

Engage the industry in open-source community and helping to develop enhancements to the product. We're looking to engage for the community with code contributions and ultimately the goal is to move the program outside of ONC management and oversight to the open source community. So, that's the path that we're on with respect to CONNECT.

NwHIN Exchange, as you know, is now eHealth Exchange so this has been an exciting transition moving the NwHIN Exchange again from ONC oversight to a public/private partnership. Healthway is now operational as the entity that will be providing the operational support to the participants in the eHealth Exchange. So, again, another very successful program that began as a pilot, pilot implementation and has developed and emerged and is now successfully transitioned to a public/private partnership.

So, as I mentioned, we spent some time this past year really looking at the FHA Program and where we wanted to go from here. What you see here is a vision of the ecosystem that we really envision with FHA serving as a convener of federal stakeholders focusing on delivery of care and bringing together government and private providers, payers to really enable interoperability across government agencies and between those agencies and their private providers of care.

We have established a set of strategic goals and established some guiding principles. Those guiding principles being stakeholder engagement, actively engage stakeholders, demonstrate through pilots. Again, open communication and transparency of what we are doing, commitment to action. We want to move forward aggressively and very much action oriented and again focusing on specifications and moving to implementation.

So, the three goals that we have set are to establish a unified federal voice on health data exchange and interoperability, again, utilizing FHA as the convener of stature to make that happen. To achieve adoption of interoperability specifications leading to active data exchange among the federal health community and with their private partners, aligning with the Standards and Interoperability Framework Initiative using that as a venue to bring federal use cases to the table to work through that process.

And finally, to align federal policies in health care data exchange looking at the various policies that are in place across federal agencies and looking at how we can better align those to achieve the goals of interoperability.

So, this is our vision and our strategic goals at a very high level. We are working now to flush out the implementation plan to put this in place. The hard work now begins and I look forward to any feedback you may have on where we're hoping to go with the Federal Health Architectural Program. Thank you.

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

Thanks, Lauren. Any comments or questions?

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

I do, I really, I recognize the time too. Lauren, first I want to publically thank you. I think this is a very difficult task to coral the federal partners.

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

How would you know? How would you know?

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

It's very difficult. You can imagine we're all little wallflowers there and don't tell Laura what we think she should do for us as the priority, but, and I think we've made tremendous progress. As you know and as everybody knows DoD and VA are actively committed to interoperability and sharing of data. I'm just wondering, do you see ways to accelerate?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Actually I'm interested to talking with Kevin and the Lean Team on how we might be able to look at other mechanisms to help us do that.

**Theresa Cullen – Director, Health Informatics – Veterans Health Administration**

Yeah, I think, because that's where we're struggling within the VA is this really active commitment both fiscally, as well as philosophically, but we'd really...I think we're not clear how to help accelerate the whole federal community and by doing that the private community.

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Yeah, it is a challenge and I think we need to think outside of the box a little bit about how we might be able to do that. So, I'll look forward to engaging on that topic with you.

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

Anything else? Mary Jo?

**Mary Jo Deering, PhD – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology**

This is Mary Jo Deering from ONC. You talked about the structured data initiative and I'm going to ask a question that betrays my lack of technical expertise, but I'm getting to something that Christine raised this morning about patient generated data and how they would like to explore structured questionnaires to capture patient data. I understand that the initiative as it currently stands is to work with data that is resident within the EHR but is there backend work in this initiative that could be useful for mapping that kind of...for developing that kind of questionnaire to facilitate its mapping?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

I can't answer that specifically. I think that's really a question that I'll need to bring to Doug, but I think it's certainly something that we need to consider.

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

Judy?

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

I might just be a little bit confused. When John was talking earlier representing the Standards Committee he was talking about the complexity with allergies and how do we map allergies when in fact the allergies and the reaction to the allergies and stuff like that isn't really a standard and I think he was saying that in a way that I was presuming that the Standards Committee was going to tackle some of that. So, maybe I'm confused in that. Is that something you're group will tackle or that his group will tackle?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Yeah, it's really through the Standards Committee and the Workgroup. We are working now to put together that work plan that he referenced that will then be brought to the Standards Committee and that will be a part of that process.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Okay, so you're working hand in glove with the Standards Committee on this?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Yes, yes absolutely.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Okay, that's the part I was missing. Now when you look at the DoD and the VA who talk about interoperating well together then will they use the same things that you come up with or will they develop their own?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

We hope that we're all part of the same community.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Because if you're going to develop your own, then you've got to work not only with what are the DoD and the VA doing to make sure they interoperate, but there's a whole lot of vendors out there who have each developed their own methods as well, so it's not going to be real quick.

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

It's not our intention to develop anything independent of the broader Health IT community and the process, the governance process that is in place. Our goal is to bring the federal agencies to the table for that dialogue and to participate in those venues.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

And with the vendors too?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Yes.

**Judy Faulkner – Founder & Chief Executive Officer – EPIC Systems Corporation**

Okay, good.

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

Thank you very much, Lauren for that interesting update and good luck to you.

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator**

Thank you.

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

All right, any other questions from the committee before we go to public comment? Okay, why don't we open it up for public comment, please?

**Public Comments**

**MacKenzie Robertson – Office of the National Coordinator**

So, before we do Paul, I'll just add for the record that two members were not here for roll call so I'll just add that Christopher Boone and Terry Cullen for Madhulika Agarwal are present today.

And I also just wanted to mention today's meeting did start a little bit earlier than normal, we usually do the 10:00 a.m. start, so in the future we'll probably be doing a 9:00 or 9:30, so if everyone is just aware that the start time may change for future meetings as well. So, with that I'll go to public comment.

Operator can you please open the lines and if there are any public comment in the room if people can please come to the table.

**Alan Merritt – Altarum Institute**

If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press \*1 or if you're listening via your telephone you may press \*1 at this time to be entered into the queue.

**MacKenzie Robertson – Office of the National Coordinator**

And seeing no public comment in the room, I believe we have one public comment on the line and I'll just also note that we will limiting them to 3 minutes. So, I will be stopping you after 3 minutes. Thanks.

**Operator**

Our first public comment comes from the line of Robin Raiford. Please proceed with your comment.

**Robin Raiford – Advisory Board Company**

Hi this is Robin Raiford and I just have a comment and a follow-up to the activities of what's gone on today and also the follow-up from last month, as some of you know I've been very ill since the 12<sup>th</sup> of December and I've kind of had seemingly an ongoing Kaizen event and what would you do with medical errors and what's happened to me.

And I've...in addition to being just incredibly, incredibly sick since the last meeting I have developed adrenal insufficiency out of just pure stupidity and ignorance of a medical team not watching a prednisone wean and jerking me off prednisone too fast and after HIT Policy a couple of days later I was in an ambulance with a blood pressure of 50/30 and my adrenal is not working at all.

I hope to one, to somehow get to HIMSS I don't know how I'm going to do that if it's some sort of mobility scooter or a whole lot of help because I am the Stage 2 Meaningful Use speaker at the Meaningful Use Forum and I have won the 2012 Nursing Innovation Award and I hope to be able to stand up and get that award.

But, I listened with great intent to the innovation that's happened with clinical quality measures and I would encourage you to include something about patient satisfaction and that quality measure and bring that forward really quickly so that people have something, like me, that happened to them that they can complain and complain loudly and it will affect them and their patient satisfaction score that can get posted in a public place so people know what's happening.

I think, just as a short-term thing, I think I personally would pay to have Dr. Phil just get up in front of those doctors and say "what is it about this generating massive medical errors situation that you don't understand that you've got to move on?" I've become now just totally intolerant of listening to any provider or any hospital administration saying this is too hard. I don't care what has happened to them, it could not possibly be as hard as what has happened to me in the last 12 weeks of my life over the screw up of some doctors that included three hospital admissions and seven rescue squad events before they figured out what the crap was going on because people weren't connecting the dots.

I would encourage all of you to go out on Amazon and get a book called "From Pigeons to Tweets" it's recently been published by Retired Three Star General C. E. McKnight who was the head of the 5<sup>th</sup> Signal Command in the J6 on the Joint Chiefs of Staff. He managed a rather large communication problem back in the 80's called the Iran Hostage Crisis. He pulled a young Captain out of Signal Corps Ball in Heidelberg Germany before that event was made public and his name is Captain Bob Raiford, my kids call him, Dad, when I see what happened with General McKnight and my kid's Dad and he went on...my kid's Dad went onto be his Aide-de-camp for 3 years and that's why I came to Washington because that General came to the Joint Chiefs of Staff, is to realize big, big projects and how big they are.

When I look at my kid's Dad now he works at Harris Corporation which most people have never heard of except recently because of the Super Bowl everybody knows what Harris has done.

**MacKenzie Robertson – Office of the National Coordinator**

Robin, this is MacKenzie, I just want to alert you that your 3 minutes is up.

**Robin Raiford – Advisory Board Company**

Okay, so I would just encourage you to look at SATCOM and what the DoD has extensively done outside of healthcare. Thank you.

**MacKenzie Robertson – Office of the National Coordinator**

Thank you very much and I see we do have another public comment on the phone.

**Operator**

Our next comment comes on the line of Susan Wentz; please proceed with your comment.

**Susan Wentz, MD**

Yes, my name is Susan Wentz I'm a physician in an academic medical center. I'm calling though to share with the committee a little bit about my mother's experience as a practicing solo rural practitioner in Virginia and I just found out about this call within the last half hour or so, I didn't really hear who I know that you are a group of stakeholders interested in these issues and I know that your intent on making them work well, so this experience goes to that point.

She got an EMR and attested successfully in 2011 and then the system didn't work quite up to par so she switched in 2012. The challenge there was several fold. It was a wonderful new system but it operated in the cloud and they weren't...they didn't quite get to the point of helping her understand that it wouldn't work fast enough. It's not a fast enough broadband. So, I would say, having worked here, it would take about 15 times as long to execute any data entry.

And, so she deals with a very underserved population, a lot of chronic disease managed well. Her Health IT Department is her, now that's very different than my situation with my colleagues, we all have lots of systems around us called lots of IT. So, you can imagine a physician, she's 84 doing this on her own. Her IT Department is herself and she did the best she could but it took way longer to execute the charts because of the barriers of implementation with the broadband.

So, finally, the other thing you need to know is that she had, in August, the emergence of a devastating cancer and so she was struggling to see patients and fulfill everything. It's been rough she completed her document. She attested in early January and her attestation was rejected because of the two time sensitive core measures.

So, a couple of things, I think that as we all try to get our whole country and all of us as physicians up and running, I know there's been discussion about the possibility of exemptions, I think that an appeals process would be useful. There were some barriers here that are unusual and by the way, on all of the other clinical parameters, everything was really good and to have things within the system that were time sensitive be the only barrier is the problem.

**Mackenzie Robertson – Office of the National Coordinator**

Susan, this is Mackenzie. I just wanted to note that your 3 minute limit is up.

**Susan Wentz, MD**

Yes, thank you.

**Mackenzie Robertson – Office of the National Coordinator**

If there are any additional comments...

**Susan Wentz, MD**

No, I would say thank you so much for your time and the opportunity to comment and I wish you wonderfully well and the good work and I hope at some point there can be some remedy for this particular situation.

**Mackenzie Robertson – Office of the National Coordinator**

Thank you and if there are any other comments that you want to be submitted you can just e-mail them to me directly for distribution. Thank you. Are there any other public comments in the room? Anymore on the phone?

**Alan Merritt – Altarum Institute**

There are no more comments at this time.

**Mackenzie Robertson – Office of the National Coordinator**

Thanks.

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

Okay, well thank you to the committee members for a very vigorous and productive session and we will see you in March.

**Public Comments**

- At any time is there a plan to include updates on Audits being performed?