

**HIT Policy Committee  
Final Transcript  
June 8, 2011**

**Presentation**

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you. Good morning, everybody, and welcome to the HIT Policy Committee meeting. This is our 24<sup>th</sup> meeting. This is a Federal Advisory Committee, which means there will be opportunity at the end of the meeting for the public to make comment, and there will be a transcript made available of the meeting on the ONC Web site. Please, a reminder for committee members to identify yourselves when speaking, for those listening on the telephone. Let's introduce members of the committee, starting on my left with Jodi Daniel.

**Jodi Daniel – ONC – Director Office of Policy & Research**

Jodi Daniel, ONC.

**Josh Seidman – ONC**

Josh Seidman, ONC.

**Allen Traylor – ONC – Meaningful Use Policy Analyst**

Allen Traylor, ONC.

**Charles Kennedy – WellPoint – VP for Health IT**

Charles Kennedy, WellPoint.

**Madhu Agarwal – Department of Veterans Affairs**

Madhu Agarwal, Department of Veterans Affairs.

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

Art Davidson, Denver Public Health, Denver Health.

**Christine Bechtel – National Partnership for Women & Families – VP**

Christine Bechtel, National Partnership for Women & Families.

**Neil Calman – Institute for Family Health – President & Cofounder**

Neil Calman, Institute for Family Health.

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

Paul Tang, Palo Alto Medical Foundation.

**Deven McGraw – Center for Democracy & Technology – Director**

Deven McGraw, Center for Democracy & Technology.

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

David Lansky, Pacific Business Group on Health.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Judy Murphy ....

**Unidentified Speaker**

....

**Gayle Harrell – Florida – House of Representatives**

Gayle Harrell, State Representative from Florida.

**Marc Probst – Intermountain Healthcare – CIO**

Marc Probst with Intermountain Healthcare.

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

Larry Wolf, Kindred Healthcare.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

I believe we have Scott White on the telephone. Scott, are you there?

**Scott White – 1199 SEIU – Assistant Director & Technology Project Director**

Good morning. It's Scott White, 1199.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you. And Dr. Sharfstein will be joining us a little late. Anybody else on the telephone?

**Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary**

Hi, I'm here. This is Josh.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Oh, good. Thank you, Josh. With that, I'll turn it over to Dr. Tang.

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

Good morning. Thank you, Judy, and thank you all for joining this latest meeting of the HIT Policy Committee. It looks like we have a very full attendance and thank you for that, because we have a lot of meaningful agenda items on the –

**Unidentified Speaker**

....

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

Yes. Unfortunately, Dr. Mostashari is away at another event, but he will try to join us either later this morning or by phone or in person this afternoon. So we will proceed with our agenda, and it starts out with the Meaningful Use Workgroup presenting its latest recommendations, hopefully for your approval, as recommendations to go on to ONC and CMS for stage two. Then after lunch we'll be talking with the Privacy and Security Tiger Team, who has a couple of recommendations having to do with the identity and authentication of the provider entities, as well as the qualification of the certificate authority, followed by Dr. Lansky, who's going to update us on the Quality Measures Workgroup. They're working on both stage two and stage three quality measures that are a very important part of the meaningful use program, and finally conclude with an analysis from the Certification Adoption Workgroup about the analysis from their usability hearing. Then we'll conclude, as always, with public comments.

Any other questions on the agenda? If not, let me also ask for any comments and discussion on the minutes from the last meeting. If there are none, I'd entertain a motion to approve those. And any further discussion? All in favor?

**Unidentified Speaker**

Aye.

**Unidentified Speaker**

Aye.

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

And opposed? And abstained? Okay, that will bring us to our first agenda item, which is the Meaningful Use Workgroup report, and I'll join George at the desk.

Good morning, members of the HIT Policy Committee. George and I are going to present on behalf of the members of the Meaningful Use Workgroup, whose names are in front of you. And again, this has been a very hard working workgroup. We've had several calls since our last meeting and we're responding here to give you the feedback from our deliberations for your discussion and ultimate approval. So first we'll start out with a context, and that's our alignment with the National Quality Strategy and update you on our discussion about the timing proposal. Then go through the revised recommendations we had, both with your input and the input of the public hearing that we had just two days following the last meeting with specialists and some very interesting early experience from the field.

I think I'll mention that one of the conclusions from the various panelists at that hearing was very gratifying to the Meaningful Use Workgroup in a sense that whether we had representatives from large organizations, one of the largest health systems, Academic Medical Center and Safety Net clinic, and to the person they all felt that although it was quite challenging to meet the meaningful use objectives they found that it helped them in the organization with their core mission of improving care. And actually given the question of whether they found any of the criteria to be something where the burden was not worth the value they got out of it also unanimously they said that none of them, they wouldn't give up on any of the criteria. So that was very heartening to the group. We understand that that was a selected group of early adopters but it was very useful to have that input. So we'll conclude with final we're asking for your approval of the recommendations we have both on the timing and on the objectives for meaningful use stage two subject to the amendments we have during this discussion.

So to remind you of the key principles we use to drive towards our recommendations for stage two, one is with the presence of the National Quality Strategy by the secretary we wanted to make sure that we aligned with those for sure. Secondly, that as part of the statute, the original HITECH statute in the subsequent Affordable Care Act we wanted to make sure those were in sync and particularly we wanted to make sure that we were moving the country on a road map towards having the HIT infrastructure in support of health reform, so that was extraordinarily important to us. The third point is the counterbalancing measures in terms of making sure that we do propose something that is technically and from an implementation point of view feasible, because it doesn't do us much good to have something that is a pipe dream and not implementable, so that's a constant tension or a constant balancing act that we tried to achieve during this whole .... Finally, the last thing we want to do is penalize any group for being an early adopter, and we have this timing list that we talked about last time and we'll cover again today that actually had an effect of penalizing early adopters.

You'll recall that we used to have that arc, and this is a presentation of that arc, in the sense that the meaningful use program is one of steps or phases of moving the country from where it began a couple of years ago, which is very low adoption on a relative scale for EHRs and Health Information Exchange, to one where we all have that as part of our infrastructure and can continuously measure and improve the outcomes that we deliver. It begins in stage one with getting structured data into these systems, and moves on to using that to improve our care processes and with the appearance of the National Quality Strategy we want to make sure that we fit in, we align well with the secretary's vision of how she wants the country to progress in meeting its health priorities. And finally, that we do achieve the goals of having an appropriate HIT infrastructure to achieve better outcomes. Another way of representing that is that at the base of this pyramid the platform is to create electronic health records and the meaningful use of those record systems, be able to create a data liquidity through the health information exchanges, and to, in the second tier, to build on this infrastructure to achieve quality of care that we all desire and coordinate the care amongst the many stakeholders and many participants of the care of an individual in the context of community and finally then achieve better outcomes where we can benchmark ourselves against our peers and to continuously improve the quality.

The first check we did is to make sure that we aligned well with the National Quality Strategy priorities, which are listed on the left column. And you'll see on the right we've listed some of the meaningful use criteria and how they might apply to the objectives set in the National Quality Strategy. The first goal is to

make sure that we deliver high quality safe care, and you see that we have a number of meaningful use objectives that address that priority, not the least of which is computerized provider order entry and clinical decision support. The second goal of making sure that we engage the individuals and family members I think are well served by not only the cluster of objectives we have under engage patients and families, but throughout the meaningful use framework.

The next priority is to make sure we achieve effective coordination of care, and we've spent a lot of time trying to advance the field in this area, particularly with stage two. We recognize that currently the field is immature in the sense of we don't have a lot of infrastructure so there aren't a whole lot of data being exchanged amongst providers, and that's something we really want to aggressively push providers to do.

The next priority is to make sure that we address prevention as a strategy, and that's one of the triple aims of the National Quality Strategy. A lot of our quality measures will be headed in that direction, particularly in stages two and three, and we do have functional objectives in place to help move that along.

The final two has to do with promoting the health side of healthcare and we have a whole category on public health objectives, and while again that is in its early stages, we're trying to move the standards and the functionality along in these systems in order to meet that need.

Finally, the affordability, again, that is something where one way we're addressing it is through computerized provider order entry, the ability to give providers as they enter the orders the information they need, which can include cost information and efficiency information to make appropriate both care and cost effective positions. I think this is something where we can improve the objectives and functionality as we go along in stages two and three, and some of that will be motivated by some of the quality measures that will be coming out.

Now, you recall last time we talked about this timing matrix and you'll see in the highlighted cell what happened with the phasing of stages one and two for the early entrants, that is, those who qualify for meaningful use stage one in 2011, they get put into a bit of a predicament, sort of in an unintended way, so in 2013, which for hospitals starts with the fourth quarter of 2012 and for providers EPs start with January of 2013, they may only have three to six months from the time the final rule is released we anticipate in the middle of 2012. That almost certainly doesn't provide enough time for either vendors to design, develop and release their functionality and new products and for providers to upgrade and implement that functionality. That's sort of a timing glitch for that one group in particular. That doesn't involve the majority, because we don't expect the majority to really qualify in 2011, but it does put those folks at a disadvantage and actually from the field we're hearing that people who are already eligible to apply are holding back, and that's again one of the things we wanted to avoid.

So when the Meaningful Use Workgroup looked at three options that we had put before you the past couple of meetings and tried to qualitatively rank how those options would play out we found that option three, delaying the transition from stage one to stage two only for those providers in that cell, that is, for providers who qualify for meaningful use stage one in 2011, that's the only group that will be affected by this recommendation. All the others, and I'll go back to that cell, so the group that qualifies in 2012 they were scheduled to move to stage two in 2014 and they still would; the only cell that's affected is that early entrant group.

Let's move through, as we did last time, through the changes, so these are changes that we made to the meaningful use objectives since our last meeting about a month ago, and those are represented in red. So we'll go through a category at a time instead of a screen full at a time, because there are fewer things to discuss, and get your feedback. The first thing we did was on the computerized provider order entry, and as you'll recall we went from a threshold of 30% to 60%. That is, for patients who have a med on their med list and have medication orders, 60% of those would be created, would be ordered through the computer. What we did was add to the medication orders lab orders, and what we also tried to do is find an easy way to calculate the percentages.

The way we put it for labs is for patients who have a lab test ordered that 60% of those patients have at least one lab test that is ordered through CPOE. For radiology we didn't change that, that is, unlike lab where we required structured results back to the EHR, we don't have such a requirement for radiology. So we don't have a denominator that matches the other two types of orders. So we felt what we wanted to do is make sure radiology ordering through CPOE was in use, and that's how we came up with just having at least one radiology test. Again, the principle is that we're not anticipating people to just turn it on, order one test and then turn it off. That's not in anybody's best interest, including the provider group. What we're doing is we're erasing the threshold for medication orders and we're adding clinical lab tests to that, and radiology orders for those who do radiology orders.

The second item on drug-drug interaction, it's just almost a technical correction. We're not suggesting that people change the database that is supplied to them by medication database companies, but that the provider organization be able to put rules into place that suit its local needs. The problem we're trying to solve is that the common commercial drug-drug interaction databases have a very high false positive rate and that is causing people not to pay attention to those alerts. So in between the situation we have now and what we're hoping will occur in stage three when we have a nationally maintained high impact drug-drug interaction rule set then we're trying to at least give providers an ability to increase the positive predictive value of what they have.

The demographic objective, what we did is originally we were hoping to include the more granular race and ethnicity categories as recommended by the IOM. But the IOM's recommendation was to create standards for those and those standards do not currently exist. We're hoping by stage three that those standards will exist and that we will implement those but we don't have those right now and so we had to back off from stage two.

On the next screen we come to the advanced directives, and we continue to iterate and hopefully we're at a point where this is a good step forward on the way to a better step in stage three. So for hospitals, where you certainly have the patients in front of you in the inpatient setting, we're asking that at least 50% of those 65 and older at least have a record in the EHR of whether they have an advanced directive in place or not. For those who have an advanced directive, we would like the providers to have access to them to a copy, one way or another, at least for 50%. That is, they could literally have a scanned copy of that in their EHR or they could have knowledge of how to access that in some other place. Clearly, as HIE matures we'll have better access to those advanced directives. In addition, we ask for the date and time stamp as one way, as one cue to the provider of how recent this is or how out of date it is and may need updating in terms of making sure that it still represents the patient's current wishes.

For EPs, the current state is not well known and the availability of that is probably low at this point. But we certainly want to put it on the escalator to being more widely available so we're starting out by, one, making sure that the EHRs serving the ambulatory care environment have the functionality to do the same thing, that is, being able to record whether or not an advanced directive exists for this patient with a date and time stamp and provide access to a copy, either in the EHR or some accessible place. In order to make sure that the functionality gets put in place we've asked for the 25 unique patients, again, thinking that people are not just going to turn it on and stop capturing that information, but that would guarantee that, one, the function's in the EHR, and two, the workflow is in place to ask patients about it and to start capturing that.

The final screen talks about some of the new functionality. Let's look at the structured clinical lab test results. As you'll recall, meaningful use does not cover commercial laboratories and so it has no way to directly ask them to provide structured test results and to use standard coding systems like LOINC. But hospitals are participants and hospitals provide some or maybe the majority of test results for some physicians. So we're asking that the hospital labs, when they do send electronic results back to providers, to their EHRs, that that be in structured form and that use LOINC where LOINC is available for that test. We're using as denominators the orders received, so if a hospital receives an electronic order for lab test results then we're asking that 40% or more of those results that they report out are in structured form and use LOINC where applicable. We recognize that there will be a challenge to some of

the smaller or rural hospitals and suggesting that CMS may want to create a mechanism for exclusions where that would be a particular hardship.

The next objective about sending appropriate reminders for preventive or follow up care, we're just clarifying that as discussed here instead of asking that 10% of active patients receive them, we know that 10% of active patients have had a reminder sent because we don't have any control over whether it's received in a particular fashion. We've also introduced the notion of "active" patients and asking the HIT Standards Committee to define that. An example of a definition is a patient that's seen within the last 24 months. One of the new functionalities that we called out last time is the automated electronic MAR, and we tried to define that a bit more precisely and we're saying that this is automatically tracking the electronic administration and basically capturing the "five rights": right patient, right dose, right time, right site, etc., and that occur without manual transcription. So what we've done is we've taken another cut and we put that in the letter that will go to the HIT Standards Committee of defining what we mean by electronic medication administration record.

I think that concludes category one, which is the quality, safety and efficiency of healthcare and reduce the healthcare disparities, and let me go ahead and open that up for a discussion by the group before we go to the next category. It looks like Marc has a question.

**Marc Probst – Intermountain Healthcare – CIO**

Yes, and it's not a huge question. On the drug-to-drug interaction we talk about the provider being able to refine it. Can a provider be a whole organization or are we talking about the individual provider?

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

That's a fair question. I think we meant the whole organization. I think you're referring to, let's say, a hospital. It's not individual providers being able to affect ... It's doing it on a system basis, whether you're a single provider in a practice setting or a hospital.

**Marc Probst – Intermountain Healthcare – CIO**

Then two other real quick questions. On alerts presented to users who can act, will someone define, I mean, that's a pretty broad statement.

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

I think it matches the definition in stage one and I think it was a bit terse in what you've gotten in your handout, but it means in stage one we use the term "licensed professional," and so that person is it. It's the same one and it's someone who can act on that alert rather than having to pass it on.

**Marc Probst – Intermountain Healthcare – CIO**

Then not a specific question but on advanced directives how will we reconcile a provider, we'll get one advanced directive, a physician's office, whereas inside a facility like a hospital we might pick another advanced directive and they may not match.

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

That's true whether it's on paper, verbal, or electronic. So the best we can do, which is a similar approach we used to medication allergies, for example, what we do is we mark the date and time when it was last reviewed with the patient and that's the hint to the reader of how current is the information. That's why we proposed that the advanced directive be stamped with a date and time stamp, in order to help the reader understand how current it is. And of course the reader, the person right there with the patient, can always check.

**Marc Probst – Intermountain Healthcare – CIO**

Thank you.

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

Thank you. Larry?

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

Clearly, a lot of work and good thinking has gone into this. A couple of questions. Some of the measures have calculations similar to stage one, but you seem to have introduced this notion of existence proof, like we want you to be using enough that we know it's actually in the tool and that it's in your work process and it's part of what you're doing. Was there any discussion about how narrowly or broadly to use that concept on the assumption, and I guess I'm making an assumption, that an organization that has made it possible to do this and train their staff, that if it's helpful they're going to do it, and if it's not helpful they're going to be beating up on all of us to say why did you make us do this at all.

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

I think you're asking the question why don't we apply that principle more broadly. Is that –

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

Yes.

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

I think that originally we were trying to make sure that it has reached a threshold where it's baked into the organization's both values and the workflow, and that's how we arrived at the percent. And probably that's still a good approach. And what we're finding is that there's a burden to calculating a percentage, and in particular finding out the denominator, especially when you'd end up having to count paper artifacts. So we're trying to avoid that and I guess we're making a transition, but still I suppose we're in favor of the percent where we could figure this out in an automated fashion and where we find that we just can't get around that we're resorting to the whole "it exists and it's being used" kind of approach.

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

I guess some of what I'm thinking about is I was at the NIST usability event last time and they were talking about some of the other environments where things get rated and they used the car crash safety things as a measure. So I can imagine that we said, you know, you have to report on these things but it's up to the marketplace to decide does it value a five star on this or a one star, or it doesn't care.

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

So I guess one of the issues there is transparency. Everybody understands what a card does and what a card shouldn't do. It's not clear that the end beneficiary, the patient, would have either control of the knowledge set in EHR.

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

I think that's probably true but there are other players in the mix. There are payers. There are regulators. There are a lot of people who can look at that and say, okay, you're only one star here. There had better be compensating control somewhere, because how are you managing drug safety, for example.

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

It was somewhat driven by the incentives, in that we needed some criteria by which to decide whether to give an incentive, as opposed to letting the market decide which product to buy. So I think that drove us to have actual thresholds and then relying on the 25 count for places where it was really going to be hard to do a percentage. So I think that's why we ended up there.

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

Then one if it shows up in the standard piece but it relates to one of these things. On the five rights drug administration you described it as correct time, but in the standard piece it says record the time of drug administration. I think there actually is a safety piece in getting the time right because a drug on a frequency might have been delayed and you're now about to give a second dose very close to the prior dose. So it seems to me correct time is important in the checks as well.

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

I think you're asking whether the functionality is to be able to automatically record, the time in this case, or to also act on alerting about it not being on time.

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

In the same way that it's alerting this is the wrong patient, to alert to say they just got a dose. It's the right patient. It's the right drug. They're supposed to get this drug, but not now.

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

It's probably a matter of degrees in terms of how far do you push the floor objective, I guess.

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

Because we're going to be doing all these checks, and not that I want to layer in more requirements, but so it feels like –

**M**

My only concern is I'm not sure if there are unintended consequences. Does the system have the timing, are we able to do that alert in an efficient manner that you don't get a lot of false positive alerts, in which case they might start ignoring the important ones, like this is the wrong patient because of the way the people administer, the nurse administers and the way it's written there may be some flexibility there normally in the normal course of care. So I'd be a little afraid to mandate that one.

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

It quickly gets into a lot of –

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

... I think we're trying to stay with the floor. And we can certainly move things in stage three, but the current understanding it seemed like the floor would be an appropriate approach, for stage two anyway. Gayle?

**Gayle Harrell – Florida – House of Representatives**

Thank you very much. I want to go back to the advanced directives situation. Certainly in hospitals the 50% is perhaps the best place to do it, but when you're talking about specialists we have a situation where many specialists don't incorporate advanced directives into their normal workflow and there are problems in doing that. I don't know many podiatrists who asked if you have an advanced directive or ophthalmologist or whatever, however, if you're doing that, you have to have 25 unique patients, and if the individual does not have one are you then obligated to give them a form and have them fill one out, or what is the obligation of the individual who asks the question to provide the advanced directive and to make sure that that then gets incorporated into the electronic health record? I have many, many of those providers out there who question this whole aspect, this whole requirement, especially if you make it a core requirement. If it's a menu requirement and it doesn't fit their practice workflow, they could opt out of it, but making it a core requirement and then what obligations do they assume when they do that.

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

This actually is a good point and it addresses Larry's question about when would you use the countable number versus the percent. I think we talked about this last time as well, so we certainly appreciate that some specialists, this is not as relevant to some specialists. That's a reason for using a number instead of a percent, so the number says not that you record even 25, you personally record the presence or absence of an AD for 25 unique patients, it's that it's in your EHR. You can expect that a majority, probably, of specialists would want to have that information available in the case of need, so this is just asking if that information is in their EHR. It doesn't say that they did it personally. And it's a little stretch to say that many specialists would not have 25 patients where that might be appropriate. So anyway, that's the reason for establishing quite a low threshold, low floor compared to a percent.

**Gayle Harrell – Florida – House of Representatives**

In follow up to that, are you required to just ask the question and record it at that point, but you then must have, if the answer is yes you must have either a copy of it or access to a copy of it? So then you have to follow up with the patient and get a copy of it.

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

We thought for a minimum of 25 that wasn't unreasonable and picking a number, without having to itemize all the specialties and deciding whether that's appropriate for that specialty, that was our compromise in figuring out that 25 is not a very high bar and make sure that the functionality's there, and it's something that we want to get in the habit of knowing about an individual, particularly those 65 and older.

**Unidentified Speaker**

Just to clarify, I think one of the things we also considered when we talk about access, and you mentioned this earlier, it's sort of directional. So if I have a copy of my advanced directive in my wallet or in whatever it may be, then my podiatrist could ask and I could say yes, it's in my wallet and he's recorded how to access, for example. We hope that they'll all be stored electronically, but we get the issues that you're raising. So I think the directions around how to get the most recent copy would be fine too.

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

I think Judy was next.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

A couple of things. One is, it says "quality, safety, efficiency, and reducing disparities," and I'm almost wondering whether it should, I don't know if this is worth changing, but be saying "productivity" rather than efficiency. Because we can do it with great efficiency things that shouldn't be done at all, and the real question is how do we have productivity. I had an interesting experience just a week or two ago when I went to see a PCP for the first time in years. And it was really not a good experience because I had a bunch of things I wanted to discuss, changing a drug dose, preventive maintenance, a letter from a specialist with some ideas, and he said he doesn't have time to read them and if I'm assuming that he can be proactive, forget it. He does not have the time. That's what he said. If we want to make sure that we pick the best care for patients we do have to leave our providers time to have somewhat of a holistic view of those patients. That's why I think efficiency versus productivity are really two different things and we really have to be making sure that in the end the patient is well served by allowing the doctor to do things that need to be done.

The second thing I have on my list here is the 50% of all discharge patients, I don't know if it's still the case but I know a few years ago there were certainly areas of the country that didn't have very good connectivity at all and where a lot of people did not use the Internet. So my question is, if they provide the 50% but the 50% don't have connectivity does it matter? Can you provide it and they can't get it because they don't have a system but you're still making – do they have to actually be able to receive it or can you provide it without them receiving it? Maybe it should be 50% of those with connectivity or those who want to participate or something.

**Unidentified Speaker**

Wouldn't that be a reason for an exception, if you practice in an area where there's no broadband?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Perhaps.

**Unidentified Speaker**

If they have the capability they can get credit for that. I think there's a couple of ways of looking at it.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay. And then, the third thing was just on the –

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

Can you clarify, which objective were you talking about?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Well, the one I was specifically looking at was the one on page eight that says provide over 50% of all discharge patients, it says actually ... patients, with an electronic copy of the discharge instructions.

**Unidentified Speaker**

We haven't gotten there yet.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Oh, okay.

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

You skipped ahead, but we'll replay your comment.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay. Well then I'll wait on that one. I'll just go back to the productivity one.

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

Did you have another one?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Well, the last one was also future.

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

Okay. Well you've done your homework. Let me just comment on your first one, which was I think you were talking about user or provider productivity. As you know, we're struggling, the whole group and we're going to hear a report out from the Certification Adoption group about usability, and I think that is a true issue, we're grappling with how to address that in a useful and –

**Judy Murphy – Aurora Health Care – Vice President of Applications**

I do think we have to separate usability, which goes with efficiency, from productivity. We can have them in a very usable way collect a ton of information, which is all useful but not have enough time to see the patient. That's my comment, which was a real experience for me, not just from the computer system. It's just all the requirements that that provider has.

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

Let me also qualify the efficiency met the efficiency of the health system, not the provider in this case, so it has a lot to do with the cost effectiveness, for example, and the appropriateness there. So since there have been a couple of public comments on doctors I think we need to help both Judy and Christine get providers that can satisfy .... But at any rate, let's see, does anyone have a comment on this section before we move on? Okay, we'll move on to engaging patients and families. Yes?

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

Paul?

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

Yes?

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

It says perspective, are you going to look for an approval today, and do you want to do that in aggregate at the end?

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

Actually, you brought up a good point. Let's do it at the end.

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

Okay.

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

Thank you.

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

Okay, very good. Good morning. Thank you for letting us come and present. I will now bring on the ones that will bring on the questions. The first line is red only because we changed it from dropped to combined. There are a couple of places in our slides that there are actual changes where we were assembling information yesterday and this had to go out, and so I'm going to describe it.

There's one on this slide. It's specifically the first objective or the second row up there for discharge instructions. Our workgroup discussed whether we needed discharge instructions objectives, and the reason was that the discharge instructions are also going to be shared in that third row, which is the second objective for hospital summary, and in our discussion it seemed that both the conservative among us and the aggressive among us agreed that for various reasons that this could be dropped. So here's the way I would put it together. We suggest that the discharge instructions objective could be combined into the next one, that is, hospital summary. If it is preserved, however, by CMS we should switch to the greater than or equal to 25 patients instead of using the 50% of those who request because of the difficulty of measuring how many requests. This gets back to Larry's question. So if we were to preserve it, we want to make it easier to count, but we believe that in fact it could be dropped altogether, the workgroup did. So instead of the black hospital is greater than or equal to 25%, it should just be red combined with next objective.

The next objective after that, which is the hospital view and download, we changed the wording, as we discussed last month, to view and have ability to download, and took out the words "relevant information." It's actually the information that's defined first suggested by the Policy Committee and then defined in detail by the Standards Committee.

The next objective, again, view and have ability to download, and we made the clarification that we discussed last month that for lab data it's four days or more, just like on the other objectives. And then, furthermore, we had discussed that the Privacy and Security Tiger Team should consider whether a privacy and security warning should be put in the Standards and Certification criteria that is warning patients that once they download this their protections from HIPAA, they're on their own basically at that point. I don't want to rephrase it inappropriately, but that's basically the concern.

On the next objective you see electronically accessible for viewing counts. That's hard to .... It just means that if they view it electronically that counts towards it and it doesn't have to be a paper summary. On the following objective for educational resources, we changed the wording from "received" to "are provided," and it just emphasizes that it has to be a countable number and how does an auditor know whether a patient really received it, do we have to actually interview patients, and perhaps now we just have to document that we provided it to the patient. Then the secure messaging we just fixed the typo that it should be at least 25 patients, not more than 25 patients.

So those are our changes for engaging patients and families, and I guess I should open it up for discussion now. We may have taken away one of our questions by eliminating the objective.

**Unidentified Speaker**

On the 10% of patients and families have the ability to download, we took out the word "relevant," and I'm wondering on that one, many of the hospitals today put out some electronic information that's just a data

dumpster, in essence, and I know we ... looking to the Standards Committee for a specific standard, but is the concept of usability of that information in any way being lost here, or is that embraced at the Standards Committee level?

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

We definitely want it to be relevant and we definitely want it to be readable, so that's our intent. It's just that when we put in the word "relevant" it raised the question of well, who decides whether it's relevant or not. So it was really an attempt to say we're going to follow our – but everything we do we want to be relevant and useful, so we didn't want to highlight this as a specific criterion for this objective. We have a list of things that we think belong in the summary, we have handed it for stage one, handed it again to the Standards Committee in stage two, and they enumerate the items, some of which may be free text and filled in. But it wouldn't count promotional materials for the hospital, for example, counting as information. We intend it to be relevant and usable, but we just don't want people to wonder what we mean by that word. Gayle?

**Gayle Harrell – Florida – House of Representatives**

Perhaps I'm not understanding exactly what is going to be within the electronic access to their health information to be able to download. What exactly do we have? Specifically, are they going to get the whole record, especially when you're talking about a hospital record, that can be a huge amount of information.

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

No, it's actually –

**Gayle Harrell – Florida – House of Representatives**

And it's just a summary. They will get a –

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

They –

**Gayle Harrell – Florida – House of Representatives**

... discharge summary.

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

No, no, no, not the discharge summary. There's an enumerated list of things like the visit date, which we have, we have that –

**Gayle Harrell – Florida – House of Representatives**

I saw that in the letter.

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

Yes.

**Unidentified Speaker**

....

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

No, no, no, for the hospital visit. It's in the letter. So there's an enumerated list of items which includes the discharge summary, I think includes the discharge summary if it's available, I actually forget. Does it, Christine? It includes the discharge summary, it's available, but it's not limited to that. And in fact, the discharge summary often appears two weeks later, so if it's not available we make sure we have the other things like the admit date, the diagnoses, the providers. So I don't want to make a mistake, but there's a list identified. It's not the whole record.

**Gayle Harrell – Florida – House of Representatives**

Is that going to be in a format that is then, is it discrete data that can be input into a personal health record, or is this a PDF? What format would that be in?

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

Christine, go ahead. Did you want to – you were about to –

**Christine Bechtel – National Partnership for Women & Families – VP**

If you move here you get called on. Our intent was not to get granularly specific about necessarily the format of the information. As George and Paul talked about, we do want it to be useful, but in stage one we did not, on the EP summary we did not specify is it a PDF, is it structured. So what we've said here and in the past, and I think this hopefully is still in the transmittal letter, is we'd like it to be both human readable but also potentially machine readable or as sort of structured as possible so that other applications, like a personal health record, could accept it. But we're going also based off of the experience of the VA and CMS, which are already doing the view and download functions for beneficiaries and veterans, and they have just literally pushed the data out in a pretty raw format, but it's still been able to be very usable for patients and PHRs.

**Gayle Harrell – Florida – House of Representatives**

So you're not delineating whether it's structured data or just –

**Christine Bechtel – National Partnership for Women & Families – VP**

No, we're not very clear about that here and now we can ask the Standards Committee to give us some recommendations, and our transmittal letter does go to the Standards Committee.

**Gayle Harrell – Florida – House of Representatives**

I would think that the vendors would want to know that so that when they're constructing their systems they would know.

**Christine Bechtel – National Partnership for Women & Families – VP**

Right, so we focused on content as a Policy Committee and then the Standards Committee will focus on standards and structure. We've tried to signal what our thinking is for the Standards Committee but not get into the level of detail where we're making decisions at that granularity that really belongs with the Standards Committee.

**Gayle Harrell – Florida – House of Representatives**

Perhaps we might want to specify as the Policy Committee that we do want it to be able to be integrated into a ... health record –

**Christine Bechtel – National Partnership for Women & Families – VP**

Yes.

**Gayle Harrell – Florida – House of Representatives**

... which then would indicate structured data.

**Christine Bechtel – National Partnership for Women & Families – VP**

Great.

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

I can probably clarify here, reading from the stage one, one, it's human readable format; two, what they're able to receive is electronically transmitted and use standards where they exist, and what was pointed out are standards for the problems, for the procedures, for the test results, and for the medications. So where there exist standards that have already been endorsed we're asking for them to be transmitted in standard, structured format.

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

And we don't want to eliminate narrative data, because that's an important part of the record also, and so we don't want to inadvertently not transmit the most important part of the record.

**Gayle Harrell – Florida – House of Representatives**

Correct. So there's –

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

Just keep that in mind.

**Gayle Harrell – Florida – House of Representatives**

Yes.

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

So you have to work through that as you come up with a definition.

**Gayle Harrell – Florida – House of Representatives**

And to follow up on how this is going to happen, I have such a great concern in many areas where you do have limited access, you have critical access hospitals with limited access to broadband, you have many, many communities where the patients themselves, there's a huge digital divide in this country, the patients themselves don't have the ability to have that information, and holding specific small group providers accountable for that win, they probably might not have 25 patients in their practice that have the ability to do that, no less trying to get them to do that. Again, my thought is this is a wonderful menu option and we're putting numbers in and saying specifically in situations that it has become very difficult for providers to meet.

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

Our suggestion on this was although there may need to be an exception in places where it can't be done, but not to make it menu. Because if this is one of the driving forces behind what we're trying to achieve, if we can avoid making it menu we'd rather, but we recognize that there might need to be an exception. So if we have that choice I'd vote for an exception over a menu item, especially on this one. Let's see, we'll go, Marc? Why not? I went in the middle. ... why don't we start in the middle.

**Marc Probst – Intermountain Healthcare – CIO**

Why not? Right in the middle.

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

... why don't we start ....

**Marc Probst – Intermountain Healthcare – CIO**

Two questions, one of them patient education and all encounters. I'm going to play off what Judy said earlier, it may be true that there is education for all encounters but is it really worth the effort or all the content that would have to be developed to anticipate all encounters and have patient education? I liked the wording before, and if education's something of value, then that's something you're going to provide to your patients and you should have the ability to do that. But I think without defining all a little bit, that could get out of hand if we're not careful, so that was one question. The second one was on the four days, and we use that on a few examples. Is that based on any kind of science or is that just a feel good number of four days?

**Unidentified Speaker**

....

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

Yes, we carried it forward from stage one and I'm trying to recall our conversations then. It's somewhat a negotiated value of what's long enough, but it was – David, go ahead.

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

It's a statement from practical experiences too. This is work ... multiple organizations and part of it is –

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

... and part of it is the weekend, so part of the days is the weekend. And if you –

**Unidentified Speaker**

..., okay.

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

So four days was based on, actually not only practical experience but policies at organizations that are doing this. So that's where we got that. On the first part, the question you're asking is, is 10% too much given that it's not that much? What we did is we raised the threshold in effect, and we raised it, rather than raising the 10% because you can't measure is it appropriate or not. How is an auditor going to know is this the case where educational material is useful or not? So instead of raising the threshold from 10% if appropriate to 40% if appropriate, we made it 10% of all.

**Unidentified Speaker**

So then you can raise the question, as you just have –

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

... too many.

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

Well, no, not raising that. So 10%, I mean, it is when appropriate. It's just the discretion of which 10% you pick.

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

Yes, that was our intent.

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

All right, thanks.

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

Let's see, who was up next? I ... see Paul and Judy, Larry and Adam.

**Paul Egerman – Software Entrepreneur**

First, great work. I just want to join everybody in saying that. Clearly, the questions are getting how hard this is to get done. As everybody reads this they all have these very technical questions, so I had a technical question on the one that says clinical summaries to patients for greater than 50% of office visits. My question is, do we have a definition of office visits? If the patient comes in once or twice a week for an injection, like maybe an allergy shot or something like that, is that an office visit?

**Christine Bechtel – National Partnership for Women & Families – VP**

CMS had to define stage one because this is again a carryover from stage one so they had to define office visit in their detailed guidance. I don't know that the definition off the top of my head, but I –

**Paul Egerman – Software Entrepreneur**

... the definition, okay.

**Unidentified Speaker**

... we're getting a lot of questions about it.

**Gayle Harrell – Florida – House of Representatives**

People come in for blood pressure checks. Is that an office visit?

**Christine Bechtel – National Partnership for Women & Families – VP**

I'd have to direct you to the CMS Web site. We get the point, and the point is not that – so we don't want to labor it.

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

... but a blood pressure check may be something you wouldn't mind getting a piece of paper that says what your blood pressure was that day.

**Gayle Harrell – Florida – House of Representatives**

That's not a summary.

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

It's not the full clinical summary, but the summary's generated automatically so as long as the information you want is highlighted – well, there's no extra cost to the physician of having the rest of the summary included. But I see your point; we don't want to create burdensome priorities.

**Christine Bechtel – National Partnership for Women & Families – VP**

Remember, this is also in electronic context, so I do definitely want that blood pressure that I get checked weekly or three times a week up into my health record, and this triggers that so it is good.

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

Okay. Judy?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

... the two places where it has over 50%, oh, actually there's three. It strikes me that several things are needed. One, the healthcare organization needs a portal to get that data to the patient. Is that correct?

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

That would be the easiest way to do this, and we certainly want to encourage that.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay.

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

It's not the only way.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

The other way would be a thumb drive, give the patient a thumb drive .... What other ways are there to hit that –

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

A third party.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

A third party –

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

It could be a mediator, I can imagine. There could be a third party portal. There could be their own portal. Thumb drive, I have to think. I don't know that that's enough because I don't know if that meets the consumers' needs.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay, so their own portal and a third party portal are the two main ways?

**Christine Bechtel – National Partnership for Women & Families – VP**

... messaging. ... to a PHR.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Secure messaging doesn't mean that they have to sign up with some codes in order to be able to say this is the right patient getting this message. So it does require some sign up for them.

**Christine Bechtel – National Partnership for Women & Families – VP**

Yes.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay. So then my question to both Paul and Neil is, you both have portals in your organization. What percent of patients have signed up? Because the second thing you need is you need patients with connectivity and Tony says we can rule out places that don't have enough connectivity. But given that New York and California both have pretty good, well New York City and California both have pretty good connectivity in the places you're at, what percent of patients have signed up?

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

Over 60% of ours.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Sixty. And Neil?

**Neil Calman – Institute for Family Health – President & Cofounder**

For 15 months in an underserved population, about 20% of our patients.

**Christine Bechtel – National Partnership for Women & Families – VP**

So you're in a HITECH area, which might make it easier. If you're hitting 20% in New York City where they have connectivity, you've got a patient population that, how do you get it from 20% to 50%? So that is my next concern, that in some areas even if you're having drives to do this, you might not get that percent of people who want that type of communication. Maybe what you should be saying is 50% of those who say this is a preferred method of communication. I think we need to clarify a couple of things. Okay –

**Unidentified Speaker**

First of all –

**Christine Bechtel – National Partnership for Women & Families – VP**

... one is –

**Unidentified Speaker**

... which line are you referring to?

**Christine Bechtel – National Partnership for Women & Families – VP**

You're on clinical summary. ....

**Judy Murphy – Aurora Health Care – Vice President of Applications**

I'm on the 50% of patients with electronic copy of the health information, 50% of discharge patients with an electronic copy of their discharge instructions, and 50% of all –

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

Okay, so let's clarify. One, we already eliminated discharge instructions. That's probably the easiest to clarify, because we incorporate that –

**Judy Murphy – Aurora Health Care – Vice President of Applications**

....

**Unidentified Speaker**

That first column is about what stage one was.

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

Right.

**Unidentified Speaker**

So in stage two those first two lines are gone, they no longer exist in our recommendations. That's why I was asking what you were referring to.

**Unidentified Speaker**

....

**Unidentified Speaker**

Those are the stage one criteria.

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

Then for the view and download, the threshold is only 10% and there is exclusion for zip codes where you have low penetration of broadband access. Fifty percent are provided a clinical summary electronically. They don't have to have access to it. So in other words that's already voluntary in the sense that people who don't have access unfortunately are not able to take advantage of that, but it's not penalizing the provider for not providing that access.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

How do you provide it to someone who doesn't have access?

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

It's provided by the system. So if you do have access, and it could even be from the library and other public sources, you can access your information securely. It is available to you.

**Christine Bechtel – National Partnership for Women & Families – VP**

... 50% for that EP clinical summary, this is, again, a carryover for stage one. And it was clear that if the patient prefers that on paper they can have that on paper, so that's fine. All we did was create the electronic capability for that. But the view and download is really where the usage comes into play, and so that's only 10%, but the visit summary you can have a piece of paper when you leave.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay.

**Christine Bechtel – National Partnership for Women & Families – VP**

As long as it's a piece of paper that's allowed, I think we're fine.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Okay.

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

Okay, good. Larry, and then Adam and David after that?

**Unidentified Speaker**

....

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

Oh, sure.

**Christine Bechtel – National Partnership for Women & Families – VP**

Anything that says new we really have to make sure that specs are available with enough time for all development to occur. Everybody knows that, but I want to just reiterate that.

**Unidentified Speaker**

So there's a concept that seems to have made its way into the stage two discussion, this notion of a longitudinal record or longitudinal care plan, longitudinal a lot of things. Is there a definition and a concrete focus for that yet, or is that something that's –

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

Longitudinal, okay, there's no more longitudinal care plan because that's not what we want. What we want is the current care plan, so just forget longitudinal data. That was a mistake on our part.

**Unidentified Speaker**

Okay.

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

So we retracted that. Longitudinal health record is just a distinction from the visit summary. So there's a single visit summary, here's what you do with that, and then there's the health record. We put in the word "longitudinal" to distinguish it from what's the visit summary. In other words, it's a collection of visits and it's a set of enumerated items pertaining to that longitudinal history.

**Unidentified Speaker**

So it would be some relevant aspects of some data that might have been accumulated over a period of time.

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

Yes, that's essentially what we know about what we have in their record the patient should have.

**Unidentified Speaker**

And this is not necessarily coordinated with any other records that might exist for this patient?

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

That's not our stipulation, correct.

**Unidentified Speaker**

So it's ....

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

That's our long term goal, but that's not the –

**Unidentified Speaker**

Longitudinal here means with respect to what this provider, what this one provider knows about that patient. So we're avoiding issues of creating reconciliations of all the data that may or may not be coming in from other providers.

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

Although that is our long term goal, that's not this objective.

**Unidentified Speaker**

Okay, good. That's helpful. Thank you. I maybe have a technical chip on my shoulder about the VA Blue Button. I think it's great. I think it's wonderful it's getting adoption. So the fact that it's getting used probably overrides any concerns I'm about to raise, but I can't help raising them. Looking at what's actually downloaded, I thought I was stepping back 20 years, and I was really, really disappointed. It seems like we've made the assumption that the reader tool that everybody has is able to read a text .... whereas, the reader tool that probably everybody has today is a browser. If we would have supplied an XML document with a style sheet, their browser could have read the CDA, could have read a structured

document with coded values and I think we would have made huge progress towards actually being able to move the information unambiguously into other downstream systems, and by reverting to text in sections, that we've minimized the ability to actually do something useful. We don't have coded meds in there, for example. We don't know what the lab is other than parse the text of the lab and text of the result. So I want to make a strong plea that as we move into standards here that we acknowledge that the VA's done a great job of getting traction but I feel like they've gotten traction with a horse and buggy when we're actually talking about automobiles.

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

I apologize for passing the buck to the Standards Committee, but our goal in leaving it ambiguous was because it is complicated and we want to get as far as we can on coded data and so we didn't want to tie us in to going further than we can or less far than we can and that's why we left it ambiguous. I guess maybe in the letter we can –

**Unidentified Speaker**

I also want ... that in other places we do specifically talk about structured text for exchange, and to start to create another structured thing that's a different standard, we're losing any sense of are we going to create reusability in our tool kits and in our nomenclature and all the building blocks we ought to be putting forward.

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

I think a lot of our national experts on this topic are sitting on the Standards Committee so at least we have that in our favor.

**Unidentified Speaker**

Okay, fine. I've got the chip off my shoulder. I just also want to raise a concept and give some context for this as well, so it's a little bit thinking out loud. The stage two is going to be from an organization that has, under the original notion, two years of use and possibly three years of use as we're looking to extend the timeline. So these are incremental steps to someone who's already put in place infrastructure, they've got systems in place, they're using it, they know about training and all of those things are sort of working. But I'm very aware that we've gone from a menu-based program where there's some flexibility around some of the criteria, to all or nothing and then maybe we should be retaining some flexibility in timing and pace even three years into this process.

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

There's no perfect answer to that. We followed CMS' lead, which said that these menu items shall now become core and so we followed that. As ... timing discussion said that our suggested recommendation is that we leave a little more time so we can do these things and frankly CMS's hands are, we don't believe CMS's hands are tied, that CMS may decide to create a menu system among these objectives. If we say these have to be all menu, then it's hard for CMS to make them all core. But if they're all core it's a little bit easier for CMS to make some of them menu. It's a directional thing, so think of that as we're going –

**Unidentified Speaker**

That's good directional logic for us to have.

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

Thank you. Christine, do you want to comment on that specifically?

**Christine Bechtel – National Partnership for Women & Families – VP**

Yes, I do. I would remind us that we agreed specifically at the last Policy Committee meeting that because we are in fact granting an extra year of time that it was important to make some advancements in criteria. Now, we actually haven't done that substantively in the criteria themselves, so these are largely the same criteria, with some tweaks, that we presented at the last couple of Policy Committee meetings. The advancement really is the core requirements, and I would suggest that there aren't that many new requirements but that if we are going to meet the National Quality Strategy goals and get,

we've had long discussions in the Meaningful Use Workgroup, as you know, about the relationship between meaningful use and accountable care organizations and medical homes to community based care transition programs, all of which are absolutely operational next year, so meaningful use is a little bit behind the ball if we continue with that menu approach, so I'm very much in favor of the structure here. Thanks.

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

Thank you. Okay, Adam and then David.

**Adam**

I don't even know if I have a question here. It's just something that's rolling around my head and I think maybe follows a little bit of what Larry discussed, and I don't know, Christine, if maybe you can help. When I look at terms I have the ability to download are provided with, I follow up with and do what with it for the patients, is this just something we're going to have an endpoint that, yes, we gave them something, or is it going to be something in a usable format, maybe even that patient groups out there, free market, let them decide here's actually an engagement strategy. It's just something going through my head, but I don't know if there are thoughts or comments on that.

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

Neil, why don't you talk first? I also have –

**Neil Calman – Institute for Family Health – President & Cofounder**

This picks up a little bit on Larry's comment too. I was at a meeting of Markle and we saw what kind of third party applications had been written as part of the context, and I can't remember exactly who had done this, but over a period I think people had only a few weeks to do this and wrote these third party applications that took the download button data and wrote these absolutely beautiful applications for it that were all different. And I thought that really is what's going to happen here, because different people are going to want to do different things with the information. And to the extent that we specify this all the way down the road, I think we're going to lose some of the creativity that's going to come, especially I think on the patient interface, look what's happening throughout the rest of this field, and I think that that's where we're going to see a tremendous amount of innovation if we just put the stuff out. They were using the data in its current format, just categorized, but then when you think about it, it's not that hard to identify the name of a drug and stuff like that and people were able to do an enormous amount with that information.

So I think we don't want to go too far to be too specific to the point where I think, and we've had this discussion, where we're now saying well, this is what it looks like, therefore this is how people are going to be able to use it. But rather to say here's the access to it and a year after that ... 100 applications written by people that say if you want to create this kind of a summary or look at your weight over years and compare it to something else, you'll be able to input your information. That's the discussion that we've had. It may or may not be on the mark exactly, but I think that we're looking to start a process but not necessarily to define the endpoint of the process.

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

Okay. And David?

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

Thanks. I just wanted to follow up on Judy's comments from before. The experience across a variety of organizations is that with little stimulation about 15% or 20% of people sign up. We just did a study in which we quantified the degree of the digital divide and that did show that there was one that minorities and people of low income are less likely to sign up for PHRs, but that they do want to do this and they report interest, and we're doing a ... now actually on how to encourage adoption. Once people had adopted they actually used the PHR just as much, even if they're minority or disadvantaged, and at the end of the day I think this will eventually become a powerful tool for reducing some of the disparities that are so common in our system today.

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

Okay, if that's it I'm going to move to the next one, to the next category, improved care coordination. This was the other place I mentioned where there's a modification in the last 24 hours. If we see the objective about the summary and care plan, the third row up there, for eligible hospitals 10% of all discharges have a summary and care plan sent electronically to the EP or to a post-acute care facility. Remember we had clarified it's not just nursing homes, but it's a broader definition of what can count. Let me just point out if they can send it they have to have recorded it. So really half of the objective is really to record and then send 10% of them to those other places. For the eligible professional it should read, and this is not an uncontroversial number, it should be recorded for 10% of patients and sent to at least 25 counting, not 25%, counting 25 patients electronically, and there's an exclusion for lack of electronic recipients and if the exclusion is met then you have to send it on paper.

Let me say it again, so what's being inserted is where it says EP before it says at least 25 transactions recorded for 10% and then transmitted for at least 25 of them, the intention there being that we should have a summary and care plan recorded for as many as we can, 10% being the threshold we're setting right now. And because it seemed especially challenging for the eligible professionals to find the counterpart that they need to send to and have them set up in a way that they can receive it, and that's why we said it's a 25 plus there's the exclusions, so we think that's feasible.

Let me just comment that the summary of care plan we've enumerated a list of elements, and that list of elements actually includes the care team, which is the next objective, so it includes what would have been the summary record that would be appropriate for a care provider, as opposed to the previous screen was for patients, this is for the next care provider, and the care plan, which we can enumerate now is the goals and the instructions. At this point we'll want to be a little bit open. There are several standards efforts going on that are not complete to define what is a care plan. At this point our intent is the goals and the instructions and the care team. We've left intact our next objective, which I would just clarify that when we have the care team members it includes the PCP if available. Remember, that we had combined care plan with summary of care record.

So that's this screen and I'll open it for questions starting with Neil.

**Neil Calman – Institute for Family Health – President & Cofounder**

It feels to me like we're, and I'm not exactly clear since I was part of the group that did this, we started out in stage one in the final rule, we said that we needed a summary of care record for more than 50% of transitions. And it seems to me that what we should be doing is saying at least 25 transactions electronically, but why are we only now requiring 10%, which doesn't really make sense. We've sort of moved backwards here, and I think that we shouldn't move backwards, because I think that we don't want to, while we're trying to move the electronic part, we're also trying to make sure that we're moving the patient goals here forward and I think –

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

This is a side effect of combining the care plan and the summary of care record. The summary of care is electronically generated and we think that that should be fairly easy to generate for more than 50%, hopefully almost everyone can generate the items necessary for the summary of care record because it falls out of the EHR. But in addition we're asking people now for the first time to enter a care plan, that's the goals and instructions, and that's where the 10% goes. Now, if we desire, we can keep the two objectives separate and keep one high and one low, but by combining it we went for the lower one.

**Neil Calman – Institute for Family Health – President & Cofounder**

Well, I guess I would make the point that it's not a big deal to add the care plan into what we're already calling out as a summary of care record, because the care plan is really part of the standard progress note that's written. And the way we're currently defining it, we're not defining 15 elements of a care plan. We're basically saying that the care plan is adding goals and instructions and members of the care team, which is a small addition to something that's a document that we're already asking people to put together, so I don't know. It just feels to me like we're going to end up losing something around these

transitions and we're kind of losing one thing and adding something else and I'm not sure that the net of that is really a move forward from where we were.

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

Good. Let me remind you that this is an important transition from just having this recorded and we expect that actually most of them would be delivered to the provider on paper, and now we've moved to sent electronically. That's a huge leap, and that's why –

**Neil Calman – Institute for Family Health – President & Cofounder**

... 25. I mean it's –

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

On the EP side and 10% for the hospital side.

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

We were considering also, so you have specialty, specialists, and I don't mean the ones that are the most different from PCPs, say, pathologists, radiologists, but I mean ophthalmologists, orthopedic surgeons, so everyone in a sense has some kind of plan for their patients, that's why they're seeing their patient, but we're asking for perhaps a change in workflow in the way it gets recorded. There are different types of visits, the BP check, does that need you to sit down and update the plan of care for each BP check. So we were worried about what the, since this is the first time we're asking for this to be entered we didn't want an unintended consequence of adding to the workflow.

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

I guess I would just follow up by saying I feel that part of what is being done as we ask people to enter progress notes electronically sort of almost automatically takes care of this, because it's part of a well written progress note. What the "P" is in the SOAP note is plan, and every progress note, whether it's a blood pressure check that just says continue patient's current medications or whatever, is part of a well written progress note. I don't see that as being a big add.

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

But are you suggesting a percentage? Remember, progress notes are only up 30%, not 50%, so even there we –

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

That sounds good to me. Let's have other questions specifically about this topic, and I assume, Christine, this is about this topic?

**Christine Bechtel – National Partnership for Women & Families – VP**

I completely agree with Neil. I think, you're right, George, that it was a byproduct of trying to combine things. But I think the context in which we combine the summary of care record and the care plan was the context where we thought the care plan was going to end up being a more robust thing, and what we realized is that we already had most of the elements in the summary and we were really only adding a free text field for goals and then clinical instructions already in the summary. I think given that, it probably does make sense to have two separate objectives, one for recording and one for transmission for both EP and hospital, which is not, we have one really for hospitals here. But I think given that we also, I think I would also add that we need to specify that a copy goes to the patient since it now has a plan element to it, even though it's just goals and instructions. And then that way we could have two, in fact, separate and distinct record for 50% and, Neil, are you saying transmit 30%, is that what you were suggesting –

**Neil Calman – Institute for Family Health – President & Cofounder**

I was saying it depends on what we're doing with the –

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

Okay, so number one, on patients the way I'd like to fix the ..., that's good, I would do it by adjusting the fields that are included in the visit summary. So include fields in the visit summary that make sense for this. Many of the fields in the visit summary are give this if it's available. So in fact the thresholds don't need to conflict because of the, if available, construct in the visit summary. So that's how I'd get it to patients, rather than a new objective to get it to patients.

**Christine Bechtel – National Partnership for Women & Families – VP**

Right.

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

.... Yes, on the thresholds we're now mixing the two thresholds. Let me see, do you have other comments on this exact issue of thresholds, so David and David were next.

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

I just wanted to say that I'm also in favor of splitting it. I think it's confusing the way that it is now, and I don't know –

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

Splitting record and transmit, or splitting summary and care plan?

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

Summary and care plan.

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

That's not what Christine – Christine, you were putting recorded –

**Christine Bechtel – National Partnership for Women & Families – VP**

I'm saying record and transmit, because then the care plan only ends up with two fields and because we're already, as George explained, giving patients the summary of their either hospital visit I just thought it would be easier to –

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

I think the care plan is going to evolve quite a bit, and I think it will. I disagree some with what Neil said before, that I think the care plan will be substantially more robust than just what we've put in our P today. It should be where we're trying to aim for a patient, and I know that we don't have it worked out now and this is essentially a placeholder.

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

Okay, let me go to David Lansky next.

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

I want to support Neil's framing of it too. I'd really be concerned if we published something, which lowered the visible threshold to 10% on something as important as the summary and care plan. So whether we do that by breaking apart the summary and care plan and having a little 2x2 table or whatever we need to do to illustrate this, it may end up with the same parameters at the moment in both cells, as David now says, knowing the care plan may evolve into a more robust tool that has variable applicability to certain specialties and settings. But at the moment I think we want to send a signal that it's an expectation of care with EHRs to capture both even if it's a modest care plan, and it's transmitted whenever we can and not have a 10% number appearing as a lowering of our expectations of this kind of behavior.

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

Then we had Adam and we had Marc.

**Adam**

More just following up on that, but also I think the separation of a summary of treatment, summary and a care plan is going to be important. I'm certainly no expert on what the threshold should be, but particularly for cancer patients that care plan is an incredibly important transition from their oncologist to their primary care doc, and IOM has looked at this very heavily, is that is something that's needed.

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

Let me just get, Marc –

**Marc Probst – Intermountain Healthcare – CIO**

It's a different topic if you want to –

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

Oh yes, let me hold off on that, can I? What I'm hearing is that we don't want to change the existing stage one requirement of 50% have this clinical summary. What we're trying to do then now is add a care plan to that. Am I catching the drift here? So if we didn't do anything and continued then, and maybe explicitly continued, that's sort of a good question whether these are cumulative, but we're continuing the stage one criteria as is and we're adding the care plan to this existing document so that it becomes summary and care plan, and for the care plan we're establishing some new thresholds for both provider types. Is that –

**Gayle Harrell – Florida – House of Representatives**

Can I get a clarification on that? Are we doing 30% on the care plan?

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

We haven't gotten there yet, but let me see if we've addressed at least the distinction between clinical summary and care plan. Neil?

**Neil Calman – Institute for Family Health – President & Cofounder**

I think what David was speaking to and the way I'm thinking of this, I think we're going to move backwards if we say these are two separate documents again, because basically we're saying it's okay to do this 50% stuff without the care plan piece, but here is another document that's called a care plan and this has to have these other elements. So I'm wondering if we couldn't say that we call it a clinical summary and say that that needs to be provided in 50% of the cases, and in at least 10% of the cases that clinical summary should include the patient goals and instructions so that in phase three we're not saying oh, now we're going to do away with this document and put the two documents together.

So we're calling out a single document which is called a summary and care plan, and we're saying that that summary needs to be there for 50% of the cases, like it was before, and in at least 10% of the cases include the elements that we're now calling out should be part of this more advanced care plan. Because then you're creating an evolutionary phase where I think what's going to happen is as people start to realize there's these other elements you're going to see that included in the 50%. People will start collecting them, and as you said, Paul, they're not going to create stuff and say, well, I'm just not going to put the plan in this set of documents, but you're not requiring it and we only end up with one document and not two.

**Christine Bechtel – National Partnership for Women & Families – VP**

Why wouldn't we simply, since we're talking about two, in my non-doctor opinion, pretty easy fields to fill in in terms of goals and instructions, actually instructions are already in there, so it's really just adding a field on goals, why wouldn't we do what I think I heard Paul say, which is simply add the care plan element of goals and potentially care team members to the summary of care record and leave the threshold at 50%?

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

I don't think that's what you said, is it, Paul?

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

Yes, I didn't actually –

**Christine Bechtel – National Partnership for Women & Families – VP**

Well, whatever, whether it's not what he said but it's what I'm saying. I heard him, but I thought it was a good idea.

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

Remember, this was the menu item in stage one, so you would be making a core item that 50% of transitions has, electronic transfer of a summary –

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

... electronic part. We're not there yet ....

**Christine Bechtel – National Partnership for Women & Families – VP**

Right, all I'm suggesting is the existing summary you make it core, you just add one new element of content, which is the goals that are the formation of the care plan because the instructions are already in there.

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

I'm sorry. stage one, actually what's the stipulation? It's menu and you had to send the document in 50% of –

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

No, ....

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

... which will provide –

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

... on paper.

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

Yes, yes, yes, yes ....

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

... not electronic. So now we're going to record a summary of care for 50%, so that's okay because that's going to be mostly electronic. Neil was suggesting that a subset of those would have the care plan fields filled in. Christine is suggesting it should be all of them, so there's that distinction. That's for recording. And then transmitting electronically would have to have some reasonable threshold given the state of the art in electronic transfer. Let's move from agreement to more agreement, because I think the first agreement is to maintain the summary of care record, that you record that for over 50%, and the second agreement is that we would add a care plan to that document, and where we need more agreement is at what threshold for the second part of the care plan.

I'll just throw out what's down here right now is, let's start at 10% and hear whether people disagree.

**Unidentified Speaker**

....

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

Right now the care plan as described by the workgroup is the goals and the patient instructions and what we expect that to evolve over time.

**Unidentified Speaker**

Care plan, those are two different –

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

Right now we're saying the start of the care plan are goals and patient instructions.

**Unidentified Speaker**

Are those goals and patient instructions just free text?

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

Right now they're still free text because we don't have the standards.

**Unidentified Speaker**

Okay, because my concern is the significant difference between the ... SOAP note and the inpatient care plan module, which is a complex thing. And by using a term that covers both it gets pretty confusing.

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

David Bates?

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

I would vote for a lower threshold of around 10% and flagging this as being separate. I do think it's really important. I think that there will be a lot of work on this area over the next few years with the development of ACOs and so forth. If we're really going to change care, a very big part of the way that we'll do that is by having a pretty detailed care plan for people and then figuring out whether or not we're actually getting there. So I'm expecting that they will become more structured. I know that this is the way that we have things here, but I don't want to just fold it in. I think we should underscore this.

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

Gayle? And then ....

**Gayle Harrell – Florida – House of Representatives**

I have a great deal of concern that this is a classic example of committee at its best. This perhaps needs further conversation in the workgroup before we, really, there are so many questions that have been brought up here that we're constructing a camel instead of a horse. And we want to make sure that we do this appropriately. It's a very important thing and let's not just throw numbers at something when it hasn't been thought through. I don't know if you want to table this little section and have you come back.

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

Maybe yes, maybe no. The workgroup discussed it at length. The workgroup couldn't come to agreement on the thresholds. The workgroup can work further and try to come to agreement on the thresholds. But then to come to agreement on the thresholds and come back and then – do you want to go back –

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

I don't care.

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

I think we're close so –

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

... close. I think Art and Larry and David.

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

In the introductory comments, George, when you presented this, I thought I heard you say that the care team was going to be part of the content –

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

That would be one of the fields in the summary of care record.

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

And the fact that we have suggested a 10% threshold for the care team and if it is a piece of this document then that would be consistent with the 10% threshold that was previously suggested. I understand, we don't want to backtrack, I agree with that. But this care team is something much bigger than we have yet thought about. I think, just like David said, this is going to evolve over time, this care plan, so setting a low threshold at this point might be valuable.

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

Larry and David, and then –

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

Art, thank you for the segue on care team. I have a vague memory, we talked about what makes a care team last time, but could you refresh my mind who –

**Unidentified Speaker**

... of providers including the PCP, if known. So when you say providers you're thinking who are the specialists involved with this person.

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

It's up to the provider to decide who's most relevant. If you know there's 50 doctors out there that treated the patient as an inpatient during the transplant, you don't need to name those 50 providers. It's the providers that would be a relevant part of the true care team that's relevant at this point in time while you're recording it. We're leaving it somewhat vague, I realize on purpose.

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

But by your answer it sounds like you're excluding the nurses and the therapists and the other folks who may be hands on with the patient while they're in the care setting as well, either.

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

It doesn't have to be an eligible professional, whoever's relevant in the care team, so a nurse, the care manager.

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

Okay, you just meant –

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

... whether or not ... we'll let practice inform ....

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

Because it's free text, I think, it's easy at this point.

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

... it's a coded –

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

... meant to be general, that's fine.

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

That's our intent.

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

Good, thank you. On the sending, I think it's important that we get, the organization's able to send and able to receive. But I'm wondering, given some of the discussions about infrastructure, and maybe this is what your HIE profile preamble means, that if you have an HIE in your community that's sending these summaries to the HIE would be an acceptable option as well. Was there any discussion about that?

**Christine Bechtel – National Partnership for Women & Families – VP**

We talked about a couple of modes of transmission, whether that be through an HIE or whether that be through direct, particularly, or some comparable service. So that is part of what we, I think, have to do about ... we're finding in the transmittal letter.

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

Because my thinking is that sometimes you don't know who they're going to see, maybe this is the end of a cycle of stuff, but you want the summary to be part of a community health record on the assumption that your community has decided it wants to do that and that that would let you then check off that yes, I'm sharing the information and I'm trying to contribute to the local pool, recognizing that those record repositories raise lots of privacy questions.

Okay, one other comment that maybe is completely irrelevant, we've been talking about the visit that's just a blood pressure check, which got me thinking about there seems to be a growing use of telehealth as a way for patients to have values checked at home and electronically transmitted to a PCP or some other care team. And how that changes and where we may be going and how we provide care gets reflected in what we're doing, because it seems like we're kind of, I don't want us to be building in a process and a structure that says the only way you can provide care is in a hospital or in a live visit and those are the only things that we're going to –

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

Meaningful use shouldn't keep the healthcare system at a standstill, so we definitely agree. That talks a little bit about the definition of a visit, which we're leaving for CMS.

**Christine Bechtel – National Partnership for Women & Families – VP**

It also signaled that for stage three we are looking at patient reported data, which I think that's what we would consider patient reported data.

**Tony Trenkle – CMS – Director of OESS**

I just wonder, we do have the definition of a visit in the regulation, also in the specs that we did publish on the Web, so there is already a definition out there. I just want to be clear on that.

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

David, you had a question?

**Christine Bechtel – National Partnership for Women & Families – VP**

Tony?

**Tony Trenkle – CMS – Director of OESS**

The definition of office visit was in the regulation and it is also in the specs that we put out.

**Christine Bechtel – National Partnership for Women & Families – VP**

....

**Tony Trenkle – CMS – Director of OESS**

Do you want me to read it to you here?

**Christine Bechtel – National Partnership for Women & Families – VP**

Well, we've all been tossing that around a little bit, so it might help.

**Tony Trenkle – CMS – Director of OESS**

... for one of the following. "Office visit is defined as a billable visit that includes one concurrent care transfer of care visit, two consultant visits, and three prolonged physician service without direct, meaning

face-to-face patient contact, such as telehealth. A consultant visit occurs when a provider is asked to render an expert opinion service for a specific condition or problem by a referring provider.”

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

I think David Lansky was next.

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

Yes. Coming back to Gayle’s comment about what we can do to not build camels here, I do think both the issue of the definition of the care plan and the issue of the numeric threshold, this is not a good forum for trying to resolve that. And for me personally I’m wrestling with, I like Christine’s formulation and Neil’s that the care plan was very modest enhancements to the summary of care record, and if we can agree, if we can send a policy signal that we agree that that is a valid direction to set for stage two, then the Standards Committee or the workgroup can go back and refine exactly the scope in a way that is specific and actionable or reflects the spirit of our discussion, which is, I at least hear and I personally feel we want to under the rubric of care coordination we have very few elements at this point and it’s very important to send a signal that stage two meaningful users should be transmitting to other interested parts of the care team a summary record which includes the goals and instructions for a care plan. And if that needs to be defined very modestly as free text, global language, good, that’s fine to move us to stage two. And then we’d want to signal that stage three should be a more robust, as David had suggested, a more robust and standardized tool, but I would really want us to say we expect meaningful users to be taking these steps as part of this work and let the Standards Committee or another body find a reasonable way of capturing that in specifications.

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

Let me try to summarize. Actually, I think we cannot have this discussion because, as George said, we have this discussion in the workgroup. This is, one, extraordinarily important; two, a target for stage two, and three, unfortunately, not well defined yet, even in people’s minds, let alone in standards. But I think we have before you those three dimensions that we clumsily tried to combine and consolidate into one and it turned out not to be a good idea. But we actually have those three elements there and probably even have the numbers and let’s see if we can get agreement.

So one, as a result of discussion we can maintain and reinforce that 50% have the summary of care record recorded in the EHR, so that’s point one, which we didn’t explain well as we came out this morning. Two, that there’s an addition of the care plan and in fact we have the elements laid out and they propose we do exactly as people have been suggesting, turn over that list to the HIT Standards Committee and the two new crucial additions to the list that differs from the summary of care, are the introduction of the goals and the patient instructions, and those things will be passed on to the Standards Committee and say, hey, look, here’s where they exist in conceptual form. Is there any way to improve these in standard form? And if not, let’s still maintain the conceptual and probably text format of these, but make sure it gets included in the document. And three, that there’s a notion of the team members, again, loosely structured, but what we did to set as a floor, that includes the PCP, if there is one for that patient.

I think we’ve maintained what David Lansky just summarized and have been said here, those three components are on the screen in front of you, we just haven’t put them all in the stage two column. I think if we do that and even use the numbers there we’re accomplishing the goals of the discussion we just had. There’s one more piece that I didn’t mention is that’s the electronic transmission, which is another addition, particularly for stage two. So let me try to summarize –

**Christine Bechtel – National Partnership for Women & Families – VP**

We need to correct your framing, because my read of the menu option from stage one is not record summary of care record. So it says, “The EP eligible hospital or EH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of those transitions or referrals.” So it is the transmission, not just the recording.

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

But we allowed that to be on paper. So, just like Neil explained, when you're "providing" you obviously have to record it.

**Christine Bechtel – National Partnership for Women & Families – VP**

Right, but I don't think we want to lose the provide element –

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

No problem.

**Christine Bechtel – National Partnership for Women & Families – VP**

... so I just want to make sure that it's in your contract. The other two things that you're suggesting we ask the Standards Committee for advice on is it should be goals and care team members, not clinical instructions. I think that's already in there.

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

Okay, so let me try to summarize and include the numbers that we have on the screen before you and see if we can have agreement on that. One is maintain the record and provide the summary of care record as defined in stage one and keep the same threshold of over 50%. Two is to record the care plan, which in its infancy includes the patient instructions and the goals asking the Standards Committee to render an opinion about whether there are standards applicable to those two pieces of information. Three, that there's another requirement about a list in the record of the care team members, which right now is at the discretion and only has a floor of including in the PCP where that exists for 10%, that's the number in front of you. And four, that there's electronic transmission from the hospital setting of 10% of all discharges of the summary of care record and the care plan, and for EPs for 25 transactions to be sent electronically. That's all actually on the screen in front of you and it's just categorized differently to reflect this discussion. Does that seem like it meets the points raised in this discussion?

**Christine Bechtel – National Partnership for Women & Families – VP**

You're suggesting, what is the threshold for the recording of the care plan, because there's a separate element that is not on here.

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

The recording of the care plan would be 10% for EHs and we at one point in the last meeting had 10% for the EPs.

**Christine Bechtel – National Partnership for Women & Families – VP**

I guess since my microphone's on –

**Neil Calman – Institute for Family Health – President & Cofounder**

We can take care of that.

**Christine Bechtel – National Partnership for Women & Families – VP**

I know. I'm sure you could, Neil .... I like the idea of maintaining a 50% provide. I think the concerns I have are that recording the care plan, the concept we're thinking about in stage two, which is a very simple articulation of really goals and care team members is much too low, for 10% of patients, and I think the transmission side thresholds are also low, particularly on the EP side. But let me clarify, so the denominator for electronic transmission for hospitals would be 10% of all discharges, not 10% of the provide, in other words 10% of 50%.

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

So that's how it's written, 10% of –

**Christine Bechtel – National Partnership for Women & Families – VP**

Yes, I just want to clarify that. Okay. I'm more okay with that. I don't think that a hard count of 25 does anything, really, to change workflow, and I think that if this is supposed to be the stage of information exchange we have to do better than that, and we can, given where direct is at today and will be at in two years when these criteria are really in play.

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

Does provide mean, since there's no longer a menu and it's half of all transitions of care, that means provide directly to the other provider and get acknowledgement that they received it. What does it mean to provide? Does it mean hand a copy to the patient and let them go with it? Because if I have 50,000 discharges in my hospital, that means that 25,000 of them I have to find out where the patient went and make sure that their PCP who's in Alaska received it. What is the stipulation for provide ... a menu item before. That's the only one I'm worried about.

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

The definition would not change, which includes paper.

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

It includes paper, but can I give it to the patient?

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

Yes.

**Unidentified Speaker**

Yes.

**Christine Bechtel – National Partnership for Women & Families – VP**

I think we have to look at the stage one definition that CMS already put forward to know the answer to that. I don't know if giving it to the patient is okay.

**Unidentified Speaker**

Give it to the patient.

**Unidentified Speaker**

... CD or paper.

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

You need to speak up. The answer is, yes, you can give it to the patient on various mediums like paper. If you can give it to the patient then it's doable.

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

Okay, so let me, I saw some head nodding in terms of the construct of saying reflecting the discussion that we just had, which we had in the Meaningful Use Workgroup as well, do you agree with the construct that's in front of you, and then we'll address Christine's change in the threshold percent. So recording and providing the summary of care records remains in stage one, as it always has, to add care plan elements, which are goals and patient instructions, and ask the Standards Committee to rule on that, to add the care team members, which at the floor is just the PCP where that exists, and to transmit the care record and care plan electronically. So those are the four components. The numbers remain the same as on the screen.

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

... percent –

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

The construct is there and then we can talk about Christine's amendment. Does that satisfy the discussion? I think it's a reflection of the discussion and I'm seeing some head nods, okay. So now are there any changes to those numbers, and Christine is suggesting a change to the threshold for –

**Christine Bechtel – National Partnership for Women & Families – VP**

Recording the care plan given that it can be part of the care summary for stage two should be the same at 50% given that it's only those two fields. Then I think the care team members, did we say that remains a separate objective?

**Unidentified Speaker**

Yes, ... separate.

**Christine Bechtel – National Partnership for Women & Families – VP**

Okay, fine. Then I think the electronic transmission for eligible providers should be 10%, same as hospitals.

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

Okay, so there are two proposals on the table. Let's take them one at a time. Christine, is moving the recording of the care plan on both sides, on both settings to be 50% versus 10%?

**Christine Bechtel – National Partnership for Women & Families – VP**

Yes, right.

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

Any discussion of that?

**Unidentified Speaker**

Other than we're saying it's easy, and I guess I'll look at the physicians to presume that it's easy and when it gets to standards it's defined as something that's easy. But a care plan could be significantly more complex than that, and actually to be valuable you probably want it to be significantly more complex. And it may be better to have a smaller number and a more complex care plan that actually has more value.

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

David Bates?

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

That was essentially the argument I was making earlier. I think we should go with a little lower number.

**Christine Bechtel – National Partnership for Women & Families – VP**

... complex care plan. Right now we're talking about goals and instructions.

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

I'd leave the care plan the same as it is for now. I think it will get a lot more complex in 2015.

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

That's just where the state of the practice is in response to Marc's point. Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

It's always hard to figure out these threshold numbers. We're just guessing. Having said that, 10% of just adding what are the instructions to the patients and the overall goals of care to a document that already exists, feels, it does, it feels pretty minimal and so a threshold of 10% doesn't seem like a lot. I think we have to keep in mind that we're a recommending committee, so why can't our recommendations reflect the fact that some of us disagree about what the threshold ought to be, that we're all in agreement that these are the right elements to add, at least initially, and we think that the definition of care plan will get much more complex as we move more rapidly into healthcare reform and the demands on providers with respect to other programs and sharing data increase. The environment we hope will be radically different in another couple of years, so while 10% feels really empty to some of us, and 50% feels, whoa, too high for some of us, why can't our recommendations reflect that there is a difference of opinion and

that we want to send ultimately a meaningful signal on this. And that for some of us 10% felt too low and for others it felt just right, because ultimately we're not decision makers. Maybe Tony would wish that we would be more specific, but that may be the best we can do. We did fight about this a lot already. I'm not sure taking another bite of this apple is going to get us any closer to Nirvana, right? There's no perfect answer here.

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

Larry?

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

Deven, thank you. That's great. I'll say this anyway, though, so –

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

....

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

I should just be quiet, right? That's I think for anything new that we're introducing setting a threshold of 50% is a pretty high bar because the odds of our getting that right seem to be questionable. So regardless of how easy or hard it looks like to us, to the people implementing it it's going to be new. We also have some roadway to get from here to there, but what is it actually going to turn out to be that they're implementing. So I think starting out of the box with something new at 50% is just too big of a gamble. And giving 10%, we can probably always find 10% in an organization that can make anything work and hopefully they will be the trailblazers and hopefully it won't be hard and we'll have much higher levels of adoption and once we get to stage two we'll be actually reporting data, right, not just attestation, so we'll be beginning to get actual detailed feedback on what people have implemented.

**Unidentified Speaker**

Take Deven's suggestion and record that there's ambiguity here ... opinions.

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

I think that's what we do, having argued this for three weeks, having sent e-mails with one word in it, "10%" twice. So I think we recognize that range in that one item and otherwise we use the framework that Paul just identified.

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

So... Judy and Gayle and then let's try to come to a vote on this one.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

My question is, is there duplicative work for the physicians if they do this? And what I'm thinking of, and some of the ways that ... are collected right now it may be voice recognition with a physician reading off the SOAP note, how does that plan portion of that SOAP note get identified and separated out and put through? Does the physician have to enter that in again, and different ways also to enter SOAP notes that might not be the voice recognition, it might be macros or other matrices being filled in. I'm just nervous that are we creating duplicative work. I don't know if some of the physicians feel that it might be that way for some of the doctors in their organization. For others maybe the way they do it is not duplicative.

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

Gayle?

**Gayle Harrell – Florida – House of Representatives**

I have several issues. First of all, are you going to re-draft the letter? I have read the letter and I think that it's going to need some major re-drafting of the letter given the conflicts here and given the range that I think Deven hit the nail on the head in indicating the diversity of opinion as opposed to a consensus view. So I think –

**Deven McGraw – Center for Democracy & Technology – Director**

... misstated. I thought the diversity of opinion was around the number, not around the concept.

**Gayle Harrell – Florida – House of Representatives**

Yes, not the concept but certainly the number. I think that it's difficult to, are we all going to have access to that re-drafted letter, especially given the other changes that you've indicated on the slides. So I would suggest that perhaps we give a tentative approval to the concepts with a range of percentages and then perhaps have a re-look at the letter so that before that letter is formally transmitted we can at least look at it electronically and perhaps give our approval or disapproval via e-mail.

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

So let me acknowledge, we have been working off the slides, the PowerPoint slides through the course of the workgroup discussion. Only recently did we get a draft of some words to put into a letter. So that hasn't been fully reconciled with the slides. We've been showing you and working off the slides and I'd say this is what we'd like to get a vote on. Then we will work to reconcile the letter with both this discussion and slides, and if you wish to have a look at that before it goes out in its final form, that's certainly fine.

**Gayle Harrell – Florida – House of Representatives**

I think there have been so many different comments that how that is captured in the letter is going to be critical, and a word here or there can change in intent. This is a very important communication setting stage two, a very, very important communication, so I think either we need to have a real look at that letter at our next meeting, but if we're in a time frame and we need to have that transmitted to Tony in an appropriate time frame, then we at least need to have some consensus via e-mail on the letter.

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

So maybe – Marc, is there something ...?

**Marc Probst – Intermountain Healthcare – CIO**

You actually answered my question earlier in the conversation. But I'm a little concerned that this provides value. Is HHS going to define those two simple terms? And do they really provide value or are we creating something that's a vehicle that will provide value in stage three and are we just having someone jump through hoops in stage two so that they're prepared for stage three? And it seems important. I think there's a lot of value in care plan and what we're talking about here, but the way our conversation has gone it's minimized it and is it going to be of value when we hand it to Tony and say, here, go implement it?

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

I hope both the concept and the recommendations provide that .... I certainly hope that's true.

**Marc Probst – Intermountain Healthcare – CIO**

I do too.

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

I think if you enter the goal and the instructions, whether it's on 10% or 50%, that will provide some value when it gets transmitted. I think we're headed in the right direction and we're just saying how feasible it is right now.

**Unidentified Speaker**

....

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

Yes, I would just emphasize that we just re-looked at the whole process of our medical home transition, and actually the development of the care plan was one of the things that was highlighted by almost

everybody that was interviewed in our study as one of the most important transitions that took place when we became a medical home. It was the thing that made the difference between where we were before and where we went was the fact that people actually sat and established a care plan as a team and there was something to follow the patient. I think it is important and I think we are just, as David said, just at the beginning of this process of understanding what the elements of that are. But I think there is a transition that's going to take place around that, and I think the identification of the team members is critical in terms of especially as patients how all of the studies that have been out that patients can't even identify the names of the doctors that they've seen, either after they leave the hospital or when they leave the office, and I think it's incredibly important that people just have the ability to know who the folks are who are taking care of them. So those two elements I think are critical and the instructions have been there all along.

#### **Unidentified Speaker**

... real quick. I would rather know specifically what we want then in care team members and implement it once, then implement a text field where we're going to go through some process, and we're talking millions of people here that are going to go through this process and do it once. Like I said, it's an invaluable step. Other than saying we're going to get in the practice of it, I'd rather go to the next step and say this is what a care team is and these are the people that will provide value having that information in the interim ....

#### **Unidentified Speaker**

So the discussion of that, which again was quite lengthy, really was that every setting is completely different, and it also, to some extent, depends upon the patient's interaction with different systems. So patients, you can have a diabetic patient that interacts with a diabetes educator, plus somebody else who got their diabetes education from one of the nurses on the floor. So you want people to be able to, it's going to be different for different interactions. So I think this is one of those places where our experience is going to help to educate us for how to do this going forward.

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

Let me try, the committee has given very good policy direction and that this then can be taken then to the Standards Committee. There's been work going on on the Standards and Interoperability framework on many of these very questions, so I think that that will help to build the full recommendations for both the meaningful use rule and the standards and certification rule.

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

Let me try to summarize this point, because one, discussion's been helpful but it also illustrates the kinds of points that the entire industry, I'm talking about the healthcare community, is going through, and remind us of what Tony Trenkle said. We're in a context here. There are lots of drivers to have this information, whether it's the care plan or the healthcare team, to move forward. What we're trying to do as part of the EHR adoption incentive program is to make sure that EHRs can capture and easily captures information and transmit it amongst ourselves. They cannot today. These requirements alone make that possible. Continue to discuss the number is probably not going to be in the best interest and use of our time and there were no right answers.

So, may I just put a straw man on the table for essentially a vote, which is the four things we mentioned before, which are pretty much on the screen, the numbers on the screen, and let me add to what Christine and Deven said, which is, and our recommendations to CMS and ONC can reflect the discussion and say here's the reason we recommend a low number. It's brand new. Even the concepts are fairly new to the healthcare professional teams. Let's start with this. Let's make sure it gets in the EHR and recognize that at your discretion you can set the thresholds in ways that support the other initiatives going on in terms of health reform. But obviously they can do whatever they want anyway, but to illustrate, to represent this discussion and the arguments in terms of pushing forward. Christine?

#### **Christine Bechtel – National Partnership for Women & Families – VP**

Paul, the way I'm hearing you you're asking me to recommend those numbers and then say on top of that but if you want to go higher you could, and I'm not comfortable with that. So I think what I heard Deven

say, which I think is a brilliant suggestion, is to simply characterize the debate. Here are the four elements. We discussed a number of thresholds. We discussed 10%. We discussed 50%. We could not come to an agreement. So we're recommending a structure and we're describing the spectrum that we discussed, but we could not come to agreement.

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

Let me see if we can come to agreement with the additional information, and if we can't, because with what Larry said, it's not helpful for us to recommend to CMS, well, here's a concept that's really important. Why don't you do something about it? I think we need to go with something and reflect the discussion.

**Deven McGraw – Center for Democracy & Technology – Director**

Again, I may be mischaracterizing where I'm sensing the consensus, but I think that people are bought into the four elements. But you're asking me to endorse the elements plus the percentages, and that's where I have a problem. You can't do that. I want the discussion to reflect agreement on the four elements, and disagreement on the percentages, because if you tie the two together I can't raise my hand.

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

Okay, but –

**Unidentified Speaker**

... how many people ....

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

Well, let's see –

**Deven McGraw – Center for Democracy & Technology – Director**

Yes. That might be most. I just want the letter to reflect the difference of opinion on the percentages and what's the right threshold to get the workflow changes that are going to be necessary to move real change even early on and some discomfort for some of us, and it may be a minority, 10% being too low, I suspect there may be only a small number of us who agree with that, but I would like the letter to reflect that versus asking us to say yes to ten but CMS can always increase it because they can always do that.

**Christine Bechtel – National Partnership for Women & Families – VP**

... of the vote, I think the letter needs to reflect it.

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

I think we're all in agreement with that as well.

**Unidentified Speaker**

This is a process question. Can a range be recommended, or that's not how it's done?

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

A range can be always recommended. It's probably not as helpful to the recipients. I think –

**Unidentified Speaker**

But I think it reflects the reality that this is a difficult decision, that we could not arrive to any decision here. So I –

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

Let's do get a sense from the group about this wording. The four elements and the numbers that the latest rendition of the workgroup's suggestion, what was on the table, let's see what our sense is, so all in favor of the four components and the numbers that are before you? Okay, I can do that. It's 50, 10, 25, and 10, the same things that are in front of you. So is someone counting?

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

I can't vote, so eight.

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

So what did you get, ten? Okay, raise them up high.

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

Eight. Nine, I can't vote.

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

And we'll ask Neil when he gets back. So the others, so how many are opposed, let's just get the number, four, okay. So we have a ten to four –

**Unidentified Speaker**

Nine.

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

Nine to four in favor of this. On the phone, are there members on the phone?

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Joshua Sharfstein, do you care to vote? Are you here?

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

Maybe you're on mute. Okay, so can we report out that the majority were in agreement with the numbers, that we had a vigorous discussion on the range, the thresholds particularly on the –

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

... care plan.

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

... plan and the transmission and mention the desire of some to move that to a higher number. Is that fair? Okay. Why don't we finish the last two categories, because we do –

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

For public health there are no changes. There's a red line just because that objective, which had two halves, was simply split into two separate objectives, but it didn't change. We do mention on the bottom signaling to the Standards Committee defining a single standard for submitting public health data for across the objectives, and I just want to point out there's something there that's called "CMS to Consider." Remember we had discussed last time if there were a menu construct these would have been on the menu. We don't have a menu construct. I guess the intent is if things are going extraordinarily well these might be considered for stage two and they might be deferred to stage three or if CMS decides to do a menu construct these might be two good candidates for it. They're being put forward less strongly than all the others, is basically what we're saying, because it's a little bit more of a reach in these two cases and it's a narrow scope.

Any questions about these? Okay. The last category is privacy and security. The first one is unchanged other than the word "update." Perform an update security risk assessment and address deficiencies. The second line, please ignore the parenthetical expression. Basically, develop a policy or adopt a policy for data at rest. Deven, why don't you say it?

**Deven McGraw – Center for Democracy & Technology – Director**

So this is just supposed to reflect what the Policy Committee already adopted from the Tiger Team?

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

Yes, yes.

**Deven McGraw – Center for Democracy & Technology – Director**

Which is that part of the security risk assessment needs to include an attestation that you have addressed the issue of encryption of data at rest, period. We don't need any additional policy. We have it. It's already in HIPAA. We're just shining a spotlight on the HIPAA requirement as part of the meaningful use requirements. So encryption of data at rest, the implementation specifications in the HIPAA security rule are addressable. We want providers as part of meaningful use to attest that they have addressed this particular implementation specification as part of meaningful use. There isn't any additional policy that's needed here. It's just reflective of something the Policy Committee has already adopted. It's just not well articulated currently on the slide.

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

Any questions about that? Art?

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

Yes, I just had one question going back to the letter. We have in the letter a discussion about how, and there's a comment on one of the earlier slides about allowing the patients who receive information on USBs or whatever other method, that this is maybe not as secure as we would like. Why have we not added that to these meaningful use recommendations at this time? I just wondered if there's any comment about whether this could be something included in the Privacy and Security section for meaningful use in stage two.

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

It's not an objective exactly, but, Deven, you're welcome to ....

**Deven McGraw – Center for Democracy & Technology – Director**

It's related to the issue of patients. This is a separate issue from the issue of patients viewing and then downloading and taking possession of data and what the inherent risks might be with what they might do with it going forward. We acknowledged as a committee when we looked at the privacy and security issues related to view and download that there was likely a transparency aspect of that that needed further work. We haven't had the time to shape something that would be specific enough to be included as a meaningful use objective along those lines. But it's definitely in mind and noted and we have some time really to develop that.

I don't know that it would be a candidate for a specific meaningful use criteria, but as most of our recommendations, the Tiger Team's recommendations on privacy and security policy issues we've sort of looked at feeding them into the conditions of participation for the Nationwide Health Information Network, and as you'll see in the subsequent recommendation we do sort of signal that we're going to look at tying meaningful use to the conditions of participation in NW-HIN once we see what those conditions look like and what the governance rule says. Believe me, Art, I'm all in favor of putting some more on privacy and security criteria for meaningful use, but we do have to be able to articulate those objectives with some level of specificity, and given what the time frames were for us to be completed with this letter and when we could take up in more detail the issue of transparency to patients about risks associated with how they share their data once they get it from a provider, the timing just didn't match up well to be that specific here.

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

Christine?

**Christine Bechtel – National Partnership for Women & Families – VP**

It seems to me that part of what we want to accomplish is that the technology itself has the capability of delivering that notice, and the issue is what's in the notice. So I'm wondering, and I don't think we're ready to do this today, but I'm wondering if over the next month or two the Tiger Team might look at whether they want to separately recommend to ONC and CMS that the criteria provide notice to patients

and that the Tiger Team can't figure out the content of the notice, but at least it gets a meaningful use criteria that could drive the electronic capability, which is really what we're talking about here, to deliver a standardized notice to patients for view and download. Does that make sense?

**Deven McGraw – Center for Democracy & Technology – Director**

No.

**Christine Bechtel – National Partnership for Women & Families – VP**

Okay, I tried.

**Deven McGraw – Center for Democracy & Technology – Director**

I didn't see how it was different from what I just said, but that's –

**Christine Bechtel – National Partnership for Women & Families – VP**

I think I'm suggesting that there actually becomes a line on this slide that says the criteria is provide notice to patients regarding uses of their data, view and download, or whatever the language is, but there actually is a criteria that says provide notice.

**Unidentified Speaker**

....

**Christine Bechtel – National Partnership for Women & Families – VP**

Right, the transparency notice.

**Unidentified Speaker**

... in this letter.

**Christine Bechtel – National Partnership for Women & Families – VP**

I'm sorry?

**Unidentified Speaker**

It's in the letter. You recommend that, right, earlier? You're just saying call it out here?

**Unidentified Speaker**

It's in ... too.

**Christine Bechtel – National Partnership for Women & Families – VP**

That's what –

**Deven McGraw – Center for Democracy & Technology – Director**

So in other words reiterate it here as well?

**Unidentified Speaker**

....

**Christine Bechtel – National Partnership for Women & Families – VP**

... have a problem with that.

**Unidentified Speaker**

That was all I would say ....

**Unidentified Speaker**

Yes.

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

Deven, deleting that second sentence and saying instead in parenthetical ... to include addressing data at rest or just drop the –

**Deven McGraw – Center for Democracy & Technology – Director**

No, these are two separate issues, George.

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

I don't mean data, for what we did previously, data at rest.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I've got the encryption of data at rest.

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

Period.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, I mean, again, it's already been transmitted through the Policy Committee.

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

No, but we want to get our transmission to CMS coordinated well. So address encryption of data at rest, period.

**Unidentified Speaker**

... wordsmithed a little bit. It depends on how you read it. What we really want to do is people need to attest that they have a policy that addresses encryption at rest.

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

Well, that's what I thought I said. That's not quite right either.

(People talking over each other.)

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

... that would be the best.

**Deven McGraw – Center for Democracy & Technology – Director**

I tell you what, I'll just cut and paste it out of our transmittal letter.

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

Very good.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay.

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

Great.

**Christine Bechtel – National Partnership for Women & Families – VP**

But what I'm hearing being suggested is actually in addition of essentially a copy of the earlier criteria that's on the patient engagement piece about requiring notice to patients regarding risks be inserted here too. So in other words this discussion was actually proceeding along two points.

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

Are we measuring that? Are we making it into an objective with a metric, or are we signaling to others that this has to be part of the process?

**Unidentified Speaker**

That was what I was suggesting. But I understand that the Tiger Team needs time to develop that, so if Deven says that the team will go off maybe within the next month or two it could come up with something, that was what I was suggesting.

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

Right. Because I don't think that what's in the letter is naturally set up as a set of metrics that are measurable that we would put in and give to CMS. That's why I wanted you to say, okay, what goes in this objective column.

**Deven McGraw – Center for Democracy & Technology – Director**

Right, that was my concern is that we hadn't really fully, fully baked it yet. I think we have enough of a signal in the earlier criteria, we have some work to do on it.

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

The other section that was here is in the letter under the section, by the way. Anyway, you'll see it in a second. All right, so we're completed with that. Paul, do you want to vote on it, or do you want to go through the signaling thing?

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

Yes, go ahead, signaling and then we'll vote on it.

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

Priorities for the HIT Standards Committee, here I'm just going to list, go through three or four slides that enumerate the items. I'm not going to go through them in detail. Demographics mainly about the ethnicity and race, expanding those fields, CDS attributes for certification we've talked about before, the medication administration, those are the rights that Paul talked about earlier. View and download capabilities about tracking views and downloads. The summary of care record plan, we've talked about that at length. Hospital labs, providing structured electronic lab results in LOINC where available, so them actually working with the LOINC part of that. Public health objectives, again, repeating a single standard to use across the submission of all public health data. And second, for that one objective about submitting reportable conditions considering the IHE cancer reporting implementation guide as a source. And then this again talks about the warning message before downloading personal health information, which we just talked about. Privacy and security, these are probably best quoted from the letter that Deven talked about a moment ago rather than trying to re-list them in other words, you probably just get in trouble having two copies that don't match. So I think in our real thing what we'll do is try to quote that. Then signals for stage three about family history. Patient generated data submitted to public health. Demographics we talked about. Capability to retrieve the advanced directive and mechanism for patient entered data. That's the patient entered data into the EHR as opposed to public health. Those are the things and enumeration of what we are requesting from the Standards Committee.

**Deven McGraw – Center for Democracy & Technology – Director**

I think the only thing that isn't necessarily reflected in our previous Tiger Team recommendations that I want to call out is the item number five here, the compliance with NW-HIN governance policies should be included in stage three certification criteria. What I recall that we had discussed as a workgroup and began discussing with the Policy Committee actually in our last meeting, and my memory is that people thought it was a good idea, which is that when the governance rule, which will set the conditions for participation for NW-HIN comes out in the fall, that what we're signaling here is not just that we're going to look at it for certification criteria, because that just focuses on the technical functionality, that we're going to look at whether it ought to be tied to meaningful use in terms of that you might need to meet that in order to be meaningfully using by stage three, not just with respect to whether your certified EHR has all the bells and whistles on it that make you in good standing for NW-HIN, whatever that's going to be.

So consistent with the notion that we don't know what NW-HIN governance is going to look like, but that we have expected that many of the Tiger Team recommendations that have been on the policy side of the fence might land in some form or another in that governance rule, that we would take a look at that as a committee and decide whether it was a good candidate in stage three for a meaningful use objective,

both with respect to policy as well as with respect to certification requirements. I'm calling that only because of the way that it's articulated here is limited to certified EHRs.

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

This sentence is probably right because this is a sentence that comes under HIT Standards Committee. However, what you want to signal is in stage three we could make certificate of participation a condition of meaningful use.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, and again we're looking at it, just signaling that we're looking at a way to make the privacy and security category more meaningful, that may be one way to do it obviously at stage three. So there are some unknowns here that we need to take into account.

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

Let me just make sure that I have this right, because you may be about to vote on this, so back on here my understanding here we have perform or update security risk, number one; address the encryption of data at rest, number two; number three, signal that in stage three COP may be a required part of meaningful use.

**Deven McGraw – Center for Democracy & Technology – Director**

COP being conditions of participation in NW-HIN.

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

Yes.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay. I'm just making sure we're all on board with what COP means.

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

Are they conditions or certifications?

**Deven McGraw – Center for Democracy & Technology – Director**

They're not certification criteria. They're conditions of participation.

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

Okay, thank you.

**Christine Bechtel – National Partnership for Women & Families – VP**

... in terms of what we're asking the Standards Committee for now. I know we have family health history under stage three and I think there's not agreement about whether the standards are ready. We got a letter from the assistant secretary for health and director of NIH that really seems to read as though the standards are currently available. So if we can just get an answer on the state of the standards for stage two, just to inform our thinking, I think that would be better than waiting until stage three.

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

Okay, so now we're getting to the final ask, which is, we're asking for your approval of the recommendations we've put forth before you. One is to delay for that one cell only for providers who qualify for meaningful use stage one in 2011 that they would not need to meet stage two requirements until 2014 because of that timing glitch, that in that context we put before you recommendations to advance to CMS and ONC for stage two meaningful use objectives with a caveat, and particularly in that care coordination, the summary of care and care plan that we just had we would state that the majority agreed with these numbers we had for thresholds, but there was a cogent argument about the possibility of raising those in the way that we described and that we're going to put before the Standards Committee a number of requests for assessing whether there's a current standard or standards that need to be developed and to identify within the LOINC case where LOINC applies.

I guess those aren't votes yet. I think we have more comment, so let's go around the room. Okay, Charles?

**Charles Kennedy – WellPoint – VP for Health IT**

I've been trying to figure out the right time to make this comment, and probably right before lunch might not be it. But I understand why we're going down the path of a delay, but relating this to my experiences deploying large systems at large organizations, you know you get into it and the first thing you do is, this looks a little more difficult so you push the timeline back. The next thing you try and reduce scope because it's difficult when we have a very nice letter from the AHA asking for specifically that. I'm worried about the trajectory of where we're headed, because we have the additional complexity that people can choose not to play. If you look at how much money we spent or that has been allocated, not a lot of playing. I'm going to support delaying as a tactic but with the, I guess, advisory that I think we need to do a more fundamental look at meaningful use and maybe even consider some additional or alternative path to achieving it simply because of where the market is and our initial experiences with it.

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

That's a fair comment. Paul?

**Paul Egerman – Software Entrepreneur**

Thanks. I share some of what Charles just said. I'm concerned about the delay. I'm interested in how will this delay impact stage three, the timing of stage three? Do we have a plan for that?

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

We don't have a current plan for what the implications are for this. Now, this is almost not a voluntary delay, it's sort of a delay because there's a timing glitch and I don't think that people can actually meet that. It then went on to have an unintended side effect of actually having people who want to meet meaningful use in this year not doing it. So it's actually had a very bad side effect and so we're trying to, on the one hand, remove this unintended glitch or penalty for early participation and at the same time win earlier, potentially even secure more early participation.

**Paul Egerman – Software Entrepreneur**

But I'm just a little concerned that while it makes sense to do this delay we're not thinking through the impact of that. And if we think that we can delay stage two by one year and then do stage three on schedule, I don't think that that's possible to do. You only have a one year gap between stage two and stage three then, and I don't think that's realistic. I think if you're delaying stage two by one year, you're probably making a decision to delay stage three by one year, although I'm not sure you can do that, depending on how the regs work.

It depends on what you're delaying. There's the delaying of the vendors developing the product, there's the delay of the installation of the product, and then there's the delay of when you actually have to meet the objectives in that thing, and those are kind of, obviously they're ordered but they're not the same time. So theoretically, for example, we could start working on stage three very quickly, theoretically, so that we don't end up in the same boat next time and we'll actually give a signal to the vendors 18 months ahead of time what they'll need to do. Then the only downside is are we forcing customers to install a new version two years in a row, which is something we'd rather avoid, so we have to consider that.

But on the other hand, as Paul said, we're worried that if we don't do this delay, which only affects a minority of people for that one cell, we'll end up with a much bigger problem because we won't get everyone installed by 2013 when they need to be installed, because whether you're moving up the stage two you have to move to the new product. George, if we were starting on stage three right away that would actually make me comfortable because I figure maybe there's a plan for how stage three is going to work relative to stage two. I'm concerned that we don't have that plan and if we just think we're going to do it in stage three one year after stage two, I don't think that's going to work. I just don't see people doing that much upgrade and change with such a short time period in between. Plus, everyone's going to want to evaluate stage two a little bit, they're going to want to do some level of evaluation and there's not going to be time to do that. So I'd like to have a picture as to where stage three fits into this.

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

Let me mention a couple of things. One is, CMS in their final rule, has not even defined what happened to 2015 or beyond. So in fact there is no current schedule for stage three. The second point is that there's nothing that prevents there from being a stage four. So the statute allows the secretary to advance requirements in terms of participation in meaningful use because, as you know, the penalty phase goes on in perpetuity. Then the third point is, and this is still in a bigger context, we don't know how ACOs or PCMAs or all of these other initiatives are going to either depend on meaningful use or the benefits of meaningful use, for example, in the quality measures, and the way that CMS may set thresholds there. So there are a lot of degrees of freedom that HHS and CMS have in piggybacking on this program, but there's no defined ... by statute. Similarly then, the timing of stage three and four, if there is going to be, doesn't have a time frame yet.

**Paul Egerman – Software Entrepreneur**

So if I'm hearing you right stage three probably will not be one year after stage two and ... whatever time period we want. Is that what I heard?

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

You're not hearing that from me. All I'm saying is in the final rule there is nothing specified for 2015 and beyond on purpose, they said that.

**Christine Bechtel – National Partnership for Women & Families – VP**

The other thing that gives me comfort is that because we are also sending signals now, the fact that stage one becomes a three year stage does allow them to use that year to plan and begin the workflow change and the associated other kinds of changes that they need to do before they install the technology and do the attestation, they can get started on it earlier.

**Unidentified Speaker**

That's for stage two.

**Christine Bechtel – National Partnership for Women & Families – VP**

Yes, for stage two, right.

**Paul Egerman – Software Entrepreneur**

You understand, I'm looking at this and I'm saying, okay, I assume that your team did everything right and stage two is going to go perfectly, how is this going to work for stage three? What is the downstream implications? That's the question that I'm asking. And I don't feel like I have an answer to that. I don't understand that.

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

As George mentioned, we can start working on stage three just to start clarifying things tomorrow. We want to do that. We can start discussing this with industry earlier. There are lots of things we can do in order to try to open the dialogue, not just signal on how we should meet the objectives for the health system by using meaningful use stage three. We can go on to the comments. Gayle?

**Gayle Harrell – Florida – House of Representatives**

Thank you. First of all, I absolutely agree with the continuation of the extra year. I think that is critical. We need some feedback as to what has happened in stage one, it gives us the time to do that. It also gives the time for the vendors to be prepared. I think it's absolutely essential and I want to commend the workgroup for that recommendation. I think I have some issues with moving so many of the requirements to core. I really, as you've heard me many, many times, how difficult this becomes for many of our providers who are not PCPs, who are not internists, who really are a key part of that care team, and I'm afraid by not giving that flexibility and having menu items that you're going to really exclude a large number of significant providers. And in order to have that coordination of care and do what we really want this to do, you've got to have everybody playing at the table. So I think this is going to happen so I

just want to voice my concern for perhaps Tony to hear, that we need that flexibility of menu items in there and I hope that as CMS looks at this and looks at these recommendations that with boosting the thresholds and making them core I think we're going to have a lot of fallout. And my goal is to make sure that every single person has a complete EHR when we're all done, from every single provider that they have in the care team. That is so important if we're going to go forward with ACOs.

Also, I think that as far as signaling stage three, I think this group has been very forward thinking in establishing already those signals for stage three. As for Paul's concern, I think that we need to continue to do that and perhaps even have stage three complete before stage two is truly out there so that the vendors may choose to build stage three into stage two and you do one upgrade and you meet stage three at the same time. However, you don't have to turn on all aspects of it, you can transition through your facility and your team so that you can move your capability of being reimbursed as things work for you and change your workflow appropriately, but you don't have to upgrade your system and spend that money a third time.

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

Marc?

**Marc Probst – Intermountain Healthcare – CIO**

I'm concerned about the delay as well and not surprisingly, I don't think it's long enough. As you look at it, what did the AHA tell us, under \$200 million has been expended right now in the incentives that are being done. Most of those people, they're probably receiving, I don't know, it would be nice if we based some of our criteria on fact, but I'll bet I've been using EHRs for 10 or 15 years and have a lot of experience in all the technology associated with it, all the components of it, all the pieces probably had CPOE in place, and had to do some tweaking to get there by 2011. So essentially we have people doing a ski race that started three-fourths of the way down the hill while we still have to deal with people that are at the top of the hill. And what we've done is we've used it for the people that were three-quarters of the way down the hill, but I'd love some facts to show where are people really. Are the AHA numbers real? Are they something that we can attribute to fact?

And if so, it's going to be very difficult for people to get there by 2012. It just is. And then you start layering on everything else that's being asked, we're asking that people by the time October 1, 2013 hits and they've now made ICD-10, within three months they're at stage two. All these sprints that we're asking people to go through, and again I'm not seeing where we're layering in all the different things that are being asked of these providers and coming up with a date that's truly realistic. I know that didn't shock any of you.

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

Fortunately, CMS does have another year of input before they make their final rule and they'll have some of that experience. Larry?

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

.... I'm the only one who makes the rules, so ... CMS.

**Unidentified Speaker**

....

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

You can blame me, right?

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

Let me pick up on some of Marc's comments. I think it's really critical that we get much better and much richer feedback from the field on what's actually happening, what are people implementing, how far along are they, where are there specific barriers. We've had various hearings, and I commend all the things that we've started to do, but we're clearly early in the process and we're speculating about what's going to happen in two or three years when we're really at a place of unknown, where we don't know who's going

to implement what in the next year. And to Marc's point, how many of them are old adopters, now early adopters, who have been doing this a long time and they didn't do very much. Or the flip side, maybe it's someone new ... implementation, takes this on, gets it on, it's sweet, it's done, we're there, and people who have been doing things for ten years are actually hitting the biggest resistance. I think we need to learn. And maybe to that end a recommendation to ONC to consider research and best practice discovery, so enact not just casually collecting feedback, but actually actively collecting feedback and funding some research of what have people done, what are the best practices, and what's the variability. An organization may be 10%, 20%, 30%, or superb users, but conveying that to the next group is a hurdle. Or some organizations have nailed it, and let's do a more exhaustive job of actually finding our winners out there and the folks who are laggards to better understand what's making them be laggards.

I want to pick up on Charles' point, and we've discussed this on and off over the months about alternate ways to achieve meaningful use, and so that we look at and possibly not in this immediate timeline, but we start to look at, so people have put in basic infrastructure and the goal is to improve care, do we really want to switch to some of the other measures that are being put in place, success under ACO, or levels of quality measures that are being proposed, that those become the primary things in that we require minimum things, we require privacy and security, we require the ability to exchange information, but a lot of the details of what's on our ever growing list of requirements, that we start to back away from that and say okay, we don't need to define that cars have doors. We just need to make sure that people aren't falling out of the cars.

Finally, that maybe we take on in some form some kind of planning exercise. We have some workgroups that are doing a variety of exercises under the broad notion of a strategic plan that we actually bring that together and take a look at, so we have this strategic plan with some big goals and we're doing a lot of things to get there. I still have the feeling that there's some kind of road map in there that's missing that lays out, okay, so we're putting in this thread of technology and this thread of use, and that's going to enable a bunch of things. And we're putting in this thread of technology, this thread, and it's going to enable another bunch of things, and they come together. So the comment about progress notes feeding the summary is the kind of thing that maybe we need to highlight more of, that those are not just arbitrary things we've thrown in here, but they actually fit together. Okay, I'm done.

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

Those are fair comments. I like what Charles started. As we look at stage three with the world having changed so much is there an alternative pathway. So let me get David, Judy, and Christine and Neil, and then let's try to call a vote, please. David?

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

I really appreciate what Larry just said. I had many of the same ideas and I'm wondering, at least I propose that we insert in the beginning of the transmittal letter four points that I've heard raised that I personally think would be helpful. I am reluctant to support this delay, but I would be more comfortable with these kinds of points being suggested. One is that we take on what Larry has described as some kind of a timeline and strategic plan that looks to stage three and beyond and we do that immediately, very soon, and we give ourselves a short timeline to at least put a skeleton out for public discussion so that the industry and the providers and the committees are all signaled about the staging timing pathways.

Secondly, that we ask ONC to develop some mechanism for updating us frequently on implementation learning, whatever that is. ... that we had in one of our Quality Measures calls some very helpful anecdotal comments from people in the field that was just brand new information to us, and if we don't have that kind of conversation happening we're really inhibited. And as we get deeper into this and we want a more real time flow of information into our discussion about what's happening in the field.

Thirdly, that ONC consider creating a test bed of virtual stage three environment, of some real sites out there that are following both the stage two as now was described here, and whatever we know about stage three, and do we have an avant-garde learning laboratory out there which is very close to what's prescribed from which we can gather empirical data in real time.

Then lastly, that we include ... on the strategy side a tighter re-analysis of the market and policy changes with ACOs, medical homes, episode payment, value-based purchasing, etc., as the input into our planning discussion so that the policy directions are more tightly linked to the IT direction. I would suggest that those four points be at least mentioned in our letter as requests to ourselves or to ONC for further action to address what we've heard from the field.

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

Judy?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

I want to support Marc too on the timing. If in fact we don't really understand how long it will take the vendors to do the work and we don't really understand how long it will take to ask the organizations to do the implementations and it doesn't work, then we're not successful, so that's critical.

The second thing I did want to mention, though, is we can't be overconfident in the value of signals. I've heard them say we're giving the signals to vendors, and my analogy is that if in fact you're building a building and you've got all the details for this four story building and the last portion of when the building is supposed to be done you're told it's now a six story building, those who understand the engineering of that know that that's a ton of re-work. We have found that the signals in phase one caused thousands of hours of re-work as the finalization was what might have seemed insignificantly different, which was really from a technology point of view significantly different. So I think we have to be careful that the meaning of signals, we may be feeling better about the signals we're giving than the recipients of those signals. And I'm wondering whether there's some way to finalize things incrementally so that instead of waiting until the very end we can finalize things as we go and therefore the vendors can know that that's the way they have to work on it.

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

Okay. Christine?

**Christine Bechtel – National Partnership for Women & Families – VP**

Well, lest there be any question I think that my perspective on the delay is that I was very, as you know, concerned about having any delay at all, because if you look at every public opinion study out there, most recently the Markle Foundation, patients don't want to wait for these capabilities anymore and it's astounding that we haven't been doing them already. I do, though, think that while I am hesitant about the delay I want to give meaningful use the best shot that it can of succeeding, and I understand that there are a number of providers who have said we may not attest this year because we don't think we can succeed in that kind of a time constraint next year. I think that's not a fair scenario to set up and so I support this option.

The second piece that I want to raise is the specialist issue. I think it's a very valid issue. We held a hearing a couple of weeks ago where we heard a lot from specialists, and I think we are not done on that topic by any stretch. So rather than going back to a core and menu approach, I think what I would suggest is that we approve the recommendations today as they are but that we do some work over the next month and bring back some thinking about how to handle particular kinds of specialties so that we can get everybody on the team on board, but do it in a way that is probably more workable for most specialties, recognizing that there is no option that's going to be workable for all specialties. But I'd like the workgroup to pick that work up over the next month and come back with a set of recommendations soon.

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

Neil?

**Neil Calman – Institute for Family Health – President & Cofounder**

I think it's inevitable that we agree to the delay, given all of the things that other people have said. But I think there needs to be sort of a preamble to our letter, because whatever we put out there is going to generate an enormous amount of pushback and I think the things that really stand out for me are some discussions we had early on in this process. This program that we're involved in is not a subsidy program. It doesn't subsidize people purchasing and putting electronic health records in their offices. I think we were clear on that in the beginning. That's not what it's meant to do.

The second thing that I would point out is that no matter what we do if the program went away tomorrow ten years from now you wouldn't be able to go to a doctor or a hospital that wouldn't be electronic. That's just the way the market's moving, it's the way patient expectations are moving. People are walking into my office today going, well, I'm glad to see that you can send my prescriptions electronically like my other doctors are doing. How long do you think it's going to be before somebody walks into the office and says, what, you still print your prescriptions on paper? This stuff is moving really, really quickly. So we have a public responsibility to make sure that the dollars we're spending are truly incentive dollars and incentive dollars to me means we need to use these funds to accelerate a process that would otherwise take place. If we're not accelerating a process, if we're just supporting a process that's otherwise going to take place, then we don't need to put all of these dollars on the table to do that and it's not really an incentive program. I think we need to highlight the fact that if we built in this delay already it's with an expectation, at least on my part, that we stay true to what we've originally said, which is this is a set of market driven things that are going to happen anyway and the dollars are used to do two things: to make sure that they move in the right direction, and that the things that we think are critical to improve people's health get built in early on in the process and don't get added on after people are just typing notes into a system.

And second of all, that it accelerates a process that would otherwise take place normally. If we're not going to do those two things then we're wasting our money. I totally understand the fact that that requires some timeline, for people whether they're providers or vendors or whoever, that want to run on their own timeline, well that's great. But our dollars need to be spent to make sure that the things that are critical to patient care get built in now because I totally agree with Christine, the things that are still happening to people, for lack of this information and coordination are tragic and we see them every day in our practices. Second of all, that we're clear that we're accelerating that process and that that's the objective. Hopefully that will reduce the amount of, I think that should be in a preamble to our letter and I think we should continue to view that and state that so that we don't end up further diluting the things that we're doing through the public comment period and everything else to a point where we're back at stage one all over again.

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

Well said. Now you've heard the rich discussion and we'd like to call the vote in terms of the timing recommendation as a package with the stage two recommendations for the objectives. This doesn't represent a single best right answer, but it's our best thinking as a group of folks really committed to what Neil just articulated. These are recommendations only and fortunately CMS has another year in which they get the input of the various people in the administration and the public and I think that the suggestions that were made, starting with Charles and Larry and David saying let's start tomorrow in mapping out a broader strategy and open to other alternatives in what does stage three even mean, because we can start having that discussion and it doesn't have to be limited by current timing or even style of how we've been setting up meaningful use, because the world has changed even in the two years we've been in existence. That's a commitment and I think it's a terrific idea, and to get ongoing reports from CMS on what's going on in the field will certainly shape that, if not shape stage two and stage three.

With that caveat, I wonder if we could hold a vote, and Paul, is that germane to ....

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

I thought David made a great suggestion about some sort of strategic plan or preamble. In the process are we going to talk about that also, or are you saying that that's part of this vote?

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

It's not part of this vote, but that sounds like a terrific idea and certainly as chair of this group I'd like to act on that.

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

Okay.

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

So as part of our process we'd start working on stage three and with a fairly open slate. Okay, so before I use the recommendation of the package of the timing for that particular cell, the criteria, including especially on the summary of care and care plan, the caveat about what the majority felt that there was a compelling argument to be made for higher thresholds in that case and movement of requests to the HIT Standards Committee. May I have a vote of all in favor of that package? Do you want to count? Yes.

Hi.

(Background conversation)

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

Okay, so 11.

**Unidentified Speaker**

On the phone.

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

On the phone, Josh?

**Scott White – 1199 SEIU – Assistant Director & Technology Project Director**

I, Scott, am in favor.

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

Okay, 12, and Josh?

**Unidentified Speaker**

....

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

Okay, so 12. Opposed? And abstaining? Okay, so it's 12 to 5. Is there something that was a deal breaker for the people who voted no that's easy to fix? I heard the timing, so Marc I'm not sure –

**Unidentified Speaker**

I agree with the other two bullets 100%. But it's timing for me.

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

So you mean option one, the first of the bullets is what you're –

**Unidentified Speaker**

Yes.

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

You're agreeing with the criteria but not the timing?

**Unidentified Speaker**

Correct.

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

Okay, that's helpful to know. Gayle?

**Gayle Harrell – Florida – House of Representatives**

Mine is flexibility.

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

Paul?

**Paul Eggerman – Software Entrepreneur**

To me there's too much stuff here and it would be easy to fix.

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

Judy?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

I'm okay with timing. I think it's fine. But I'm kind of with Paul here. I'm worried about, if this is what you mean, Paul, I'm worried about extra effort on the physicians and I think someone needs to look at that and see if it's really there.

**Unidentified Speaker**

Okay. I'm not sure that's something we can take apart to address those things. Okay, so I think the vote stands and we'll certainly try to reflect those concerns in –

**Unidentified Speaker**

So?

**Unidentified Speaker**

I guess I'll support both sets of things. I think I'm probably not as strong on the timing as Marc, I think the timing is important, but I'm more concerned about the lack of flexibility in some of the requirements, particularly things like the lab is a disproportionate burden on hospital labs versus non-hospital labs doing reporting, and that we have a long-standing issue of getting labs involved and that maybe we need a better method outside of meaningful use, whether it's through CLIA or through something to move forward the lab issue. So I feel like there's a bunch of things throughout that I would say tweak this, tweak that.

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

I'm hearing two things from the people who voted no. One is the timing, and I'm almost guessing that could address – sorry?

**Unidentified Speaker**

....

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

Yes. I think that that can address Judy and Paul's concern because the amount of material in the objectives could be alleviated by timing, I would guess, too. So timing's a big one and flexibility, and they're very related. So we certainly will express that as part of our letter going forward.

I'm afraid we've gone late into our lunch. David, is there any flexibility in your hour?

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

It depends on what people want to discuss. We're going to present a fairly bold recommendation, or ask for the recommendation of this group, so we'll probably need a good part of it, maybe 45 minutes.

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

Okay, could we limit lunch to 40 minutes, and it's not a matter, we can all eat faster, it's getting service and getting the food –

**Unidentified Speaker**

... option report to maybe 15 minutes, particularly ....

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

Okay, so that gives us –

**Unidentified Speaker**

Read it over lunch.

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

So let's take the 45 –

**Deven McGraw – Center for Democracy & Technology – Director**

... we asked them to do, we can probably cut ours to like 15 minutes.

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

Deven, you saw how well that was. Anyway, let's adjourn until 1:40, please. Thanks.

Okay, I think we're going to get started, please.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

We're ready to begin, if you can please take your seats. Thank you.

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

That was the ONC privacy officer bringing us to attention to hear the report out from the Privacy and Security Tiger Team, who has a couple of recommendations for us.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay, great. This is Deven McGraw. I'm just going to do a very brief introduction and then turn this over to Paul Egerman to lead us through the recommendations, because he really, with a smaller task force, did the bulk of the work on this issue. We're putting some recommendations before you today on the issue of certificate authorities, provider entity authentication recommendations, and the ties to some of our earlier recommendations, which Paul will go over, but that we got some additional questions on. So we're just adding some clarification. As usual, we thank the members of our Tiger Team who worked tirelessly, as do the members of meaningful use. This is not a fun volunteer job, but it's an important one and we have a really good and committed group in addition to members of the public who follow us regularly and keep us on our toes. So with that, I'm going to turn it over to Paul.

**Paul Egerman – Software Entrepreneur**

Great. Thank you very, Deven. It's Paul Egerman. This is a great presentation to have right after lunch because this is going to be the most interesting presentation on digital certificates you've ever heard in your entire life. Because we are probably the only group who have been able to turn digital certificates into a controversy, and so we will be going through that issue.

First, I'm going to quickly do a couple of definitions here just to briefly remind you what a digital certificate is, it's like a metaphor, it's not like something you can actually frame, and the concept here is that it really serves two purposes. It provides basic information about the entity, and we're talking about entity level certificates, so it's sort of like the entity's name and other information about the entity. The second is it's involved in the entire encryption process, so that's what a digital certificate is. In this presentation we're going to talk a lot about this thing called a certificate authority, which we abbreviate CA. Certificate authority is an organization that issues the certificates, or has the authority to issue the certificates. So that's the certificate authority. We have this slide, and this slide was actually from a presentation we made last year. It's trying to give you a little bit of sense of what it is we're talking about. You see here a triangle of three different provider organizations. The concept is in this slide each of these three provider

organizations would have their own EHR systems. They would have, on their own EHR systems this concept of a digital certificate and then they would be able to push information among themselves.

So you sort of see ... that there are arrows going back and forth. The cloud in the middle of the diagram is to indicate that this is being done over the Internet, and so the idea is that this is part of the authentication environment. The recommendations we made last year on this, we were clear that the provider who drew this diagram was showing provider organizations, however, there are a lot of other organizations that would be part of NW-HIN that are not necessarily what we might call treatment providers. So you might also have digital certificates that are held by retail pharmacies or DME suppliers or commercial laboratories, imaging centers, payers would have these, claims clearinghouses, state health agencies would have these, the VA, CMS, CDC, so this is all sort of like a vehicle for organizations to communicate with each other. That's what a digital certificate is all about.

We made a previous recommendation on November 19, 2010, which I'm sure everybody remembers in great detail, and so we had four or five basic recommendations related to these certificates, which are again done at an entity level, not at an individual level. The purpose of doing all those recommendations, though, is that these are really security recommendations. These are to provide a level of trust, the idea that you would be able to do this information exchange and in an environment where you could have a sense of trust that if you're submitting information from one provider to, say, a hospital, that the hospital receiving that information was really a hospital, that it was really the hospital you intended to receive the information. So it's part of a trust framework. It says here in the second bullet that we recommend a high level of assurance after we produce the slides one of our colleagues, David McCallie, said that you talk about high level of assurance, you might actually be creating some ambiguity because levels of assurance is terminology that is sometimes used for individual certificates. What we meant when we put together this slide is we wanted to create a high level of certainty that the organization was who they said that they were.

As part of that, in our original recommendations we did say that the organization's identity had to be validated before the certificate was issued. So on one aspect of our original recommendations we simply said ONC would establish an accreditation process for the certificate authorities. So the issue came up for these certificate authorities and we sort of said, well, ONC will establish an accreditation process and we figured that was good and we were done. And the Standards Committee came back to us and said, nice job, but not so fast. Basically they pointed out that what the qualifications of the certificate authority are is interrelated with the types of certificates that are being issued and requested that we provide more information.

That's the basic history. We really are focused on the certificate authorities and their qualifications. The way we address this issue is we sort of look at it and say, there's a lot of technical aspects to it, so we've put together a special task force of experts who can do this, and it was headed up by Dixie Baker, who chaired it, and David McCallie was the co-chair. We had Deborah Lasky from ONC who provided a huge amount of technical help, and we had a number of other people involved. The task force met and really considered three different alternative approaches. The first one was the same as the original recommendations, you have an accreditation body, which we thought would be a good idea until the Standards Committee passed it back to us, to pass it back again to them and say now we're going to stick with it. But that was one alternative we considered. The second alternative that we considered was certificate authorities would conform to the best practices of what's called the Web trust or the European Telecommunications Standards Institute, ETSI, and these are commonly available, commercially available certificates. That was the second alternative.

The third alternative is where the certificate authorities must be cross-certified with the Federal Bridge Certificate Authority, which is like a lot of words but basically says that the certificates have to be acceptable to a federal agency. So those are the three alternatives that we consider, or a task force considered. Then the task force looked at two issues. One was called the exchange functionality considerations, which is we sort of said, well, who do you have to talk to. And one of the conclusions that we came to was we said almost every healthcare organization, or a large percentage of healthcare

organizations, will at some point need to exchange information with a federal agency, a federal health agency, like the VA or CMS or IHS, and we just felt that sooner or later they would.

Then you see a lot of words there on the page, but basically we investigated this and we said, well, what do the federal agencies really require. Then it seemed like a simple thing, a simple question to get answered, but Deborah Lasky actually had to do a huge amount of work to figure this thing out. The information that we got back was that basically the agencies would not accept anything that was not cross-certified with the federal bridge, that that was the basic requirement. And we did see, as an example, that the VA requires these kinds of certificates in what's called the Direct pilots that are currently in place. So these were in use and some projects where people were non-federal healthcare organizations were communicating with the VA. This all said to us this is what message it sort of pointed towards, these federal cross-certified CAs, then we looked at what we called the security consideration, and this sort of high level of certainty was really very important and we felt it really was actually extremely important that you validate the ... identity before you issue the certificate. So that's the second bullet there. As a result, the Tiger Team rejected the second alternative, these frequently available Web trusts, or ETSI, because it does not include entity validation. What that means is if I wanted to I could make up the name of an organization, called the Renaissance DME supplier, because we're here at the Renaissance Hotel, and I could get a digital certificate for that. That could be done. Or I could actually, even if I wanted to, choose the name of an existing organization. I can say I'm Palo Alto Medical Foundation and I could get a certificate for that. We say, well, that's good, but it's not good. It doesn't work for the environment that we have.

Those two issues actually pointed us very clearly to what's called the third alternative, the cross-certified federal bridge. Once we had that the next issue was, well, what's the implementation impact of that? Fundamentally, as we've talked before, you always have a balance between risk and utility, that to whatever extent you try to improve security, there's always some disadvantage. There's always something else that you have to do as a result. So you have to balance these things together. The issue was, well, we sort of did the security side of it and now we've got to look at the cost side and the utility side. So again with a lot of help from ONC and Deborah we looked at that information and the issue of cost, we looked at what it would cost to get these certificates, and there's actually a range of costs and the costs seemed to be in the range of around \$50, and there was some ambiguity as to whether it was \$50 per year or just \$50 at one time. And we did get some feedback on the Internet that people said it might be as high as \$100, but I looked at that and I think the Tiger Team looked at that and said, well, for an entity, whether it's Palo Alto Medical Foundation or Intermountain Healthcare or Kindred Healthcare, or a small group practice, \$50 to \$100, it's per year, certainly a reasonable cost.

In terms of the competitive environment, we determined that there's currently about a half dozen of these certificate authorities in place. There is a process for additional ones to be, I don't know if the right word is qualified or for organizations to be qualified or cross-certified on the federal bridge, so there could be many more of them. And so we felt that that also meant that there's a competitive environment for these things, which is again reflected by the cost and the fact that the costs are low.

The third issue, there's actually a fourth issue, but the third issue we looked at is the technical requirements for entities that did not have an IT department. So we looked at small group practices or community hospitals or rural hospitals and said well, if we go this way what's the deal for them? Are they going to have to, is this like doable for those kinds of organizations? And the feeling we had there that was really important is that it was doable mainly because the certificate authorities all had reseller arrangements, and so basically what that meant was, for example, whoever was the vendor for that organization's EHR system could simply install the digital certificate at the same time. The complexity of these certificates is really very small when you compare the total complexity of an EHR system, and basically somebody else is taking care of that for most of these groups. So that would be one source. They could also be installed by HIE organizations, vendors, service organizations, and there was a lot of choices. So we thought that technical requirements are reasonable.

We also looked at the entire process very briefly of how these things work and there are two or three different processes but the process that is frequently done, which is a good process, is a face-to-face

meeting. So what that means is that if somebody applies for one of these certificates, maybe somebody ... who's qualified ... is meet with them face-to-face, see that the organization really does exist, see that there's some organization paperwork that exists, maybe get some officer of the organization or an office manager to sign that they're responsible, to make sure that this thing really exists, but we thought that that was reasonable, especially since it happens once. It's not like this happens every week or every month. We had some conflicting information. At one point somebody said that it has to be repeated every five years, somebody else said it had to be repeated every nine years, but at the same time this all seemed like from a process standpoint it was better than just downloading something and getting whatever you were. We thought it was a very reasonable implementation consideration.

So we put these things together and we came up with our recommendation, and the recommendation has two parts. The first part is simply a restatement of the principles, and the principles were at a high level of certainty related to organizational and entity identification that's needed. The second principle is that it has to be acceptable to federal agencies. We didn't want people to have to get two certificates. The third one is that there has to be multiple competitive sources. So those are our principles.

Then based on those three principles we came up with the conclusion also, which I'm going to read the words because otherwise I'm going to accidentally state it wrong. We said all certificates used in NW-HIN exchanges must meet federal bridge standards and must be issued by a certificate authority or one of its authorized resellers that is a member of the Federal Bridge PKI framework. So that was our recommendation and we completed it, and when we completed it we felt great about it. We felt like it's one thing we can cross off the list. What we learned from this next part of the process is that it's almost impossible to make any recommendation that somebody doesn't disagree with.

So fundamentally we got some disagreement and actually we got some fairly enthusiastic disagreement about this process. The slide here says it comes from some Direct stakeholders, so it should say from some Direct Project stakeholders, so the Direct Project, as you probably know, is this effort that ONC has that's actually been a very major success. And there are a lot of people involved in it and because it's like a Direct Project it's not like this Policy Committee where there's a group of 20 people and it's like well defined. It's just lots and lots of people. It's coordinated by Arien Malec, and two of the contributors to the process, David Kibbie and Sean Nolan, were very unhappy with us. Even though there's a project where there are lots and lots of people, it sometimes happens that there's sometimes a core group of people who really do a ton of the work. And these are two of the people who have done really a ton of the effort, so we were very concerned that they were concerned, so we spent some time listening to their issues and some of the issues are written up here.

There were some concerns that there might be operational issues that had yet to be discovered. There was also a concern that it could adversely affect the deployment of the Direct Project, but the Direct Project, the people involved are very committed to the Direct Project, they're very committed to the expansion of the Direct Project, because they didn't want this process that added some additional qualification of face-to-face meeting being like a speed bump that would prevent the process. And so we invited them to send a letter to the Policy Committee to reflect what their issues are and they didn't quite do a letter, although Sean did do an e-mail and we distributed the e-mail so that everybody could read that and see it in greater detail because I wanted to make sure that I articulated correctly what their issues were. Well, we had a conference call with them and we heard their concerns, and then what we did was we took those concerns back to the entire Tiger Team and we spent time, even though we had already approved our recommendation, going back over the recommendation and we went through all of their concerns. The response basically from the Tiger Team sort of said, well, these are reasonable issues and there are some things that they have some anxiety about, but they really hadn't presented any facts and any specific issues that caused us to rethink our decision, that while there were things that they would worry about, it would be different if they had said, here's specifically why this doesn't work.

It turns out, fortunately, and somewhat in parallel, that there's this other group, the S&I framework that started its own process to evaluate some of these costs. They did this also at the request of the HIT Standards Committee and what the S&I framework is doing is slightly different than what we did, because we looked at the entire issue almost entirely from the standpoint of the end user healthcare organization.

We were also looking at this from the standpoint of what it takes to be a reseller or a certificate authority because within the Direct Project there are some people who are interested in actually selling certificates as part of the business model. So they're doing some additional cost investigation and also investigation of the implementation burdens. We altered our recommendations, though, and said if that process comes up with some new facts that we haven't considered or somehow some facts or information that was inconsistent with what we did, then we're going to revisit this issue. So that's what we said and when we said that everybody was happy and just so everybody knows, we had participation in our Tiger Team that overlaps with the Direct Projects, we had people that are on both projects, and we also brought in Arien Malec, who's the coordinator of the Direct Project, and he participated in the discussion. He was the one that actually suggested this and he is firmly supportive of this solution.

So that's where we are. I don't know, Deven, if you want to add anything to it.

**Deven McGraw – Center for Democracy & Technology – Director**

I think the only thing I will note is that maybe under some circumstances, given that people had raised some questions or expressed some concerns, we might otherwise have said, well, let's wait and hold the recommendation until we see how this pans out. But because a lot of time had been spent investigating the very facts that were the foundation of our recommendation, and we were, quite frankly, we didn't see that there would likely be some, obviously people had anxiety, I think, as Paul characterized it, as a good way to go, and we didn't want to step on some fact finding processes that were already in process, but at the same time we really felt like the principles that we had agreed on as the basis for certificates and the facts that drove us to the recommendation of requiring cross-certification with the federal bridge, felt very sound to us. So this seems like the right way to move forward, which is to get the Policy Committee to say this is the right approach to take and if there are some facts that come out that we didn't surface in the initial investigation that throw the conclusions that we made into question, then we can revisit it. But otherwise we think it's important to be on the record that we're heading in the right direction.

**Paul Egerman – Software Entrepreneur**

That's great. Is Deborah Lasky on the phone?

**Deborah Lasky – ONC**

I am.

**Paul Egerman – Software Entrepreneur**

Great. I was just wondering if you had anything to say or if I made any mistakes along the way, if you wanted to correct anything?

**Deborah Lasky – ONC**

No, Paul. You've become an expert.

**Paul Egerman – Software Entrepreneur**

This is a frightening concept. Thank you, Deborah. Anyway, this is our recommendation and we feel very good about our recommendation and we're asking for the Policy Committee to consider it.

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

Good. Thank you very much. Gayle, do you have a comment or question?

**Gayle Harrell – Florida – House of Representatives**

Yes. First of all, as a member of the Tiger Team I appreciate all the time and work that everyone put into this whole conversation again, and especially Paul and Dixie, who went even further into it. But I can tell you that authentication is a key component of what we're doing in building that public trust, and I don't think we can back away from that. If it is a little inconvenient and if it is a little costly, I don't think \$100 a year is unreasonable, to make sure that you are dealing with the person you think you're dealing with, this is key to security and key to developing that public trust.

I would just ask, since I missed part of that conversation the other day on the Tiger Team, did they have a specific recommendation that they would like us to put forth instead? What were the other options that they would have presented? I know that they are doing some investigation and that they are moving forward on that, but is there a direction they would see us go, more stringent, less stringent? What would they say?

**Paul Egerman – Software Entrepreneur**

It's hard for me to predict what they would say. I don't think they'd put forward a separate alternative. The Direct Project currently uses this second alternative, which we rejected, but for their purposes right now it probably works fine because they know, even though there's no validation, the project is at a stage where they probably know all the participants. To me it becomes a very different environment when you try to do this thing on a nationwide basis, but from where they stand of course they're very committed to the project. So they want to make sure they don't accidentally cause a reason for people to not participate.

**Deven McGraw – Center for Democracy & Technology – Director**

I would say that they didn't propose a specific alternative, but I think they were considering similar issues about cost and there were lots of myths floating around about how expensive in particular it would be to be certified to the federal bridge, and that was why we took the time and asked ONC to help us investigate the facts in that regard, and that's another reason why we are committing, even within our recommendations saying if there's some facts that are uncovered that we didn't surface the first time around then we would want to look at it. Our principles are firm. We need high assurance and we need it to be workable and I think everyone would agree with that. Our investigation, you know, our process revealed it to be workable. If we find out contrary facts we'll look at it again. But obviously it's an important project and we want to leave room for working that through.

**Paul Egerman – Software Entrepreneur**

Christine?

**Christine Bechtel – National Partnership for Women & Families – VP**

I have some questions. I understand, you'll all be shocked to know, what the federal bridge is. But what I don't understand is what the relationship between the NW-HIN, or whatever we're calling it, and Direct is. In other words, they seem to be very linked. Your recommendation is very specific to the NW-HIN, participation in the NW-HIN. Did I read that correctly? So I don't understand how it would impact Direct. And the substantive question that I have to that is in the context of Direct where I think Sean's right, that a lot of exchange will happen provider to provider if there's not a federal entity involved and probably in the next year or two it's not going to be through the NW-HIN. So how would they be required to have certificates under this and how does that impact their exchange?

**Paul Egerman – Software Entrepreneur**

It's a great question. You should just say that you were surprised that Direct would be impacted, I think they were too, this is part of the reason why we got some pushback on this, and I can't tell you that I know what the answer is to what extent the Direct Project is part of NW-HIN. I would tell you, though, in my opinion it doesn't make sense for these organizations to end up having to get two certificates. It would be nice for them to have one certificate ... but there could be ways that they could continue to operate and just not be part of NW-HIN. That would be part of their choice.

**Christine Bechtel – National Partnership for Women & Families – VP**

But to participate in Direct, which is basically secure G-mail, you don't have to have a certificate today, right? The model was let's do it like we do it now on fax, where I can communicate with another doctor through fax machines and I don't have to have a certificate. So I guess I'm not understanding why Direct would be impacted by this recommendation. It seems to me, tell me if I'm wrong, but that seems to me to be like the threshold question here.

**Paul Egerman – Software Entrepreneur**

Well –

**Christine Bechtel – National Partnership for Women & Families – VP**

Oh, Joy.

**Joy Pritts – ONC – Chief Privacy Officer**

Yes. This is Joy Pritts. The Direct Project is a pilot project to test standards for secure transmission. Directed exchange is anticipated to be part of NW-HIN, so the Direct, when we talk about Direct exchange it's not the same as this project. This project is a pilot project, just like, what is it NW-HIN Exchange, is that right, Doug?

**Paul Egerman – Software Entrepreneur**

NW-HIN Exchange so you're talking about the VA?

**Joy Pritts – ONC – Chief Privacy Officer**

Yes.

**Paul Egerman – Software Entrepreneur**

Yes, that's correct.

**Joy Pritts – ONC – Chief Privacy Officer**

That's a project also. But NW-HIN itself is moving towards encompassing all methods of exchange. These are two different pilots that we're talking about.

**Christine Bechtel – National Partnership for Women & Families – VP**

They might get subsumed later by the NW-HIN –

**Joy Pritts – ONC – Chief Privacy Officer**

Yes. That's the idea.

**Christine Bechtel – National Partnership for Women & Families – VP**

I understand.

**Paul Egerman – Software Entrepreneur**

One way to understand NW-HIN is really a collection of standards and policies that are put together, and presumably what's happening in the Direct Project and what is happening in NW-HIN Exchange, if I'm saying it right, will prove various standards that will be part of NW-HIN, that NW-HIN will hopefully be like this greater nationwide thing that these two become hopefully subsets of.

**Christine Bechtel – National Partnership for Women & Families – VP**

If that occurred they would not need two certificates, because one gets subsumed by the other and they don't need a certificate under Direct today. So if that's correct I'm less worried about that. I think all you're saying here is –

**Deven McGraw – Center for Democracy & Technology – Director**

It sounds like, Christine, you're asking whether from a technical standpoint you could exchange as part of the Direct Project, without any digital certificate at all, and I don't believe that's the case. They're going to need digital certificates to, I mean, people have used the secure G-mail analogy so that people understand the simplicity of it. But I don't think that establishing the ability to exchange is like opening up an e-mail account. You need the authentication aspects, which is what a certificate provides.

**Paul Egerman – Software Entrepreneur**

I have a feeling that Doug would like to say something. I don't know why.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, and he'll probably say Deven was totally wrong, and that's okay.

**Doug Fridsma – ONC – Director, Office of Standards & Interoperability**

Deven was totally right. No, for Direct Exchange there is a requirement for certificate to ensure that it's encrypted and the information is kept private. Both NW-HIN and pilots that the federal agencies are using and some of the larger –

**Joy Pritts – ONC – Chief Privacy Officer**

NW-HIN Exchange.

**Doug Fridsma – ONC – Director, Office of Standards & Interoperability**

Exchange, NW-HIN Exchange, they use certificates for secured transmissions, as well as the Direct Project. And so in fact it would be useful to have those be similar certificates so that if people were to use one or both ways of exchanging information they had a common certificate that would represent them.

**Christine Bechtel – National Partnership for Women & Families – VP**

My guess is that part of the issue is that the certificates that folks are getting today in the Direct pilots are not cross-certified with a federal bridge, so in fact you might need to.

**Paul Egerman – Software Entrepreneur**

That's correct. Most of them are not. But your question is a good one. Our recommendation is specific through NW-HIN. You can still exchange information outside of NW-HIN. One simple example is one physician can telephone another physician, that's really an exchange of information, and it's really fine. If it's in NW-HIN we're saying this is what the certificate needs to be. It's also the case that once we say that it hasn't influenced a lot of other things, and people will start to go that way because they figure that's the right way to go.

**Christine Bechtel – National Partnership for Women & Families – VP**

So you may need to upgrade your certificate later. I got you.

**Paul Egerman – Software Entrepreneur**

Right.

**Christine Bechtel – National Partnership for Women & Families – VP**

Thank you.

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

Larry?

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

Thanks. I guess when techies give me a bunch of answers like this I wonder what's the real issue. I don't know the answer to that, but it sort of feels like there's something making them uncomfortable and it's changing an assumption. It's probably worth driving home with them maybe separate from what we do here but certainly worth driving home with them what really is going on here, because it sounds like something other than what they've described is driving this. I'm not saying they have ulterior motives, I'm just saying that there's something that isn't clear yet.

**Doug Fridsma – ONC – Director, Office of Standards & Interoperability**

Yes, great observation.

**Joy Pritts – ONC – Chief Privacy Officer**

But I don't know that we have to speculate about that. Honestly, the Direct Project has been going along quite well and for whatever sets of reasons I don't think we need to speculate about why. They've raised some concerns about whether the recommendation that we've put on the table is deployable by them in a short period of time when they want to be up and running, and so whether there are in fact cost issues that despite very due diligence by ONC did not uncover or operational issues that we did not foresee, to the extent that they've questioned some of the facts that were the basis for our recommendation I think

it's worth leaving open the possibility that something might be discovered that would cause us to reassess this. But beyond that, I think we should stick with the facts, right, as we know them and consider whether this is the right way to move forward, and the Tiger Team thinks that it is.

**Paul Egerman – Software Entrepreneur**

I guess I'm also hearing that there's the opportunity to learn if they switch to the certificate, assuming that they will switch to the certificate in the pilot, that they'll discover some of the operational issues.

**Unidentified Speaker**

Right, and also because they're doing great work. That's why we're trying hard to listen to them.

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

I guess I'm hearing another theme in here, which Gayle touched on briefly, about authentication, and that that's a continuing story. That comes off in the provider directories as well, organizational directories of how do we know who these organizations are. So separate from this specific technical piece it sounds like this is one piece of a broader how do we know this organization is who they are and that the method of authentication may in fact down the road combine those things. You demonstrate who you are, you get your digital certificate, you get your XYZ ID that you can say who you are in some lookup table.

**Paul Egerman – Software Entrepreneur**

Larry, that's really an excellent point. One of the things that was in our original letter that I neglected to say in my presentation is this is really only also one component of an entire authentication process. This is not the only thing. It's an important component but it's not the only one. Because there's a lot of things that have to occur and ultimately this is about privacy and security to get patients to be comfortable, so we need to keep that in mind. We need to keep in mind that this is about the patient and provide a high enough bar to make sure that patients and clinicians are comfortable exchanging information.

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

Maybe my comments are more a message or a request to others as they're looking at some of the directory questions and how we authenticate people to be in directories, that we look to bring these processes together and not have people going through multiple authentication site goals to say I really am who I am and this is the third time I've said it this week. This is as bad as the patient clipboard. Come on, guys, help me out here.

**Deven McGraw – Center for Democracy & Technology – Director**

Yes, good point.

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

Art?

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

I just want to get back to this discoverability part. I know you really didn't talk about it here, but in this Direct Project is the address of the person to whom I want to send my information discoverable? Is that something that we've shared, like someone gave me their phone number to make a call?

**Paul Egerman – Software Entrepreneur**

If I understand your question correctly I think you're asking like a directory question. It's sort of like if I want to call you how do I know your number? If I want to exchange information how do I know how to do that? And it's a good question. That's not what this recommendation addresses, though. This recommendation assumes that somebody else is going to address that question.

**Christine Bechtel – National Partnership for Women & Families – VP**

In fact we've had some recommendations from the Information Exchange Workgroup on entity level provider directories that have come through the committee. But I think the point Larry made is well taken. These all need to be knit together in a comprehensive way.

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

Gayle?

**Gayle Harrell – Florida – House of Representatives**

I get a second bite at the apple. Thank you Paul. I still have one more question. If we have, for instance, the direct project issuing a different kind of certificate, and if we want ours that are linked, that are cross certified to the Federal Bridge, is there a higher level of security going through the Federal Bridge, or would the one that the direct type of certificate—are they issuing a different type of certificate? And which has a higher level of security would you anticipate?

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

Well, the claims that we are making is this is better security because this validation process has to occur before the certificate is issued. Certificate is really a certificate. It's not that exciting by itself. The issue is, is how do you decide who gets it.

**Unidentified Speaker**

Correct. I could clarify point. The direct project does not issue certificates. The participants in the direct project obtain certificates from primarily commercial entities at this point, as part of their pilot.

**Gayle Harrell – Florida – House of Representatives**

So, would they be more secure, less secure, are they equally secure?

**Deven McGraw – Center for Democracy & Technology – Director**

I mean the one point that the task force discovered is that with respect to the commercial issuers of digital certificate, it was the sense that their processes for properly identifying and authenticating the entities who apply for the certificates. Certificates was not as robust as we would want, based on previous recommendations. So again, we thought to sort of marry our previous recommendations, which ask for a high level of assurance and a desire to have sort of multiple certificate authorities available to do this. We had originally called for certification process to be stood up by ONC and then ultimately recognize that if you do federal bridge cross certification, based on the data that we uncovered, you could do it at reasonable cost, and with multiple availability in terms of participants. And you'd get double bang for the buck, you also get the authentication that comes with those certificate of authorities are required in order to issue the certificate.

**Gayle Harrell – Florida – House of Representatives**

So presumably if you had one of those cross certified certificates, then you should be accessible to the direct project and you wouldn't have to have further certification through them, or through another commercial entity.

**Deven McGraw – Center for Democracy & Technology – Director**

That's right, but keep in mind here, we're setting requirements that would apply to exchangers across the board, not setting requirements for direct per se. We've actually scrupulously avoided as a tiger team, saying direct shall do this and everybody else shall do this, so one set of requirements for every exchanger. They've raised some questions about whether it's doable for the direct project and we have left some room for some additional fact finding that might call into question, again the conclusions that drove us to this recommendation.

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

So I think we are ready to act on their recommendations, which appears on this slide number ten. So their recommendations stand with a caveat that if the S&I framework activity that's ongoing uncovers some material evidence or basis for which this group would want to re-assess their recommendations they would, but right now their recommendations stand because of the amount of work and they've put into the evidence that supports their recommendations. So, ready for a vote? All in favor? Is there any opposed? And no abstentions. Very good, thank you very much.

Okay. We're ready for the Quality Measure Workgroup discussion on the core menu framework will advise David Lansky. We're all expecting a bold recommendation coming forth.

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

Thank you all, thank you Paul. We have had a series of meetings, very productive meetings with the Quality Measures Workgroup. I would add that there is now an also workgroup with the Standards Committee, and we've been working jointly, in ... the joint hearing recently. So I think as we'll talk about shortly, some of the challenges we have in developing the methodologies and technical support to quality measurement is being conducted jointly with the Standards Committee and with our group.

What I want to do today, we actually are now in the middle of drafting a transmittal letter, which would in a sense be a complement to the transmittal letter we looked at this morning from the meaningful use program for the functional criteria. That's not yet ready for review, but should be shortly and I wanted to summarize what's in that letter for you today and ask for your conceptual support hopefully, of the things we're going to recommend in that letter. There really will be three areas we'll touch upon: the framework we are suggesting from reporting on quality measures going forward, the actual measures and the types of measures that will be in that framework, and a request for support on the methodological developments that need to take place by this group and the Standards Committee and others. So let me just give you, before I get to that, the punch-line of the request for support for the recommendations, let me tee up a little bit of the context where we're at.

First of all, to just remind you all we have these two arms of our program in meaningful use. We have the functional requirements we talked about this morning, and then the quality measures, which support those and extend them really, into performance in field. We'd like the quality measures to reward outcomes of care as much as we can—we're trying to drift the measures in that direction. We have several criteria as we think about quality measures. We want them to be sensitive to health IT implementation. That is we're not just measuring all the dimensions of quality, we're measuring dimensions of quality which we believe could be hopefully supported by IT adoption. We want these to be measuring meaningful improvements in patient care. We want them to be consistent with the other reporting systems and not add unnecessary burden. So there are now many, many quality measurement reporting requirements on providers and from local, private sector, public sector, federal agencies. We are trying hard to harmonize these requirements, but at the same time move them forward in a direction supported by the policy goals we all share.

We would like the methodology we develop here to be consistent with both HHS and private and public sector strategic directions. So we're all very sensitized to what's in the Affordable Care Act. The National Quality Strategy was recently released, and that gives some broad guidance to many of the federal programs. We want to be consistent with that. Recently the Accountable Care Organization Regulations came out with 65 quality measures, so we're trying to keep our eye on that. Some of you may be aware that the health insurance exchanges, not information exchanges, but the insurance exchanges will have a quality reporting requirement in them. That's not yet been developed, but we're trying to anticipate that meaningful use is one of many strategies to provide more data and we want to have these all work together in harmony and drive a constructive agenda.

Our process over the last six months, we've had quite a bit of input, including a call for public comment in which more than 100 organizations responded and provided us with about 500 measures that could be used to populate this framework. We also had a public hearing a few weeks ago to get input on what the experience to date has been with stage one quality measurement reporting, and just to flag a few of the things we heard there from our public outreach, and it certainly shapes the kind of proposal we're making to you today. We don't need more measures; nobody was enthusiastic about more measures, they were interested in better measures. So we are trying not to simply extend the very long list of measures that are familiar, but instead focus our light on things which will really add value to the decisions that providers, consumers, and purchasers have to make. Specialists have not felt well represented in the model to date. So we want to get some thought to how we make sure that specialists who are eligible to participate in the program have quality measures which speak to their competency and their professional responsibility.

The alignment of measure, as much as we aspire to keep these systems aligned, isn't working out yet. So if someone reported to us that they may have to report certain measures for PQRI, now called PQRS, and for meaningful use, but the specs are slightly different. So we have a responsibility to get as close to identical as we can where we're really measuring the same type of concept. It's not yet clear how many providers we'll be able to satisfy the core measures in stage one. So you recall we have a set of three core measures and if it turns out that a lot of meaningful users can't even meet what we define as a very small core, we really have to question whether that model is working, let alone that we could expand upon it.

We heard from consumers, payers, policy makers, and purchasers that we really have to give attention to the new domains that are policy relevant: care coordination, patient engagement, patient safety, efficiency, so that again, adding more process measures to our already moderately robust list was not the priority that we heard from the community. Then finally we heard from vendors that it's proven to be difficult to code new specifications for new measures, and that the platforms that many of them are using are not very flexible. We can't just come up with a new measure and expect the vendors to fairly trivially bring that into their product. So we have to be very thoughtful about either giving a lot of advance notice, or building flexible requirements into the measurement strategy we put forward.

So finally, I think we came away from all that wanting a measurement set that has ... to our various stakeholders that is understandable, that's meaningful, obviously. We want those people affected by the measures, those who are reporting the measures, the eligible professionals in particular, to feel like they can see themselves in the measurement set, that this is not an externally imposed peculiar, federal obligation, but it reflects what they believe to be their professional obligations and goals.

We noted that in the final rule from stage one, CMS, though they specifically withdrew the structure of having specialty reporting menus, did say that in stage two they would bring them back. So we actually have a signal from CMS that the specialty reporting menu structure will come back once we figure out how to populate it. So we certainly took that as one of our charges and challenges. I think we want to send a signal to the community, including the vendor community of what's coming. So we want to give a framework now for measures. Now we have a couple of years of experience with it that is durable, and that people will feel like this will be around for a few years and there won't be big structural surprises to it. So that's the context with the background, and with that I think I can take you through the specifics of what we're proposing here.

This is a modification of what I brought to you last month, and where once you saw a disc like this with five pie shaped pie pieces in it, it now hit six. Essentially the reason for this is after much discussion in our committee, we decided to add a category—and these may be deserve to be renamed, but one that here is clinical process. The fear was that a lot of the measures that have been in play for quite a while that are in the re-tooled 113 measures we've seen before, or in the PQRI system that you've seen before, could be categorized into these other policy relevant categories, like patient and family engagement, or efficiency or patient safety. But not really achieve the goal of meaningfulness that we've aspired to. So we needed a place to put a lot of very useful clinical measures that many of the societies and others feel are valuable, so that you can see yourself in that category. If I am an endocrinologist or a plastic surgeon or a primary care physician, I want to be able to go to this menu of measures and see my area of practice visibly there. So this will allow us to do that as you'll see shortly. The other five areas we talked about before, and these are the same ones that our tiger teams have been working on for quite some time.

So in this proposal there would be a small core, and essentially we are continuing, and in a modest way expanding upon the old core, the stage one core, and then we are creating six menus from which each eligible professional and hospital would pick. Now just to reaffirm or assure you that this is not an eccentric proposal, you'll see that the National Quality Strategy that HHS has adopted and that many of the other programs are using as their template, maps very nicely to the six categories that you saw in the last slide. So we will be capturing or asking providers to capture a clinical quality measurement in each of the six areas that have been determined to be of public importance and public interest.

So the basic approach we're recommending here, and we'd like your support for, is first that we do maintain a core, but we add additional measures to it; you'll see that in a moment. Second, that we maintain the concept of the menu and we add measures to it. Third, that that new menu set now includes six domain areas or six little menus comprising the overall structure. Providers would pick some measures from the core list; they would also then have to pick measures from the menu list. The exact thresholds or numbers of how many measures from each bucket is not something we are yet feeling strongly about; that's the fair subject for discussion. We would assume that providers would need to pick some number of measures from the core, and at least one from each of the domain areas.

So here's an illustration of how this might look to a primary care doctor. We actually did a series of storyboards like this for half a dozen different specialty practice areas to see how this model might play out, and obviously, we can share that with anybody who's interested. But here is set of now you see eight measures comprising a hypothetical core; six of them are measures that have been around for a while, and two of them are in development now, under support from CMS and ONC. So these are not yet specified, and of course they may or may not ultimately be successful and accepted by the process, but we expect that they will be. So in this scenario there would be eight core measures and a menu of core measures of which, in this example, a primary care doctor would have to choose five measures out of the eight to report, and the diamonds you see on this menu here are the ones that this Dr. James, hypothetically chose to report. So this is a core, but it has some flexibility to it. Now as you recall last time we had to have an alternate core to achieve similar kinds of flexibility so this is just a different representation of the similar kind of flexibility and in part, responding to what we believe is the difficulty many specialists are having in satisfying the core as we initially proposed it in stage one.

Then in this next listing, here on the pink columns on the right side of the slide you see the six categories of measures. Now in this example Dr. James is only picking one measure in each of the six categories going down the list. You could imagine this being displayed and presented differently, perhaps under patient and family engagement. There are four measures that a primary care doctor might want to consider of which only one would he or she actually choose, perhaps under care coordination. There are six measures, they may choose only one of those six, etc. But in this case Dr. James actually selected one from each of these available menus and constructed his or her own little menu.

So we think the advantage of this approach is that we would begin to give all the participating users a requirement that they have to address our six domains at least to some small degree. That they can't construct a menu for themselves, which omits any attention to care coordination, patient engagement, or whatever might be that may seem more difficult for them. The burden on us, and ONC in particular, will be to make sure there are ample measures in each category so that providers can find themselves on this diagram. We're just beginning the work of populating these to see if we can satisfactorily build out enough menus with enough content that everybody can find themselves on there.

I'll just say as a footnote that many of the re-tool measures we talked about with you before show up in the clinical process column. So probably you'd have a much more robust set of opportunities to choose measures from that column within your own specialty, and there's going to be frankly a shorter menu in the other categories.

So just to conclude our recommendations to you today, we've mentioned some of these to you in the past and we've done a little more vetting on these, and now we've narrowed this down to a set of five topics we believe need some attention in the next several six to twelve months, depending. In order to populate the kinds of measures that we think policy requires, we need to do some ground work on methodology. So we'd ask the Standards Committee in many of these cases to do some additional work and come back to us as soon as is reasonable with recommendations that can guide ONC and CMS in selecting actual measures for use on those menus I just showed you. So again, the food chain here is, we have policy objectives, those policy objectives dictate a new kind of area of measurement, except we don't have a lot of measures in some of those areas, and one of the constraints is not having answered some methodology challenges. Conversely, a lot of the methods that have been widely accepted only apply to the clinical process measurement area. So we have a little bit of a self-perpetuating pattern we have to break out of, and this set of research and methodology work might help us get out of that pattern.

So the five or so areas we think we need some additional work. First is capturing patient reported data. Many of our new measures would come from the patient or caregivers. One of the things we need to do is make sure we tag the data so that when that data from a patient or caregiver or someone else is available in the EHR, it's visible to the health professional that that's where the data came from. That doesn't imply a judgment, just implies representing the sources of data and this same logic could apply to many other data sources, as well as data that comes directly from a patient. So that's something that's been discussed for some time. I think we now need a standard for that. Some of the other data items like the race ethnicity language and gender information is something we have talked earlier about needing standards for ... sharing that information. Standards for patient experience data and for home devices—there are standards out there, I don't know that we have brought them into our fold and accepted them.

The second methodology area of great interest, especially looking more toward outcome measures, is the delta measures, measuring a change in a status over time. So whether someone before and after an intervention has improved their symptoms that are functioning, or whether a measure like blood pressure has increased its control over time. So we don't have—there are many methodology issues wrapped around that that we need to get progress on. We need standards to be agreed upon for problem lists, and actually the Standards Committee's working on that already this week—have been working on the problem list harmonization and standardization.

Capacity and scalability of EHR's is partly meeting to work with the vendor community to see that the EHR products understand the future pipeline of measures, and that the computational and data aggregation capability is there. So measures can't be an afterthought, they have to be anticipated in the product development of the vendor community. A complimentary question to that is what should not be done in the product level, but should be done by some aggregation layer, whether it's an HIE, a third party vendor, federal agency. Who does the computation and aggregation of data that comes from multiple EHR's to compute a quality measure.

Then finally attribution is, of course, becoming an important policy question around ACO's and other models. We had a similar question in this more pluralistic environment, which providers should be attributed to a particular quality measure on these additional methodological work. So we would like your support in taking this list of methodology tasks and handing them off to the appropriate parties for further work as a policy requirement that we all share.

So to summarize, we're coming to you hoping for a recommendation regarding the framework, the core plus six domains, and some guidance as to how to set requirements around reporting against those. Secondly, with this very brief summary, which will be more fully reflected in the transmittal letter, on acceptance of the types of measures that will populate each domain and then thirdly, recommendation to refer this list of methodology issues to the appropriate other standards and advisory bodies. Thank you Paul.

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

Thank you. Questions, comments? Gayle?

**Gayle Harrell – Florida – House of Representatives**

I certainly would like to thank you for addressing and looking at the specials list and the flexibility that needs to be really developed within those core measures. They need the opportunity to be able to become part of this whole endeavor that we're embarking upon, so I think that's an excellent direction that I see you going and I hope that that continues. As far a clinical processes go I think that's certainly a tremendous addition.

**Unidentified Speaker**

David, do you want to comment on the timeline and how it fits with stage two versus stage three, and then for the methodologic issues; is there a sense of priority just because there's so many things you can do and only so much you can accomplish in a short period of time?

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

I think those two questions are very nicely related and certainly Josh may be able to give more light on the timeline. I think one of our challenges is the newer measures, some of which we think would really help populate those menus, we don't know if they'll be ready in time for stage two. We're going to hope that they are, we're going to encourage development and testing and endorsement, but we don't know. So I think what's likely is there'll be some lower hanging fruit that are pretty well—for example, patient experience measures we've all had a lot of experience with, and they should certainly be specifiable in time to be available. Some of the others—let's say the delta measures for blood pressure control, maybe not. So on the other hand, I think if we get guidance quickly on the delta measures framing for a couple of the most high visibility measures, for example, blood pressure control over time, it may be worth taking one or two exemplar measures, asking a methodology group to see if those are easily solved. Then they could be available for stage two. So there's an interaction between our judgment of what's low hanging fruit, what the methodologist can do quickly, and then the endorsement process.

Josh, ... more on timing.

**Josh Seidman – ONC**

Well I guess I'd just say that part of the idea here is to identify where we can methodological issues that have an impact on potential functionalities, so that that can be part of what we're working on as we work on the development of the NPRM. So for example, the first one patient reported data—that obviously has significant implications for developers and providers and so forth. So that's a set of issues that, if we think this is potentially on the table for stage two to sort of get ONC and CMS thinking about the standard certification criteria and the meaningful use rule and what issues would need to be addressed in the rules. The goal is really to get measure definitions—numerators, denominators into the NPRM the same way it was in stage one with actual XML electronic specs by the final role.

**Unidentified Speaker**

I support and encourage some of the statements you made because this is a really great presentation and great summary of some work. I'd like to say that we don't need more measures, we need better measures. And particularly the observation that alignment hasn't really been fully work out yet, and this is not just an ONC issue, this is a general federal issue, legislative issue, I mean there's a lot of mandates creating quality reporting with inconsistent measures. So putting that front and center and highlighting the ones where there is a conflict, and getting some attention on those would be really great. So I really encourage the work, I think it's a great step forward and the feedback you're getting sounds like it's right on.

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

Well, great. Judy.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

David you mentioned that ample number of measures per menu. I just wanted to comment that the Electronic Health Record Association's members have said that if there are quite a number of measures, and it looks like that's the plan, that it would take them about 18 months to test and validate them. So I wanted to at least present that to be considered as you factor in a number of measures and time available.

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

Any other comments? Christine?

**Christine Bechtel – National Partnership for Women & Families – VP**

So I really—

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

Would you like me to clarify that. ... to Judy's point is that I think it would be aligned with the proposals that you had with delaying stage two, one year was that extra time would give the vendors to actually do

the development for developing the logic codes and developing the computational codes for those measures. It will also allow the measure developers and also NQF to think about the robust testing methodology to go out to the field and test the implementation of these measures. In measures, that work in a sense is pretty well defined right now.

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

Okay, Christine?

**Christine Bechtel – National Partnership for Women & Families – VP**

So I think this is really great work David. I really like the categorize menu and approach. I really liked the addition of the clinical process category, and I think the category consults are really a nice match to the National Quality Strategy, so I think it's terrific. My question is whether or not you would expect that the measures in the core would evolve at all, because as I look at them, they do look primarily to be all process measures. I'm wondering if you expect that they would evolve at all to be any more outcomes oriented for either stage two or in the future?

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

I don't know. I personally tend to think the cores are relatively short life span concept that a little bit, as David in the previous discussion we had about the care plans. There's going to be more specialization of competency and it'll be hard across a broad range of settings and provider types to have a core that works for lots of people, but that could be wrong. I suspect we'll continue to hear some pushback, but there's so many elements or the meaningful user community for whom its heart conformed to a core.

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

David?

**David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine**

I really like this overall as well. I just want to push back a little bit against the notion that we are not eventually going to need more measures, that we can do with better measures. I think eventually we're going to have more measures. If we want to really have a complete picture of quality, I think it will take a lot of measures. I am really sympathetic to the pace issue, because for each one that you added it's a lot of work and we add them up too rapidly. I do think it's also really important to get to the outcomes part of things, and I was going to make that point too. We're not ready to do that yet, but we need to be thinking about that soon or I think people will be disappointed.

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

Very good. Okay, then you're looking for endorsement of this approach I think, is that correct? I think you're getting the sense from other group that's spoken that this is a good approach and get on with it and hurry up. No, I think this is super and this is the thing that's going to outlast all at meaningful use in terms of every incentive program and really be the driver for not only quality, but a better quality of life. Thank you very much.

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

I want to thank the committee members who've been working hard on this and the staff that's done a really wonderful job inventing and designing this as its played out, so thanks to all of them too.

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

And we're back on time. Okay, we're next going to hear from the Certification Adoption Workgroup—an update on their findings for the usability hearing.

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

So it's good to be back here, one month later with an updated summary for the committee. Mark has asked that I carry the ball on this, he's sort of doing a ping pong ball adventure today, so he's already on his flight. So the first piece should be a big thank you to all the members of the workgroup. This has really been an interesting and engaged month of what did we learn from the hearings, what do we think about what they mean, and how do we go forward from here.

What we're going to be presenting here—and there's an attached letter that I'm not going to walking us through on the slides, and I'm actually not planning to walk through everything in the letter, but it represents the summary of what we heard at the hearing. It contains suggestions not recommendations. The reason we're doing that is our sense was that there was a wide variance in what we heard, based on the perspective of the people speaking, and that there probably needs to be some clarification brought how we're using concepts like usability that they're very broad in some ways, and also can be very narrowly focused in other ways. Depending upon which definition people are using, or what perspective they have, we heard some very different things.

Another piece that's really clear about usability is that there are many inner-connective factors. I was at the NIST event yesterday—the workshop on building community, and it was encouraging to know that there've been people working on this for a long time. Not just in the EHR context, but broadly for information systems and usability, and that there are some frameworks out there. So it seems like maybe we could work on actually applying one of those more closely to what we're trying to do here, and it would help make sense of the various things that we heard.

Finally that this is a community journey that involves sort of all of the stakeholders that we've been talking about for all of our other activities, so this is not something a vendor can do in isolation. It's not something a provider does simply by training a user on how to use a screen. It's something that involves patients and their other caregivers as well, so it's a very broad based thing to get broad measures on usability.

So having said that, a quick recap; these were the panels that we had covering what felt like a pretty broad view of folks who were involved with the HR's. We also had a blog that got a fair amount of response. I was pleasantly surprised to see that there were over 30 comments made on the blog, so that seems to be an effective way to actually get an input into this process.

It's sort of interesting, at the NIS meeting I think that this quote was up on the screen at least five times during the day. What was helpful to me was to finally track it down and put it on the slide, and then pull out some things about specified users, specified goals, and specified context of use because I think that working more closely with those three elements actually would simplify and clean up a lot of confusion and discrepancies that we were hearing. Who are the users we're talking about? So if the users and everyone who interacts with, or potentially interacts with the EHR, is a pretty broad definition. So if someone is speaking specifically about a patient interacting with their view of the chart, that's an important user, but they're going to have different concerns perhaps as a more casual user. Not that they're use is casual, but their frequency of use may be a lot lower than someone who is spending eight hours a day interacting within EHR. So we're going to have many different qualities around who the users are.

What are the goals we're trying to accomplish? Is this about—sort of going back to the circle of measures that was just up on the screen, you could look at all of those and say those are relevant goals that we think usability can have an impact on. But if we don't sort of focus on those particular goals, we're not going to be able to actually get to a common understanding about what we mean by usability and what we're trying to measure.

Context for use: So this is everything from sort of the physical set up of how the information is being served up. Is this provider and a patient looking at a tablet together at a bedside? We heard examples of clinicians with big dual panel computer set-ups, so it's overall extremes. Is this something I'm reading on my mobile device because I just got paged in transit and I want to see more of what's happening, so many different context for use.

We sort of heard two themes going through here about, are we looking at the outcomes of improved usability and or are we looking at the attributes of usability. Once you say it, it's obvious that that they're different thinking's, but in a lot of the conversation they were blended together. I guess I would say that first one increased safety seems to be an actual theme that I think there's beginning to be some ...

around. That was part of the NIST work as well. That they're specifically looking at work that addresses improving safety and reducing human errors related to using the EHR as part of providing care.

There are seven sections in the sort of details of the letter. These all struck us as important themes that we were hearing, and you sort of see how this is not themselves a framework. This is a laundry list of things. Multiplicity of systems: So this is everything from all the ways in which an individual, whether they're a patient, a provider, some supporting individual—it could be a payer doing case management. It could be a caregiver trying to make sense of someone's care that they're trying to help with—that many people are involved with, many, many systems, so we have some examples in there.

Another piece that's not specifically highlighted in the document that came up during the meeting is team-base care. That this could be people working together with the patient, one of whom is—and I hate to use the word scribe, because they're more than a scribe. Someone who's sort of an enhanced clinical facilitator who's interacting with the computer and compensating if you will, for deficiencies in the system, but is acting on behalf of say a physician having a live interaction with a patient. That there's like a dual sign-on of some kind that's happening, so if the doc isn't separately signing everything later.

Standards versus guidelines: So there was a really be emphasis yesterday, actually at NIST on guidelines as opposed to tight standards. So that's the theme that we wanted to convey as well. That that seemed to be consistent with what we were hearing. That developing things like a library of icons so that we actually—when you see a particular thing on the screen, that you know what it is without having to click on it and see what it does. The confirm what I want to do, as opposed to go on to the next thing, but throw away what I've done, because it's not finished or it's not right—there were examples of confusion about that, so terminology guidelines as well. We don't have specific recommendations here, just that these feel like we could tighten things up.

Physician/patient interaction: So it was pointed out to me that while the example in the write-up is that of a physician and patient interaction and that this really needs to be seen much more broadly of any caregiver and patient and patient advocates, patient caregivers working together. That getting the interaction right is, if you will, a new clinical skill. Sometimes it's been described as a new kind of bedside manner, sometimes it's just how do you interact with the computer system so that you're doing more—we don't want to see behavior of clinician turning their back to the patient and spending all their time interacting with the computer and talking to the screen while the patient's behind them. We don't want to encourage that, we want to find ways to address that.

We heard issues about cognitive load so it's not necessarily doing a task in isolation; can you put this order in, but it might be an order to put this order in; I need to look at three or four data points. If the computer system brings those all together on one screen for me, then I can actually compare it, look at trends. A powerful example given yesterday was the growth chart example. That one of the powers of the growth chart is it has both height and weight on a graph together so you can watch the progression together, and that it has the ranges so you can see what percentile an individual's in at the same time you're looking at their own path. So they could still be within normal for height, but they've fallen off a curve they were on. They used to be tracking low and suddenly they're high. They used to be tracking high and suddenly they're low. So a lot of important feedback that you would get from a well-designed tool like growth chart that the various computer systems have tended to pull apart. So they show you height on one screen and weight on another screen, but you need to see the two graphs together to diagnose certain conditions. Bringing those back together would be a very powerful thing and reduce not only cognitive load, but the ability of a physician to diagnose what's happening.

Abilities and disabilities: Whether it's visual acuity, color, perception, the ability to hear and speak—I mean lots of things that are being built into the systems, and how do you support people who don't have that full skill-set or perception capability to still be able to participate in the healthcare process. It was sort of interesting going into NIST, we were joking about the presence of the standards world and what we were walking into. So the administration building has these great set of steps going up to it, and we're walking going, well where's the ramp? Oh, well there's the ramp. It's like well, okay it's there, it looks

usable, it meets the standard, but it is certainly not universal design. If you were ever confined to a wheelchair, you would certainly feel like you were going way out of your way to make use of this.

System configuration: so building these systems as we've been discussing is a complex process. We go through the kind of functional design discussions we've been having earlier today that get embedded into products, and those products get tested. So we go through a test cycle, both inside the vendor and with the certification process. Now we show up at a site and we're installing this system. In order to install it we need to configure things. The configuration process is essential—can't do without it, because it's got to manage the workflow of this organization. It has to embed their standards for the test and treatments that are available, their protocols for doing things. But in doing that, we're actually changing the behavior of the system. So we may be improving usability or worsening usability as we go through the configuration process. We have examples that were—lots of anecdotes of some customers with the same system do amazingly well with it, and other customers with the same system do really poorly with it. So it's not just a system characteristic. Again, this is not just what's inside the computer screen, so it may be as much about the physical configuration that makes it successful. It might be the use of a change in care process and what provider is doing a function that make it more successful than another.

Impactive regulation on usability; testing and measuring usability: so this is not that we should put in place regulations for testing. The discussion here is that the regulations, by creating additional requirements in the EHR's may be creating usability problems, where one example is extending an answer set. So maybe there used to be a simple answer for smoking—currently smoking pack-years, maybe that was it. Now we have a much richer set of questions and answers about smoking, and we're talking about adding more for secondhand smoke, so the smoking part just became bigger. The user interaction of now how do I find the right answer became bigger. If we look at things like the demographic choices that are being considered for extending to ethnography, so we have a list of hundreds of answers and people who have mixed heritage may need to pick multiples of those.

So the style of interaction is going to change and what the systems have to do to support that is going to change. Things that used to work as a simple pick list or menu option suddenly become a search problem. The regulations can be changing the whole interaction style, and they could also be increasing usability. If we look at automated med administration, when that's done well, it should be a great increase to both safety and usability. If it's done poorly, it's going to be a huge usability problem. It may do great on safety, but maybe a huge usability problem of what is it I'm bar-coding, and can I find the bar-code, and is my scanner working. Is the packaging for the med sufficiently sized so I can scan it and hold it at the same time—I mean lots of details that need that need to be got right to make things work well.

The other piece that on testing and measuring usability, which was clear at the NIST meeting, is there is a lot of effort that's already gone into testing. NIST likes to point out that they're over 100 years old, so this is not a new thing that we're doing. There's a long history of doing testing and having it improve results, so I think there's a lot to be learned. I was very encouraged at the NIST meeting on the desire to build a community and bring this forward; HIMSS has already done a lot of work to do that. NIST is looking to also build an open community and move this forward, so it looks like a lot of people are coming together and recognizing the importance of this.

Okay, questions, comments? I think I'm done, right? I'm done. Oh, one more. Okay. It's important.

The sense is that we really need to start to figure out what the key use cases are. So all of this is very broad, very general; if we don't start to get concrete, we'll never move it forward, so let's do that. Let's start to learn where are the key use cases and where can we actually make a difference, and that will then give us a context for measuring usability. So let's not create an artificial measure of, you test really well, this car is really safe except on the highway. We don't want one of those situations to happen.

The notion of being able to develop guidelines for providers so that this is not just a technical capability of the system, but something that the RECs may be taking on, and others in industry may take one for, of how do you in fact get high value and high usability out of these tools. And that we should be looking at the effect on regulations. Given sort of the dual unknowns—you're introducing a new reg, there are

many, many ways it could be implemented, and the system's already in place could be doing things very differently. So given those two sets of unknowns, I don't think we could do a real effective assessment of the impact of a regulation on usability, but that we should start to consider that as we write the regs as one more factor to bring into play.

Okay, I guess now I'm done, ... I open for public comment yet. Paul?

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

Thanks a lot Larry. I just wanted to say that we should be all thanking Larry. You've done a terrific job in leading this whole group. I mean this is a very important area, and your leadership has been terrific, and I just wanted to say that.

I also wanted to comment on actually the very last thing on your slide where you said the effective regulations is you sort of bringing this discussion back to the discussion we had this morning, which seems like you mentioned being 100 years old. This is like seems like 100 years ago, but it was actually just a few hours ago, and we were passing through all these like stage two meaningful use concepts. Those all have usability impact. A lot of those issues, even the quality discussion that we just had, I mean physicians have to enter data differently. That all has a usability impact and that could be some of the issues or one of the issues like physicians, clinicians are pushing back. That basically even considering what Judy said this morning where the physician seemed like he or she was too busy to speak with her. Basically we're asking people who are under a lot of stress, who are doing a lot of different things, to constantly enter more data. It's hard to know what they define, what the user are defining as usability. People say, well what is the goal? Maybe the goal is to take care of the patient, in which case that at some point there's a frustration with how these systems work.

**Unidentified Speaker**

A very good point. Before we go to the next comments to, I want to mention that Farzad Mostashari's on the line now with us as well. Farzad, do you have any comments now? We're finishing up our last presentation on usability and then maybe you want to make your opening comments towards the end? You might be on mute. Alright, we'll check back, but any rate, Neil?

**Neil Calman – Institute for Family Health – President & Cofounder**

Yes. I really too think this is a really important piece, and it's something that we don't pay enough attention to. What I don't want to see is us sort of thinking about this as something that should sort of slow us down. But I do think we have to sort of examine one of the biggest factors that we've had in our practice is the extent to which the computer alerts reminders and requirements of whether their meaningful use or other things. Sort of create what I call the provider agenda, rather than the patient agenda; so the patient comes in with one set of concerns and things start firing off and we're asking them all these questions that are being prompted by the computer and prompted by requirements.

They're all important things. We want to ask about smoking and we think these things are important, but they drive an agenda for the patient that's different than the agenda that they came into the room with. I think one of the things that we've ignored is sort of setting the expectations for the public. Somehow I think we need to figure out what ONC's responsibility is here and others about trying to sort of explain to the public what's happening in this transition to the electronic environment. That these are good things that are happening, that people are being reminded that providers are working in a safer environment, that the things that are popping up on screens are safety.

We also have to teach our residents and our providers how to deal in this environment, which is a whole curriculum area that most of us haven't developed at. The people coming out of medical schools now that are starting at a residency program have not one inch more clue about this than I had, and yet they're walking out of medical school into an electronic environment, but nobody's really talked about these things. So I guess my really is that rather than see these as impediments, they create a whole new area that we need to explore and work on so that we don't end up negatively impacting on the patient experience while we're doing all of these things that we believe in, because they improve quality.

**Unidentified Speaker**

David Bates?

**David Bates – Brigham and Women’s Hospital – Chief, Div. Internal Medicine**

I'm the best big believer in usability, but I think we can get all this coded data in ways that do not affect usability if the right bases are touched. It's also not good for providers to enter a lot of free text, and then at the end of the year you want to get a report back about what happened with—how many smokers you have, or you don't. If you do it as free text, that just does not take you where you want to go. In our record, I already do this all the time, every day, it works fine and there are not problems with it. This is something that is a ... problem and vendors clearly need to work on it, and not all of them have figured it out.

What providers really don't want is to be asked things that somebody else can do. Or is that the computer already knows, and there are many instances in which the software can just take care of that for you. A lot of the medical home movement is about having everybody practice at the top of their license and do the things that only they can do. It's very likely the way things will work in the future is your practice assistant maybe will ask the patient if they're smoking, and you might not even have to do that unless they are smoking today. I think these problems are manageable, the usability testing I think has to go to the vendors largely.

**Unidentified Speaker**

Judy.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Well Larry I thought you did a great job with the ... all the nuances that are involved with this. I thought Paul, you were very astute in what is going on and what are the things we really need to do. I'm going to push back a little with you, Neil, there and that is that I think it's good to have this alerts. But when in fact I end up going to several doctors and several nurses see me, and each one asks—and they don't have to I think, but there they are in front of them. And that's not usability often, that is as you said, maybe the way they set it up, or maybe it is regulations, but their asking me smoking ones. I don't even get a chance to say what's on my mind. I think we have to respect the patient's knowledge of where the patient feels he or she may have a problem, that can't ... get brought up, because there's no time to bring it up in that period of time because they're too busy going over all those questions.

So I think we have to consider, what is our role here. Are we going back to—and what is the HIT Policy Committee's role and I think of it, in stride of that I thought one part of it was economy and jobs, and getting things moving. Another part was improve healthcare. Also, if we're going to do that, we have to make sure that the software—you can't just give the money for any use of software, for any software. It's got to be reasonable software, and people have to have reasonable use of it. But, have we moved into our role is really to change healthcare for the future and make sure it's better in our definition, and then as the vendors, who would have normally taken input for hundreds of thousands of clinicians can no longer do that because instead we're taking input from a smaller group, some clinicians, some not. Are we losing the baby with the bath water?

So I'm putting both issues out. I as the patient, if not able within the timeframes allowed, to get my own, which I think is reasonably astute; what's bothering me, to the doctor. Also, are we causing some of this in our desire to go what may be beyond what we were supposed to have done originally?

**Unidentified Speaker**

Are you posing it as comments or are you—?

**Judy Murphy – Aurora Health Care – Vice President of Applications**

It's a comment just for people to keep in mind.

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

Actually I want to jump in and one of the things that impressed me in the discussions yesterday at NIST was how much they're putting this forward as a process. So while there were some specific things brought up, some examples for example in the U.K. where they're actually looking to describe screen layout, when you identify a patient, these are the fields that should be there. That that was not the substance of the most of the discussion, but much more of a process of what are these cases that we're looking to measure? Which ones are high value, how do we measure them, how do we build that measurement into our processes, how do we learn from it? So to Judy's point, it's not to exclude the experience of the hundreds of thousands of users, but to find a way to actually build on the experience of hundreds of thousands of users.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

... meaningful use requirements and the times that the vendors are going to spend doing the 100 reports and all those things, what time is this? So normally what vendors will have is lots of different meetings. They'll have separate committees for OR, for nursing, for this, for that, and get the input from all those folks. Where's the time to do it then?

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

So I guess what I'm hearing you say is, it's not about our learning and understanding usability and heading down a road of improving usability. But it's the impact that the timelines are creating when we roll out meaningful use requirements that normally would have taken a very long development cycle because they're collecting a lot of input from a lot of users and trying things and getting feedback from the trial, but that's all being—

**Judy Murphy – Aurora Health Care – Vice President of Applications**

It's all the things that we can't do because we're busy doing this and who is there listening to the feedback and all those separate focus groups of what people need and saying, oh, is this more important or less important than what we're saying here? Then from the patient's point of view, it is all the things that come up for the doctor or the nurse that again say, which are the more important, those things that have to go down, or how do you feel patient?

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

So I guess what I'm hearing more is an extension of this effective regulations. The things that we put in place are having a lot of secondary effects.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

Yes, I think that's what it is. It's not that they're bad, it's that it's always a choice, it's always priorities, and are we doing the right things with those priorities with a much smaller group.

**Unidentified Speaker**

David Lansky.

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

Thanks Larry. ... really valuable, and important, and helpful to hear. I too—a comment and question, I guess. The comment is kind of how do we avoid being in the rearview mirror comment given the long development time of these interfaces and design work. So if we think out three years or five years to where the next generation of products will be, and take into account what we've heard and have been studying—I think about if I ask the broad question where will data be manifested to users five years from now—clinical users, patients, care givers, other types of users. It seems like there's a whole set of usability questions for each of those user types and settings, and we're obviously speculating how many people are going to be floating around in their jetpacks providing care. But I think there's another level of usability work that we should start talking about in our context to think about the other mobile home based other caregiver kind of environments besides the one we sometimes focus on.

The second question, I guess, is really a policy issue for us, which is the broad question is what's the appropriate role of government in thinking about software usability generally. Obviously, the area of patient safety is one that seems closure to our heart and our appropriate role and a lot of other areas we

assume that the market will work to drive traffic and volume toward higher—greater usability products, and it will disfavor other products. There may be some issues around legacy investments, which make that less true in the case of big infrastructure investments like these.

But I think it's worth us coming to some clarity about what we think our role is as a policy group sort of messing with the market when it comes to these questions of usability. Or conversely how can we create an environment which simulates successful innovation and usability recognizing some of the peculiar characteristics of this marketplace but also keeps a light touch in terms of the government's ability to guess at what makes good or bad usability. I think in general we want to stay away from that if we think markets will generally work to reward success and innovation in this space but was there are sense from your work up to this point of what the appropriate role of government is and what it really isn't in this domain?

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

So I think there are probably two different threads of answers to that. One is the clear innovation that's happening in the last few years in the consumer space on interfaces, and that's clearly also spilling over onto the EHR space and not wanting to slow down that innovation. It looks like it's actually getting us through some usability problems of the past, so let's not slow that down. Let's look at things that will actually highlight where success is, but there also is a persistent undertone of not all systems, not all implementations, not all providers are doing a good job and that there's a lot of variability out there.

That, in fact, examples keep surfacing of issues that when you see them you go that's a turn the system off issue. If you have a problem converting units from kilograms to pounds and you're not doing it consistently, you can't trust any weight in the system. You certainly can't do dose calculations based on weight and not expect to occasionally get into big trouble so where people surface those they go that's not a usability issue that's a core system safety issue and if that's what's going on we need to turn it off. It's better to have no computer than have one that's that erroneous, that inconsistent. So I think that the safety issues, not just the bug issues but the safety issues broadly about, it's not clear what's on the screen, some of Texas cutoff, fields run together.

I mean I don't have to tell you examples to give where I go, ah, that will drive the solution to this problem but I feel like the safety issues need to be addressed and that there needs to be a floor, and I don't know how to get that floor. I haven't seen a suggestion yet that said, "Ah, this is how we're going to get a good floor on where the safety issues are." But I think we do need to start figuring that out and that the safety issues are not just usability safety issues, they're safety issues. It may have to be part of a bigger safety push than just a IT safety push, but we do need to get a handle on that because it doesn't take to many bad examples for people to go, "EHRs aren't safe," and to lose more than the baby with the bath water, you lose the whole population of babies here.

### **Unidentified Speaker**

Charles?

### **Charles Kennedy – WellPoint – VP for Health IT**

I'm on the workgroup and participated in a couple of the meetings and I think we've tended to define usability in, I guess, maybe a traditional sense or maybe perhaps a somewhat narrow sense because when you look at for instance physicians having to do all that data entry there are opportunities to leverage that data and actually eliminate processes. I'm thinking about authorizations that health plans require. I think somehow we may be missing some of those value propositions in the way we've looked at usability to date but really might help some physicians say, "This helps me deal with having to do all this data entry because I know this other processes are eliminated or I no longer have to deal with down the line."

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

I think to that point, Charles, yesterday one of the NIST models was that you may in fact change workflow and not just reduce the doc's load by 5% or 10% but shift it so that the overall load is reduced by 10% but the doc's load might be reduced by 60%. I think the opportunities for data reuse are huge, and as we get more structured data, they should start popping up right and left.

### **Paul Tang**

And I have another comment that piggybacks on that. I'm often in search of elegant solutions where you're going to remove/resolve a problem and create better outcomes. I think, one of the biggest most time consuming things in using EHR and impact on productivity is the text entry, and ironically the tools that are built to try to solve this problem actually create a decrement in the value of the notes themselves because of the use of templates so we've almost made a problem worse. It takes more time and you get less quality, and this is in the context of us going towards a system that doesn't reward volume anymore and measurements.

So the documentation is driven by the payment criteria that are constructed to pay for transactions and how do you qualified transactions as payable? If we're going to a world where we're really focused on delivering outcomes and measuring those one would think that you could decrease the attention on documentation, which as a twofer would decrease the workload of the physicians and all of these unintended side effects that are actually decreasing the value of the text itself. So I wonder what—this came up, actually, I think, it was in our specialist hearing where the last panel talked about experience. I think that's where it's from if I'm remembering correctly. So there might be an opportunity where CMS could interject some changes and as we move towards a non-transaction based reimbursement system could we loosen up the documentation requirements, which actually is a big part of our loss in productivity and a big part of the usability issues with EHR. It might be one of those just positions of opportunities that allow us to make that. I don't know whether that's within the scope but it could be in the context of the usability of EHRs.

Any other final comments on the usability issue? So your next action then, Larry you're proposing, are to continue some of this work or look at the processes that you talk about in NIST or—?

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

Yes, so I hate to say we didn't come here with our action list but we were really looking for feedback and guidance both from the committee and from ONC. It felt like without me needing to get more into the details and actually move forward on this that we couldn't offer anything much stronger than what is in this letter. So, for example, if safety is an issue the workgroup could continue to look at so how do we bridge that? We've brought up safety in the past as well so maybe we should look at safety and usability and find some use cases that seem like they would be kind of landmark use cases that we could start to build some usability testing around, maybe get some consensus on how you'd approach that. I'm very sensitive to Judy's comment. We don't want to throw away the experience of our hundreds of thousands, soon to be millions, of users. How do we build in real feedback of what's important to fix? So—

### **Judy Murphy – Aurora Health Care – Vice President of Applications**

... I think the development is really three different stages so the ones just where you're talking about its safety, it's regulations, it's meaningful use, that's ground zero. Above that is the needs of all those hundreds of thousands of users but I wanted to add the one level above that. That is all the experimentation and there's time to do really nifty things that will become the future. That's what we want to also preserve, not just the feedback of the physicians but the playing around with—if those are the right words—the things that are going to be here in 10 to 20 years. Maybe it's just your control, maybe it's devices that move as you do them, maybe it's implants, whatever it is but we also need some time to do that to and that needs to be protected as well. I'm in absolute agreement with safety down there at the bottom. I'm more concerned about improving health through adding on lots of different things that we are not improving health because we don't realize the priorities we've made.

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

And you remind me that one of the messages, again, yesterday was the need to actually educate people about usability. We act like we know what that is and the people who get deeply involved with this go,

“No, you don’t.” It’s not just a pretty screen there’s a lot of human factors involved with this, there is a lot of technical innovation involved with this. These things will have to come together. We need to start doing some of the safety things that aviation does or auto safety does of where are our failures in a way that we could start to respond to them.

**Unidentified Speaker**

So, Neil, final comment?

**Neil Calman – Institute for Family Health – President & Cofounder**

Just to think about usability as not really the provider issue. It’s a provider and a patient issue whether it’s in the exam room or whatever. The computer is there interacting more or less with the patient as well and the extent to which we involve people in that, so I think it’s not just the million providers whose feedback we need it’s the patient experience. What’s it like to be in a room with that computer and that provider, and that was the point that I was making partially before but I think also to what extent the patients can be involved with the systems while they’re in the exam room before the provider gets in the exam room. All the things that Paul was talking about and that David was talking about, I think, all have to fit into this sort of larger picture. So I guess we’re making our work harder but I think broadening this definition of what we consider usability is really important because it’s a different type of environment. There are different people in the room now and there’s going to be things going on outside of the exam room, people are going to be doing things from home, there’s all kinds of interactions with this system that all have to be included, I think, in this process.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

But, Neil, is that the job of this committee to start saying this is what’s to be done or just does that fall into the top of that pyramid that says, “Leave some time for the vendors to be extending in those areas?”

**Neil Calman – Institute for Family Health – President & Cofounder**

Well, it’s the job of the committee not to do anything to damage that stuff so, I think, yes. I think that’s what we’re talking about, and I think it’s also the job of the committee to broaden the definition to include the patient experience, which is not normally part of what people think about or talk about when they talk about usability. They talk about the provider experience with it or the provider interaction with the system but I’m suggesting that needs to be broadened if we’re going to get acceptance of this, and so people don’t—like your experience, what was your experience? You came in the room and you said, “My experience with this doctor who’s got an EHR was horrible,” and I think if that’s what happens in this great environment and with all the work that we’re doing—

**Judy Murphy – Aurora Health Care – Vice President of Applications**

You didn’t say that was the reason though.

**Neil Calman – Institute for Family Health – President & Cofounder**

Okay, well but it was. I hope there were easier EHRs.

**Judy Murphy – Aurora Health Care – Vice President of Applications**

I would add to that as somebody who’s been there before, I would say too though that usability isn’t just a vendor responsibility or a doctor responsibility. I think I look at usability more in the concert that Neil has just described, which is there are multiple people that interact with that system and not just the doctor. Obviously, the commissions but also patients so it is my job to also provide feedback to my clinician about what I want that system to do and how it’s working for me. It’s striking to me as I listen to you earlier talk about the fact that the vendor community would talk to hundreds of thousands of clinicians. That really the first time I started to hear about the problems associated with team based care and the technical inability of a system to have multiple people logged in at the same time when they’re looking at a record that it wasn’t until really we came together and started to think about this notion of team based care and patients started saying, “I want team based care. This is my reality.” So I think it just points to the need for us to listen to more than just clinicians on this point. I think that’s valuable.

The other thing I would say is meaningful use is one piece of a much broader construct that needs to include a broader world view, right, so it's also the RECs here that will play a role. We need to think about how the workflows so that my visit isn't about a meaningful use checklist, Q&A period, but is about giving me access so that I can actually give you the answers before I walk in the door, right. This is basically workflow issue. It doesn't have to be in the office visit, so I think when we start thinking about that broader construct of ACOs and medical homes in truly a different way of doing care what our job is, is to figure out how the technology can be capable of delivering patient centered care.

### **Paul Tang**

So let me try to summarize and talk ... about next steps. One, I think it's obviously a widespread agreement that usability is an important issue, and I think implicit with that is probably widespread agreement that the current EHRs are not usable enough. They're not meeting that threshold otherwise I don't think we'd have this discussion. Try to make your job a little easier and then a little harder. The easier part is clearly usability affects patient's safety. This committee already recommended to ONC that we consider that ONC considers the safety issues associated, the unintended safety issues that are associated with the use of EHRs, and they have contract with the Institute of Medicine to do a study that's in process. That study does include usability so in some sense that's an issue, it's a recognized issue and it's being dealt with in another committee that's providing advice to ONC. So that's sort of taking that part, that perspective off the plate because someone else is—and the recommendations will probably come back to us.

The other part is I think it would be helpful for you to recommend a group to recommend an approach on usability and how it interacts with meaningful use and this whole program of increasing adoption for EHRs. So you've laid out a number of the issues and framed them, what kind of approach would the group recommend to the EHD Policy Committee? You're weighing the effects of regulations, is it guidelines, is it standards and Judy's issue and Neil and Christine's issue about its usability to whom or for whom, so if that's acceptable that would be of use to this group I think.

I think that's great, thank you very much. Thanks, Larry. Thanks, to the group. Farzad, I just want to check whether you're on the line, want to make any comments before we open it up to public comments. No, he's not on the line. Okay, then we're open for public comments.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you, Paul. Let me invite members of the audience if you wish to make a public comment to please queue up, the microphone's here on the table. Please identify yourself. Carol Bickford?

### **Carol Bickford – ANA – Senior Policy Fellow**

Carol Bickford, America Nurses Association. I want to comment on the discussion this morning about the meaningful use objectives in relation to improved care coordination. I had to get off the phone when you were doing your vote in relation to the third item where you were talking about summary care records and care plans, the way its framed right now it seems to be that the care plan is clinical summary and they're not the same. I would recommend that you clearly identify that this is a new requirement for the second stage for the care plan inclusion so that's it's highlighted clearly in the document.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you. Anybody else in the room who wishes to make a comment? We do have one person on the phone if that person would please identify themselves.

### **Kristen Werner**

Hi. I'm Kristen Werner from the Altarum Institute and I just want to make a comment on the usability discussion we just had. Last year in collaboration with ARC we convened a usability expert panel. Several of those participants were also participants on the panel we just heard about. ... reports available on ARCs Health HP Website. What I wanted to bring up here were the overall findings. While the research needs they recommended were fairly complex reflecting the complexity of the field the policy recommendations they made were actually surprisingly simple. The recommendations first surrounded

the idea of certifying usability evaluation starting with requiring the vendors to simply document their practices and processes related to the evaluations that are being conducted in-house.

The second was to encourage the development of a national usability laboratory that could encourage multidisciplinary collaboration and help to develop the tools and processes we need to define and evaluate usability and to develop basic design constructs surrounding patient safety. Each of these recommendations could be valuable first steps towards meeting the more complex and possibly longer term goals that we discussed today.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you very much and we have no more comments. I'll turn it back to Dr. Tang.

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

Good, thank you and thank you to the committee for bearing with us and thanks for going through this morning's discussion on meaningful use, which brings up a lot of the very valid points and represents the ideas and comments of the broader communities that we're working through those. Thanks so much and see you next month.

## **Public Comment Received During the Meeting**

1. Patients have ability to view. The measure is based on 10% of patients/families view. How would a provider know if the patient/family view? All we can measure if the info was placed in a location that the patient/family COULD view. Please clarify.
2. The use of '>25 patients' criteria is a bit concerning. For example, we have had the ability to provide electronic copy of records for years but in that time only 1 person has ever asked. Thus, providing it to a % of those who ask would be more appropriate?
3. IS there a way to see the voting? Who voted for what synopsis? Thank you
4. I applaud the suggestion to instantiate a "pioneer" Stage 2 Meaningful Use Program in 2013 so that CMS and ONC can collect valuable empirical data to inform future MU development and rule-making. In fact, CMS might consider making such a program available in 2012.
5. Hello, where can one obtain a copy of this transmittal letter that lists all that will belong in a patient summary. This is a question from a hospital perspective and want to ensure we can provide all that is required in a "Usable" minimal mouse click fashion. Thank you
6. Hello - Encryption of Data at Rest. Can the Committee Clarify that encryption of Main Frame Servers housing the EHR will or will not be required. We understand and support encryption of data at rest on portable devices like laptops, thumbdrives, CDs and backup tapes. But fear system degradation of encrypting active reads and writes to database machines. Thank you very much. As a follow-up perhaps this is what is listed in the CMS Fact Sheet for Patient Summary for Stage 1 and will remain unchanged and therefore we have already met this requirement and the clarification for Stage 2 is that patients can download on their own where as Stage 1 it had to be provided by the Hospital staff. Again thank you
7. I would contend that handing a flash drive or CD to someone would be MORE secure from a provider's perspective than the possible exposure of security on web sites that may not be as 'secure' yet. Just a comment.

8. Does the change in schedule for those certified in 2011 need CMS approval? If so, will that decision be made before October1?

9. I'm most interested on any insights you can provide regarding ONC's recommendation around delaying Stage 2 for early 2011 Meaningful Users (and when will this be a finalized "go" decision) - and whether this recommendation to delay Stage 2 would also delay the requirement for providers to possess a Stage 2 certified EHR in 2013 (as certification needs are tied to payment years in the graph you shared). Said another way, what does this mean to what the certified EHR needs to be in 2013 – since no providers will need to be Stage 2 until 2014 at the earliest?

10. If d/c instructions are collapsed into the other option, what about instructions at time of discharge?