

**HIT Policy Committee  
Final Transcript  
August 1, 2012**

Presentation

**Operator**

All lines are now bridged, Ms. Deering.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you very much operator. Good morning, this is Mary Jo Deering of the Office of the National Coordinator for Health IT and this is the 39<sup>th</sup> meeting of the HIT Policy Committee. It a public meeting and there will be an opportunity for public comments at the end. I would also ask members to identify themselves when speaking because there will be a transcript made. And, so I will begin by taking the roll. Farzad Mostashari?

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

Judy Murphy here for Farzad.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Paul Tang?

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

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Dr. Agarwal?

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

Terry Cullen here for Dr. Agarwal.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

David Bates? Christine Bechtel?

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

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Neil Calman? Rick Chapman? Patrick Conway? Art Davidson?

**Arthur Davidson – Denver Public Health Department**

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thanks, Art. Connie Delaney?

**Connie White-Delaney – University of Minnesota School of Nursing – Dean**

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thanks, Connie. Paul Eggerman?

**Paul Eggerman – Businessman/Entrepreneur**

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Judy Faulkner?

**Judy Faulkner – EPIC Systems – Founder**

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Tom Greig? Gayle Harrell?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you. Charles Kennedy? David Lansky?

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

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you, David. Deven McGraw?

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

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Frank Nemecek? Marc Probst?

**Marc Probst – Intermountain Healthcare**

Here.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Josh Sharfstein? Latanya Sweeney? Rob Tagalicod? Scott White? Has anyone else joined since I started on the call? Thank you, all right back to you Paul.

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

Good, thank you very much and welcome everyone. Today the major agenda items are a couple of presentations for deliberations. One is from the Meaningful Use Workgroup, we're going to talk about our draft preliminary recommendations, I'm going to go through that with you and after lunch we'll be talking about the strategy for trusted identity that Deven McGraw is going to report out on that topic and the hearing that was held last month and then we'll conclude with an update from Joy Pritts from ONC speaking as the Chief Privacy Officer and conclude as always with the public comments. So, any changes to the agenda? And if I could have a motion about the minutes that were sent out earlier from last month?

**W**

Motion to accept.

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

Okay. Second?

**W**

Second.

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

Second.

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

All approved?

**M/W**

Aye.

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

And any nos? Any abstained? Very good, thank you. And then we'll move onto Judy Murphy talking about an update from the office.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

So it's a really exciting time in health IT, not only are we kind of turning a corner, reaching a tipping point whatever words you're going to use in terms of meaningful use, just a quick update on that in terms of the June 2012 statistics. So, we're over \$6 billion paid out in the Medicare and Medicaid incentive payments with about 50% of hospitals and about 20% of eligible professionals achieving either the Medicare or Medicaid incentive payments.

So, if that wasn't a milestone enough, for the first time in history we actually have our Olympic athletes in London, their health being tracked via electronic health records, being used by themselves, their trainers and their physicians. So, it is certainly an exciting time in health IT.

A couple of less exciting updates, though very important. Certification, we've also turned a corner in terms of the certification program going from the temporary program to the permanent program. A couple of weeks ago we announced the accreditation of the five permanent certification bodies and the five permanent test labs for the certification program. And announcements went out about that, it's also on the ONC healthit.gov website if you didn't see those announcements.

In terms of consumer health, another area that we're really focusing on. In September we will have reached the anniversary of 1 year from our consumer e-Health Pledge Program. I'm sure many of you are aware of that program that was launched in September of 2011. Specifically looking at organizations both data holders and non-data holders. So, it could be insurance companies, it could be providers, it could be organizations that pledged their support to look at the ways that they can encourage consumers and make it easy for consumers to participate in their health using Health IT. As recognition of that 1 year celebration, during National Health IT week on Monday, September 10<sup>th</sup> we'll be having another celebration at the Department of Health and Human Services. So, please watch for more information about that.

In terms of our Regional Extension Centers, hopefully you've follow the press. There was the release of a GAO report last week which basically looked at a lot of things related to the incentive program, but the thing related to the RECs most specifically was that they are working with over 40% of our primary care providers in the United States. So, that represents about 135,000. And of the ones that they're working with, the GAO report stated that if you're working with a REC, a Regional Extension Center, you are actually 2.3 times more likely to achieve meaningful use than if you're working on your own. So, we're very proud of that, because I think you know that those programs were stood up with the specific idea of helping those who need assistance with selecting and implementing, and adopting electronic health records.

Last but not least, and this is something that's going to hit home to all of you, healthit.gov, I know that the last time I was here I talked briefly about that. We are migrating everything away from the healthit.hhs.gov website to the healthit.gov website, and as we speak, as we're sitting here today, the migration of the Policy Committee materials are actually taking place. And so, when you log in, in the near-term, if you go to your old bookmarks you will be redirected to the new site for some period of time, and then eventually we're going to ask you to try to re-bookmark. We will be sending out information about that process to you all so do watch for that in the next couple of weeks. We expect that migration to finish sometime...you have a lot of documents out there by the way. So, we expect that to be completed sometime in August.

And with that, again, I'm thrilled to be here, to be back with the Policy Committee and excited to look at our next step in this journey, Stage 3, today with the Meaningful Use Workgroup. Thank you.

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

Great, thank you very much, Judy and congratulations on the \$6 billion dollar mark and the 50% and 20%, really exciting after just essentially a little over one year, beautiful. Okay, any questions for Judy? If not, we'll move onto an update from the Meaningful Use Workgroup on some of our early thoughts in Stage 3.

Okay, good morning and pleased to be working with George Hripcsak from Columbia University who is the Co-Chair of the Meaningful Use Workgroup and we're going to present some of the results of our past months in deliberations in Stage 3.

I want to list first the workgroup membership, which you see before you and highlighted in red...we broke ourselves up into subgroups, the four categories. The fifth category on privacy and security is going to be a reaction to the other four, and actually Deven is going to be talking about some of the recommendations related to identity and that undoubtedly will work its way into Stage 3 recommendations. So, David Bates, Christine Bechtel, Art Davidson and Charlene Underwood acted as leads for the three workgroups, subgroups.

Let me remind you where we are in the timeline for developing Stage 3 recommendations. Our end goal is by May of 2013 to transmit to HHS, to ONC and CMS our recommendations from the HIT Policy Committee related to Stage 3. So, working backwards we have a sentinel date of November 2012 distributing an RFC, request for comments. So, that's what we're preparing for right now.

So, this is the first of four presentations to the full Policy Committee to get your feedback. So, this is very preliminary, we're looking for it where there is no approvals here; we're looking for your feedback which we'll incorporate and bring back to you in the October meeting prior to going out with the RFC.

Now, I first thought we'd share with you some of the guiding principles we used to try to develop the recommendations or these preliminary recommendations for meaningful use objectives. One is that we talked about way back in Stage 1 we want to support the new model of care that's constituted by focusing more on team-based care, outcomes oriented and population management that would line up with the ACO kinds of models of care in the future. And, of course that ties in very well and it's deliberate, we want to align with the CMS programs going in that direction whether it's value-based purchasing, Accountable care organizations, episodes of care, that's the way we want to look at things from a more team-based population orientation.

The second is that we don't...this committee doesn't set the national health priorities but we would like to support, we would like to build the HIT systems that support the national health priorities as determined by the secretary such as included in the National Quality Strategy, Million Hearts Campaign, Partnerships for Patients, and so on and so forth.

The third principle is that we want to, as much as possible, have broad applicability, because we have both a diversity of specialties, primary care specialty areas of the country like rural or urban and patient health needs, many health conditions. MU is a floor, it's not the ceiling, but we want to raise the tide so that all of the providers in the country have this rich tool in order to carry out their goals with respect to patients and health outcomes.

The fourth piece is to promote advancement. So, it does no good to keep harping on things that are already topped out and by that we mean that if the country is already doing such and such, they're already capturing this data we don't have to keep putting it in as a meaningful use criteria for collecting incentive payments or avoiding penalties.

And, fifth and very important is it's got to be achievable. Some of the objectives may be aspirational but if it isn't achievable it's still not going to have a good effect. So, achievable means things that can be put into these electronic systems, they can be implemented and they have mature standards that are widely adopted so that it can be built into systems across the country and across vendors.

So, those were some of our guiding principles as we tried to hone in on the critical few. We used the exemplar approach to putting before providers the tools they need to do the job that we expect them to do. Okay, so I'll cover subgroups 1 and 2 and George will cover 3 and 4.

I thought what we'd do...now category 1 is a long one. So, let's see if we can get through all of that. We'll go through category by category and then ask for your feedback on those and we'll duly record those and work them in to what we bring back to you in a couple of months.

So, this first you have hand outs and I believe the slides are posted on the web, because they're not that visible on the screen. First has to do with CPOE and actually the first row, 101, is the same as it was before, same threshold of 60%. The second one is really the add, which is in addition...we started out in Stage 1 with medication order entry, we added lab and radiology tests in Stage 2 at least in the proposals. And for Stage 3 we're looking towards adding referral and transition orders into CPOE. The reason is because, of course, this is the trigger for care coordination that you're going to see in later categories. The threshold that we were proposing for discussion is 20% be done through CPOE.

The next one has to do with drug-drug interaction and as you know in the NPRM CMS included that, moved that over to clinical decision support and we agreed with that. The add we're making here has to do with certification criteria. Some of the proposals we're making today are only certification criteria for EHRs and don't have an associated use requirement on the part of the provider.

So, in this case we were proposing that EHRs be able to consume, to be able use external list of drug-drug interactions. The reasoning here is because it's well known that the current drug-drug interaction databases that are available, commercial databases have a very high false positive, sometimes ranging up into the 80%. That has a couple ramifications. One is, when it's that high a false positive rate people tend to ignore them and ignore many of the clinical decisions support reminders. So, that's a bad thing.

So, what we're looking for is if you see in the Stage 4 place holder is eventually looking for some external list that is maintained and is credible and has been through peer review that would give a much higher true positive, a higher positive predictive value, that is when you see an alert there's a good chance it's meaningful about this patient and that you, the provider, should pay attention to it. So, that's where we're headed. That's the concept we're headed towards. And for that, we need the EHRs to be able to consume these external lists.

The second piece has to do with electronic prescribing and formulary checking. They're sort of two objectives baked into one. And we were...now; interestingly for EPs the NPRM had a threshold of 65%. In our comments back to CMS we were suggesting that may be a bit high given where we are and so we had proposed 50% and so our current thought about Stage 3 is still at the 50% level just because both the combination, the penetration and the ability to hone in on the right formulary for each patient may be challenging still.

The other thing we're adding to formulary is generic substitutions. That's where available substituting a generic formulation for a particular drug versus a brand name. Everyone knows that can lead to a big cost savings. On the hospital side we are recommending, as a preliminary draft, going from 10% threshold to a 30% threshold. Hospital eRx appeared first in Stage 2.

Turning to demographics, making good progress, already at the 80% level, at least in the NPRM for Stage 2 so we're continuing that but adding a few more things that have come to our attention and we're hoping that the standards are there, would be there by 2016, but this is one of the reasons we're opening it for comment. One has to do with occupation, another with sexual orientation, gender identity and the third with disability status. So, those are some areas where I'm not sure that the standards are there today, but hoping that they'll be there by 2016.

Next is the area of problems, medications and medication allergies. As you know, the proposal was to include those, pull those into summary of care and not have them as separate objectives. We had commented back, I mean, our response to the NPRM that we would like to keep them as separate because we have more plans for them and here are some of the more plans. So, it includes certification criteria so that EHRs would provide providers with the prompts that would help us maintain a more accurate and more complete list, whether it's problems, medications or medication allergies.

By that I mean, so an EHR could tell that if we're missing let's say renal insufficiency or even diabetes from the problem list, yet there's a lot of other information, it could be test results, it could be medications the patient is on that would indicate, you know, this person probably does have diabetes or this patient probably has renal insufficiency, let's get that on the problem list so that it can be front and center to everybody who is taking care of the patient but also can be used in clinical decision position support. So, that kind...everybody recognizes the value of having accurate and complete lists, they aren't always that way right now. And so we were asked...we believe, and there have been studies that show there are ways that the system can help us maintain the accuracy and completeness of those lists.

Under medication allergies we're moving towards a standardized way, as people are aware I think, medication allergies actually doesn't have a standard accompanying it. So, it's very hard actually to exchange information with other systems in other organizations. So that needs to extend not only from the ingredients but also the class of drugs where the allergy resides and we would like to have codes, standard codes for the reaction. So they can be everything from a true hypersensitivity reaction to an intolerance, but it's not clear the way they are used currently. So, that's what we're asking for.

By the way, in Stage 4 for that the notion of contraindications...so right now there's overloading or overuse of the allergy field in current EHRs and the reason is because that's the only thing that will pop up when somebody enters in a procedure or medication that is related to that field. So, what we really are trying to do is what are contraindications for this patient, it could be a drug, it could even be a procedure, that's one of the things we heard about. These are things that are not good things to do to this patient and we need fields to put those in, proper fields to put those in. So, because they don't exist in today's systems we targeted that as a signal and as our proposal for Stage 4 to look into this more in Stage 4, this whole concept of contraindications more broadly.

The next one has to do with vital signs. The good news, in the proposed Stage 2 is that we're already up to 80%, it's pretty hard to get 100% of anything, so 80% is pretty much topped out is our feeling. So, in the name of not continuing to pursue things that are ready of the country and providers have already achieved the maximum value out of, one approach is to start retiring some of these things where we've already essentially achieved universal acceptance and adoption.

The same thing would go into the next one, which is smoking status. Again, for NPRM Stage 2 it's up to 80%. Now, instead of saying retire, forget it, this is one of those...one an important topic that is smoking status, but also could be incorporated into the clinical quality measure. So, we've always wanted to go for the outcome not just the process of recording somebody's status and so this may be one of those where it fits well, that is you can measure the folks, the percent of your patients who are smoking and for which you'd like to perform some intervention to reduce that rate, but that can be baked into the clinical quality measure.

The next one is...it's just a housekeeping, the drug formulary, as we mentioned, was moved into the eRx objective. The CMS measure as proposed in Stage 2 NPRM is essentially incorporated as a separate kind of criteria and so is removed from meaningful use objectives that we have.

The final one on this page has to do with advance directives. This is an important topic for patients and families. It's something that we introduced in Stage 1. This group had recommended that it goes to...gets introduced for EPs and gets moved to core for hospitals that was not in the NPRM. So, we'll sort of have to wait to see what the final rule says. If it's not going towards being required and core than this group is still interested in pursuing how do we make this important information about patients universally known to people who take care of patients.

There are a number of implications and considerations in dealing with this subject and presumably that's why it hasn't been moved to core yet. But, we're planning a hearing in the fall on this topic. It involves everything from the state laws to the legal ramifications to the feelings of patients and their family and providers. So, we're going to dig down more into this topic to get an appropriate recommendation.

The next one has to do with clinical decision support. As you know, this is an extraordinarily important topic in terms of getting the benefits for all out of these systems, HIT support. It goes along with CPOE, Computerized Provider Order Entry, and we're sticking with the attributes of CDS interventions. So, I'm not prescribing you have to have a rule or you have to...whatever helps clinicians make the appropriate decisions is what we're after. And we're proposing to go up from five of these interventions to 15 and still tying them to clinical quality measures, so 15 interventions related to five or more clinical quality measures.

Some of the things that we're proposing, at least to explore in the request for comment, have to do with important areas where there are a lot of complications. For example, in renal dosing, if you're not excreting the drugs as you should in a normal patient, then that has complications for all medications that are administered that are excreted renally. So, including renal dosing in the check as a decision support intervention is important.

On the other hand, standards don't...well, one of the important things you need to know is what's the dose of the medication of the drug you're introducing. In order to know that you have to have what's called discrete sigs or structured sigs, if it's free text then the computer can't tell what's the total dose. So, if that's not a mature standard, that is structured sigs, then we may not be able to introduce it in Stage 3, and may have to wait for Stage 4, but clearly we're trying to introduce a signal here.

The other area that we're trying to propose as a requirement, one of the 15 clinical decision support interventions has to do with appropriateness of lab and radiology orders. This is an efficiency measure. It's a cost measure. It's one actually that we introduced back in Stage 1 but hasn't been picked up yet. But, this is an example of something where we know that there's a notable amount of inappropriate or test orders that may not be fitting to the patient's context and that generates not only increased cost but there are downstream complications such as false positives that come to bear.

The second area is to...this is where the drug-drug intervention got moved into. So, instead of a separate objective it got moved into CDS as far as the NPRM so we're keeping it there. A couple of areas where we're talking about certification only, that is no accompanying use requirement is the capability in EHRs to track what happens with the CDS. So, if the EHR produces some kind of intervention, some kind of suggestion or recommendation, then what happens to it, that's an important piece of information so one, we can build better and better clinical decision support rules and second we can track down areas where we need more tension if the rule is a good rule, but it's not being followed adequately.

The second piece is to start understanding...have a mechanism in the EHR to track, to notify the provider of a preference sensitive condition. So, for example, as you saw getting a PSA, prostate specific antigen test, in a male, the guidelines change over time and it has to do with understanding, you know, having more information, more evidence in this science but also it becomes...it's a gray area. It's not a black and white, everybody needs to have this. So, part of it is the patient's preference.

So, we need to make sure that when those kinds of decisions where there's a lot of patient preference influence, because we don't know the right and wrong answer for this particular topic, we want to give the provider a heads up but also we are intending to provide patients with patient clinical decision support. So, that's where we're headed and we're trying to signal this kind of functionality needs to be built into the EHRs in preparation for future stages.

Next has to do with the clinical labs. This is something that's always been in the meaningful use objectives. In this particular row we're talking about for the EPs, for the eligible providers and we're moving...we're suggesting that we go from a threshold of 55% up to 80% knowing how critical lab results are to patient care and it's only of use to the computer if it's in structured format, if it's structured and standardized.

The next row has to do with patient lists. We had moved from having a patient list based on one condition to in Stage 2, at least this group had recommended, having multiple conditions that wasn't baked into the NPRM for Stage 2 so we'll see what the final rule produces. But in Stage 3 we're trying to move not only from lists, which are more retrospective, so you go back and you dig out through your database and find all the patients with X. Well, in an ongoing more real time way, we're proposing that providers have instant access to...even when you're seeing a particular patient how am I doing, either the dashboard about what's going on with this patient or populations of patients like this patient. How am I doing, I the provider. So we're going towards this real-time dash board approach rather than a retrospective list approach.

Next has to do with patient reminders. As you know, a common example is preventive, you know, you're overdue for a mammogram or a pap smear, or whatever. In the past it's been 10% of all unique patients and now we're proposing going up to 20%. In 117 having to do electronic MAR, this is not only having that capability of automatically tracking medications from order to administration, but having the reports and capability to figure out, well when you're not having them what can we do about reducing that rate.

Imagining was a new objective in the proposal for Stage 2. We're suggesting...it was a menu objective in the NPRM at least and we're suggesting moving that to core. You know that we had suggested back in our comments that instead of a threshold of 40% we suggested I believe 10%.

The next one has to do with family history, that's a concept that was introduced in the NPRM for Stage 2. We're focusing in on some very high priority family history data like family history of colon cancer, breast, glaucoma, coronary artery disease and diabetes as an example. And the reason is so that it can be input and used in preparing clinical decision support interventions.

Next one is our...we'll have the wait and see what happens with the final rule, but as you know, we've been pushing for progress notes to be part of the EHRs thinking that that's something you really do want to have the same availability and access as the rest of the record we're talking about and so we're pushing this again in Stage 3 if it doesn't appear in Stage 2.

And then hospital labs, which is the accompaniment of the EP side moving from a 40% threshold to a 70% threshold, same reasoning, this is really important information, it's got to be understood by the computer so it's got to be in structured standardized form.

And, finally rounding out this category 1 draft preliminary recommendations has to do with transition documents. You know that we have a summary of care document. Transition, now, this is not completely thought out, but that's why it's labeled explore, get information from the public about the elements needed as you transit from one site of care, one setting of care to another and making sure that information is available ideally immediately. Right now we went out with a proposal of within 4 calendar days. But we're trying to develop some of...what are the elements that go into a transition document beyond those in just a summary of care, kind of a transfer of care kind of document.

So, that's what we have for category 1, improve quality, safety, efficiency and reducing healthcare disparities category and I'd like to open it up for your comments, realizing that it's a long category. So, if you could call out the ID and that's on the left hand column and/or the page number, which is in your hand out, then we'll all sort of track with you. Open for comments. Marc?

#### **Marc Probst – Intermountain Healthcare**

Going through the specific items that are here, are we going to have a chance to just talk about Stage 3? I mean, everything from timing that you outlined on the early slide to, you know, some of the objectives, because, you know, as I go through these individual requirements this is really good material. As I look at the requirement that we're going to be placing on vendors and hospitals, a lot of concern, not just in the first category, but in all the categories, so, will we have that opportunity or should we talk about that now?

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

Why don't we do at the end? Yeah, let's do that at the end, but definitely hold me accountable for coming back to that.

#### **Marc Probst – Intermountain Healthcare**

Okay.

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

So, just a little response, the cadence of stages was intended to be every 2 years and so one of the reasons for those guiding principles was to hold us to what's achievable in the every 2 year cadence. So, that's probably a bit of where you're headed. So, we should be having those kinds of filters as we go through these things. Good, and Paul?

#### **Paul Eggerman – Businessman/Entrepreneur**

Thank you, first this is a lot of excellent material, a lot of...this is very good work. I actually have a couple of questions. I mean, first the title is improve quality, safety, efficiency and reducing health disparities. So, my first question is which of these reduces health disparities?

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

It's an excellent question. So, the two that come to mind right away, one is demographics and you see that we added additional demographic information, like sexual orientation, gender identity, disability status and occupation. So, that gives us more information about an individual and the second is we've added more to the patient list and dashboard function so that we have better reporting tools and even more real-time reporting tools so that we can recognize this is important for this particular individual.

**Paul Egerman – Businessman/Entrepreneur**

Have you explored with, I don't know, perhaps safety net institutions or other institutions that there are specific things in an EHR system that might be helpful to them?

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

What?

**Paul Egerman – Businessman/Entrepreneur**

That are helpful to organizations addressing health disparities that might not be helpful to other organizations?

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

We've heard, in some of our hearings, about different areas. In fact, that's the genesis for some of these new demographic items. Is there something specifically you're asking about? We can also explore that.

**Paul Egerman – Businessman/Entrepreneur**

Okay, that's all and actually one last question. We talked about in some of these situations raising percentages from like 40 to 60 or 70 and I'm curious do we ever get to 100%? Do we ever say we say for lab or something we want 100% to be done? Are we always just going to just be incrementally going a little bit higher?

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

So, we sort of discussed this. We didn't pinpoint a number, but we sort of discussed this in the notion of "topped out." So, there are always some reasons why in this particular situation for this particular patient you're not going to get vital signs or demographics. So, there's always a thought that it's really hard and not necessarily practical to get to 100% of anything. I think we've been sort of thinking of 80% as the highest number that we push through a public policy like this. Because, otherwise you have to be able to accommodate a whole host of exclusions and that's actually where the cost and the burden comes in.

So, there's a lot of reasons why something won't be 100%. If you stay away from inching it up closer to the maximum then you relieve yourselves of the burden of trying to capture all the excuses or exclusions, or valid reasons why something wouldn't be 100%. So, 80% is about as close as, you know, we're thinking about in terms of, quote, topped out.

**Paul Egerman – Businessman/Entrepreneur**

So, are we ever going to get to 80%?

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

We are there in a number of areas and then we haven't pushed it. Christine?

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

I just wanted to come back to the disparity's piece for a second and make a couple suggestions. I would add my re-enforcement that this is very good work and I think moving us forward in an appropriate way. So, I think one of the things we talked about in Stage 2 was having the generation of list of patients be not just by specific conditions but also by demographic variables and I don't see that reflected here. So, my suggestion would be to add that in. But the item 15 doesn't...it has an objective, it doesn't have a measure associated with it yet and I think that's where the rubber needs to meet the road, at least in the version of the slides I'm looking at.

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

Say, that again, please, which one?

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

Number 15, which is the patient dashboard.

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

Oh, okay.

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

So, I wonder if it makes sense to have a measure that would be something like report dashboard results, you know, longitudinally. So, beginning of the, you know, period and end of the period or 6 months in or some, you know, kind timeframe that would make sense given the data collection. And that, you know, perhaps one way to do that would be for providers to pick, you know, one or two disparity variables that make the most sense for their population and then to report over time on that.

Now, the other way to do that is to require the stratification of certain quality measures by disparity variables. But, there needs to be a use function, you know, that was a real issue that we had with Stage 2, from a consumer perspective, was okay we're collecting this demographic data but we're actually not putting it really to use for disparities reduction.

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

And, David Lansky might want to comment on this. One of the concepts that was introduced in the Quality Measures Workgroup is sort of longitudinal measures. So, looking at a delta measure rather than just a here's what the average is for your entire population. It would be more interesting...well, that's a personal preference, more interesting to say are you moving for each of your patients? So, you might not have all your patient's below 7% let's say for diabetes but you've improved let's say 0.5% in half of your patients, that's a big win. So, that's the kind of thing where...that's a kind of quality measure type that has been proposed through the QM Workgroup. And that can go right to your point.

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

Right, I agree. I think that would be great. I'd like to see both an approach like that but also a measure around some sort of a process or structural criterion as well so that it's in sort of both places, so we know the functionality is there and it's getting used.

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

Good point. Judy?

**Judy Faulkner – EPIC Systems – Founder**

Thank you, Paul. One is you have real-time dashboards. Do you think that could be modified to be near real-time? Real-time may be...that is a very high standard which is just as...that's going to require significant processing power. Near real-time is probably good enough.

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

And that's perfectly acceptable. In other words, what we're doing is not a retrospective report that's done in the IT department; that was our point. So, point accepted.

**Judy Faulkner – EPIC Systems – Founder**

Okay. The other point is about your functionality to maintain update problem and medication list. And I'm a little nervous with the example you gave that what you're really talking about may be the concept of data marts so that diabetes here's the definition of diabetes, which becomes quite complex. And I'm wondering if, in fact, that's really what you're meaning, because it takes a long time to build data marts up and get all the definition of what this diabetes means so that you know to generate that in the problem list. You're probably thinking of something simpler than that and I was wondering what it might be.

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

Well, let me clarify that example and maybe that helps. So, for diabetes if you're on hypoglycemic treatment, you're on insulin, you're on metformin and you don't have polycystic ovarian disease, that's a pretty good indication that you probably have diabetes and it's just not...and no diabetes codes on your problem list, all it is it's a prompt to you that you missed that, should...

**Judy Faulkner – EPIC Systems – Founder**

But, it could be lab test results too.

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

That's correct.

**Judy Faulkner – EPIC Systems – Founder**

And so that's, and so you're...

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

So, it's not a...

**Judy Faulkner – EPIC Systems – Founder**

You're getting into a bit of clinical judgment there with balancing all those things.

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

So, the thought is that you would have the ability to write rules let's say that would put that in front of the clinician, should this be on the problem list, it's not telling them.

**Judy Faulkner – EPIC Systems – Founder**

Not putting it on the problem list.

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

Not putting it, right. And the other, let's say your creatinine is 2 or it's 3 and there's no renal insufficiency on the problem list which is one of those things that you just want to have in your mind, in your face when you're making decisions about interpreting symptoms, about administering a new medication, etcetera. We want to make sure that the problem list is as rich and useful as possible. And so we're just asking the computer to help that, because...

**Judy Faulkner – EPIC Systems – Founder**

And, just for certain major areas?

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

Yeah. So this is not a...the certification criterion is not saying for what areas, it's the capability within an EHR to even program these kinds of suggestions and then it's up to the provider group to decide what are the major areas.

**Judy Faulkner – EPIC Systems – Founder**

Okay, so what you're looking for is the systems to be able to have the people put in...if lab test is this or if something else is that, not that the vendors put that in?

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

Correct, correct, there's no content in here, just some capability.

**Judy Faulkner – EPIC Systems – Founder**

Okay.

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

Thanks for that clarification. Gayle?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Thank you, so very much. This is quite comprehensive. I have several questions, first of all on the clinical labs, we're moving up from 55% to 80% for EPs and for hospitals up to 70% in structured data. Now, are we going to be requiring that they use LOINC in this or are we allowing for interfaces or what's going to be the standard that's set for that integration?

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

So, I think the Standards Committee already said LOINC where available. So, there's some tests where LOINC is not available yet. But, where LOINC applies to that test the idea is that it would use LOINC.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Okay, the second area I had some question on is when we're talking about decision support and we're talking about the appropriateness of lab or radiology orders, now how are we going to determine what that appropriateness is and who's going to determine that? What's the basis of that determination? And what are the results? What are the consequences if for instance you want that second MRI?

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

Excellent question. As an example for radiology, ACR, American College of Radiologists, has extensive guidelines in terms of what are the appropriate indications for ordering such and such a test, and those would be...you could program some of those in some high cost areas where there's a gap between...we know that there is overuse for example of or potentially underuse of a particular test.

And so those guidelines could be programmed into the clinical decision support interventions. All these things are guidance only and it's up to the organization how they want to apply that. But, if you're looking at areas where the literature already knows that there's over or underuse of something then let's try to get less of that over or under use so that's...this is the capability to do that and if you apply one of these interventions in your organization that would fulfill the measure for that particular objective. I mean, that's what...

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Are these going to part of a measurement system that we are going to put in place for clinical quality measures are going to be used to evaluate at the end of the day since we're going to be tracking these now?

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

So, that would be up to the organization. So, right now it's saying two things, one the EHR system should be able to produce...should have the capability for an organization to write one of these rules that measure utilization of lab or radiology tests and then there's no...and that there has to be, at least in this proposal, one of the 15 and that's as far as it goes. It doesn't say anything about a threshold, it doesn't say what it has to be, it doesn't say how the organization uses it, but it's just that we start working on the efficiency measures.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Thank you.

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

Thank you. Judy?

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

So, I'd like to echo what other folks have said, not only the quality of the work but the timeliness of the work. I think getting this out in this kind of a timeframe is really going to help us, you know, iterate through Stage 2 and really be prepared and that's the basis for my comment and you said it a couple of times when you were presenting and I just want to re-emphasize the idea that in some cases we have mature standards and we're going to be able to use those standards and we're going to be able to work that right into the certification criteria and the implementation guidance.

In other cases right now some of these are not so mature. So, do we let them go or do we use this process to drive those issues and to get those things done, particularly because we're starting a little more ahead of the schedule, you know, we're feeling a little bit of a crunch in Stage 2 and I think most of you are aware of that, in a couple of areas, you know, like standards for interoperability specifically, but also in the quality measure space where we're kind of, you know, retooling for e-Measures, you know, on the fly here because we didn't have that infrastructure.

Well, we're at a different place now and so as we look to Stage 3 I think in some cases we're going to follow where the industry already is, in other cases we do need to drive the industry and in a third case we're going to need to let go and I think we really want to incorporate that into this process through these different stages that you outlined on your timeline and make conscious decisions about this works, this we've got to push and this we're going to have to let go. So, I just want to re-emphasize that point and you said it a couple of times.

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

Well, it's worth re-emphasizing, Judy and thanks for doing that, because that exactly the attitude the Workgroup has, you know, you see code words there, so one is we're trying to lay out a recommendations, a preliminary recommendation for Stage 3. Another code word we used was "explore." I don't think it's quite there yet, but we would love to industry input, industry means both the vendors and the providers. And there's others, and you'll see that in the next category where it's still a great idea, help us shape what we have to do, we collectively have to do to get there and try to achieve the right balance of things. Terry?

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

Yeah, and I really just want to echo what Marc said and what Judy just said. Thank you for saying what I wanted to say, because my concern is the dependencies, which are outlined here and how we're going to relate to the dependencies at the same time ICD-10 is coming at the same time while I think some measures are e-Ready there's many things in here that aren't e-Ready.

And I think there also needs to be an internal dialogue at the federal level with the federal partners on are there ways that we can accelerate some of this work to share with industry in an open source fashion? Because, I think to ask all the vendors to replicate a lot of this work will do an onerous fiscal burden on the industry as well on the provider. So, there may be segments of this that we could pull out, clinical decision support recognizing...so you might not want to tell people what chronic renal failure is, but if you want to do it here is the logic to use and I think we've historically done...HHS historically has done that. So, it might be a way to mitigate some of the concern I think this acceleration may cause.

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

Good comments, Terry. Let me just sort of comment back on that. In Stage 1 we really had to put that together in 6 weeks, so there's a lot of...that we tried to do in assessing where's the market and where are the providers right now? I think HHS and the Policy Group trying to serve HHS is doing a lot to try to give the lead time its due share, so we were...there was a lot push back on well...you know, you need the certain amount of development time when we talked about Stage 1 and Stage 2. We're trying to answer that, you know, we talked about 18 months, we're now trying to prepare for 2.5 years ahead of the due date for Stage 3 and it's a direct response to the need to make all this change happen.

There are a lot of things that take a long time not only for development but through the approval cycle and one of the examples is quality measures. That if we don't start, and this is to Judy's point, if we don't start actually developing the new quality measures now, it just isn't going to make it through the development, the testing and the endorsement cycle. So, that's why we're trying to put this out.

So, when we talk about signals we're trying every method we can to put the signal out and for those listening, and I know there are a lot of vendors that actually look at these...whether it's a talk about or Stage 4 and start developing towards that, and that's I think what we are trying to encourage people to do. But a big one is quality measures as an example.

And I like your term “e-ready.” So, I think we really have chosen, and this is an editorial remark, for example in the quality measure area we did “retooling.” I think we found out that doesn’t work. You don’t retool the paper mentality and the way we thought about quality measures and chart review of the past to an electronic version of that chart review. We’re thinking about completely different kinds of quality measure.

Similarly, CDS, clinical decision support, and the plug and play, you talked about open source, wouldn’t it be nice if not every vendor or every provider re-invent their own CDS rules, wouldn’t it be nice if you could consume something that was open source because there are people who make a living out of generating knowledge that can be put into...So, that’s where we’re headed. DDI, drug-drug interaction was another example of that. Instead of everybody fighting this battle can’t we have a group that is spending their whole research time embedding it, come up with really important drug-drug interactions or really unimportant drug-drug interactions and help us with this false positive problem. So, we’re heading in that direction. We’re trying to project that that’s where heading and we’re hoping both the research community and industry look at those signals and try to meet us, because this is now 3.5 years ahead of lead time.

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

And just one other comment and I don’t work for HHS anymore so I’m not picking on them, but there are lots of resources there. So, you think about drugs, you think about FDA, we just had a dialogue with them about teratogenicity and wouldn’t it be great if somebody owned that, what’s a teratogenic drug, how do I do it through an open source thing. So, I think that from the federal perspective we need to look inside and see what we can assume responsibility for to help the agenda.

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

So, we’re just the advisory group, but, yes I think that would be a great idea. Marc?

#### **Marc Probst – Intermountain Healthcare**

So, I do have three specific things, but we already started talking about timing and you just mentioned it a second ago. And I really appreciate we’re getting in front of that curve, but even things like we said we’d give 18 months, Meaningful Use Stage 2, we’re past that. We’re already going to be best bet if we did it today we’d have 14 month lead time. And we were talking at an 18-month lead time. So, these are compounding events.

And the other thing around timing that’s a little concerning and I was at a, not a hearing, but a meeting yesterday up in the senate and a survey came out and the survey was to physicians and specifically in a transition of care, what data do they really want, and it was a pretty comprehensive survey, and it was 5...I have them, but I didn’t memorize them, but what struck me is we don’t have that data and we don’t have a lot of data for Meaningful Use Stage 1 that should have driven Meaningful Use Stage 2 and clearly should be driving Meaningful Use Stage 3. We’re not being a learning health care system or at least a learning process because we haven’t had the time to do it and we haven’t had that data and that to me is pretty concerning as we go through all these requirements, because these are awesome.

I mean these are really well thought through functions and aspects of the systems that we could be working on, but are they absolutely the best thing for the country, because I think if you really nailed it down, there are four or five things that we could get in place that would dramatically improve security and privacy, dramatically improve interoperability between systems and simply laying on new functions isn’t answering that question and so that’s kind of going to the global concern that I have around Stage 3 and even predicting a Stage 4 when we ought to be resolving some pretty fundamental or at least putting steps forward to some pretty fundamental issues.

The three things I had, Judy hit problems and as you described the problems, Paul, problems can be used for a whole lot of things and the issue I’ve seen with problem lists is they get so cluttered that they become useless, you know, they’re just this huge list of problems and that the functionality really needs to play into how does a problem feed into a diagnosis which feeds into a bunch of orders and a care program, and I think that’s where a lot of this technology is going that’s being built today. And, it would be nice if that objective was a little more clear, because as you explained it, it sounded better than what’s written here.

On 13, just the words are said how a provider responded and do I have that one in front of me? Yeah, CDS triggers and then how the provider responded, that seems like a difficult statement. It could be clarified a little better, because they could respond a whole bunch of ways and if it's another work step for a provider to go back in and say this is what I did based on...I know that's not what you mean, but if...the way it's written it could be interrupted that way.

And then on 15 on the real-time dashboards, similar to what Judy said, I mean real-time is very difficult but there's so many different ways those could be used. It would be nice to be a little more explicit because you end up certifying for something to be able to do anything when really what we're asking is for it to do something and those were the things that stepped out.

But, again, terrific work here. Though my first part of the commentary was not to be diminutive of this, I'm just concerned about the timing and all the things that we're trying to do around Stage 3 and I know we set those landmarks out there, but were they the right landmarks now that we look backwards.

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

So, when we get to the overall comments you can give us your five things that everybody should do and we'll fix everything.

**Marc Probst – Intermountain Healthcare**

Okay.

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

Just one quick comment.

**Marc Probst – Intermountain Healthcare**

...

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

I take your need for clarification so we'll go back and work on those words, how the MD responded to a CDS, those should all be falling out of just what they do so it has nothing to do with extra work, that's our goal. Judy? And then I think we can move on.

**Judy Faulkner – EPIC Systems – Founder**

I'd like to follow up on that, if you look at 17 when we're talking about mismatches or tracks and acted upon it's similar, self-reported policies and practices could you...when you're doing the other, could you do that one too, because I know that there's confusion on that one coming out.

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

Exactly. Okay, let's try to move onto category 2, which is engage patients and families. Okay, this first one has to do with view, download, transmit; you already know that that's part of NPRM Stage 2. The explore, the code word is it's not fully developed, but it's the notion that okay, so if you transmit...let's say you transmit something to another provider or PHR service, can you make that happen in an ongoing way so the notion...it was called auto blue button, so instead of saying I want this now on demand can you also do it in a more...can you do it as a subscription method? So, in other words, the recipient subscribes to continuous updates. So, that's the thought.

There are two components of that that need to be explored. One is, you know, can we do that now, but possibility more importantly is and how does that look and what are the implications of continuously feeding these other groups. And then on the recipient side how does it look to continuously receive data from another group. And, you know, what's the step? Do you acknowledge? Do you accept? So, there's a lot of implications of this kind of functionality. And one...you're going to change something? Okay. Great, thank you.

So, in fact we had asked, and I don't know whether ONC has looked at getting a legal interpretation of what do we do with all this incoming information and how does it relate to the medical record. Maybe that's on our parking lot for figuring out what we're doing there. So that's this function and as I say that's in the "explore" group.

Next has to do with being able to...this came out of our patient generated data hearing. So, patients want to contribute and providers want to know more about what's happening outside of the 1% time that we see patients or less than that. So, are there ways to get information about patients and their lives? So, there's a couple of approaches and we'd be interested in your feedback.

We can go...one is here are eight things, that's in option one, where a patient could contribute to and there's some sort of standards or at least some ways that people proposed as a standard way of providing this information. Free text is another option, but for in the first five items are sort of questionnaire things, things that patients answer. The second three are device related and three common ones are listed, like device information about your glucose level for a diabetic or your blood pressure or your weight using available standards.

So, the one approach is to list these eight and say you need to have some way of accepting this information. Option two is really just to talk about those categories, that there is a way; a generic way of submitting and the provider organization decides what it is that you're going to submit this information in a semi-structured questionnaire platform. Structured, where it's possible and free text where there isn't a standard. And the second is the capability to have up loads from home devices using available standards that would accommodate some of the high priority data. So, that's what that recommendation is about.

Next has to do still...it's related to this 204 C, it's related to this patient generated data. This is a certification criteria only that the system gives providers the capability except pre-visit information. So, it can be for example in kids, there's a lot of information that can be submitted ahead of time that certainly improves the efficiency of the visit but also allows the pediatrician in this case or family medicine person to focus really on the stuff where you need a dialogue rather than some milestones that you can answer yes/no. Can that be done ahead of time?

And the 204 D, the next one, has to do with the ability to update or even correct...correct is always an amendment, it's not a get rid of the old, let's say it's immunization that you received at a drugstore or senior center instead or I'm not really on that anymore, I never was on it, ways to correct what is inside the EHR. Can you...is there the mechanism for a patient to submit that information and the accompanying mechanism for the provider to acknowledge, accept, review that kind of information. So, that's what's being asked for here.

Next has to do with clinical summaries. We're sort of waiting for the final rule to make any recommendations about that. And, by the way, we're hoping that the final rule does come out before we come back to it in October, 206 has to do with patient specific educational resources. The add here is language support and there are a couple of options to discuss. One is to say, well what are the top five nationally prevalent languages in the country and make the information available in those. And the other is to say let's hone in on for your particular area, for your particular geography, what's the one Non-English speaking population that's important to you and let's get information where publically available, so we're not forcing people to buy things, where publicly available and NLMs Medline Plus for example has some of that information, make sure that you have that information available in your one prevalent Non-English speaking population as a start, remember these are floors. It doesn't mean you're only limited to one, but let's start the ball rolling in that case.

Next, secure patient messaging. This is just an increase the threshold, an increase of threshold from 10 to 15%. On the communication preferences, we're looking for the results of the final rule before we're talking more about that one.

In the next 209, this is an explore, this is...it's early and we have to understand what the standards are for example. This is the try to have patients and providers aware of what clinical trials may be relevant to this individual. So, in this case...so figuring out whether an individual is eligible for a trial is actually a complicated business, which in today's world generally involves chart review. So, that can't be done in an automated fashion, but potentially you could at least try to query for what research, what trials this patient may be eligible for if they are interested. So, this is to start that process, you know, this is a Request for Comment on querying research enrollment systems and seeing if there are things available for this patient.

And 210 is a placeholder for Stage 4 talking about, you know, that on a fairly regular basis there are recalls for example or safety alerts, can we make that available to patients as well. And, of course the fewer the false positives the better, that's why we're trying to position that for a Stage 4. We're just trying to signal this is the kind of information that patients are interested in, how can we go about getting that for them?

So, that wraps up our current thoughts in terms of a draft preliminary recommendation. We're open for your comments for category 2. Christine?

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

Could I just make a quick correction, I think there was some confusion about the last item, it's listed as a placeholder for Stage 4 and that is alerts for drug recalls. It wasn't a placeholder for Stage 4, it was a placeholder in the current construct because if Stage 2 maintains two things, the ability to generate patient list and the ability or collecting communication preferences than that would be doable immediately. In fact, I don't even think it would need to be a requirement because I think there's enough of a market impedance that people want to be able to communicate drug recalls and alerts. So, as long as those two things are in Stage 2 this will come out entirely. Does that make sense?

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

Yeah, I think your point is well taken that it's...for example; we already do that, you're right, because if we have the ability to generate lists and we have secure messaging then you have the ability.

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

Right.

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

Gayle.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Just one quick question, I want to clarify on the educational material for patients in a different language, are you suggesting that the capability be there but, for instance, if you live in a community where you don't have the need you would not have to provide that information or...be a little more specific in that if you would.

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

So is there a community where there's no other language besides English? Is that the question?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Well, there are many communities where perhaps there's not a large number of people in, you know, any specific language group that you might need to provide additional language resources for.

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

So, I think one point is to say it is a certification requirement that you be able to distribute things in different languages, so that's point one. Then point two there's two ways to answer it based on these options. So, let's say option two you would have...there's probably somebody who doesn't speak English in your population and to have the public available information there to serve up is option two.

Option one would require...well, in your case it would be 80% in the population you described would probably be English speaking and so that would be satisfied largely with serving it up in English; that was one of the reasons we came up with an option two.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Thank you.

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

Paul?

**Paul Egerman – Businessman/Entrepreneur**

Yes, I was going to say I like in this section and also in the prior section that you have some things that are certification only. I think that's an important concept to have and so I like that a lot. I notice where you have it in your, I guess it's 4C and D, certification in terms of basically patient or family provided data and my observation there is the concept of provenance is very important. To simply say, gee you're going to accept this data, but make it clear that this is information that's provided by the patients.

And, I also very much like the idea that you're talking about certification to create capabilities that are multilingual, because that also is a way to deal with some health disparities to make sure that people can have, you know, educational material in multiple languages. So, I think those all are good things.

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

Thank you. I was waiting for the other shoe, but at any rate, Judy?

**Paul Egerman – Businessman/Entrepreneur**

There was no however.

**Judy Faulkner – EPIC Systems – Founder**

A few things, on the one about, 04A is blue button meaning to do it just like the blue button does it or is it the general concept? Because, I think we have to differentiate those. You might not want just what the blue button does, you might rather have the general concept and it might be misleading this way.

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

I think that's a good question, that's why it's labeled explore. I think the concept is more in the subscribe, that is continue to feed and that...you can see the good out of that and you can see the complication out of that, and that's where I think we need to understand the whole spectrum of things so that we do a good...we don't have...

**Judy Faulkner – EPIC Systems – Founder**

And how it looks and what it is and all that stuff.

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

Right.

**Judy Faulkner – EPIC Systems – Founder**

So, I'm a little nervous about the word blue button.

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

Right. I think that was just sort of a term of art, but it's more like what you're saying, which is it's an ongoing update.

**Judy Faulkner – EPIC Systems – Founder**

I'm a little bit worried about where the ability to designate where the documents are sent to specific care team members. Here's my analogy, you're a pregnant woman, you're going to a place where there's five OBs and you say it can be sent to one, two and three but four and five are the people who show up when the baby is about to be delivered. I can't make sense out of that.

**Paul Egerman – Businessman/Entrepreneur**

Well, you have team-based versus single control.

**Judy Faulkner – EPIC Systems – Founder**

It says specific care team members.

**Paul Egerman – Businessman/Entrepreneur**

Yeah.

**Judy Faulkner – EPIC Systems – Founder**

So, I've heard people talk about that as saying everybody on our team has got to be able to get information and I worry about that.

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

I think...it's a fair...so Christine is the lead and she was going to clarify?

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

Yeah, I think the concept, Judy, was really more as...so we were assuming that if you're seeing an OB/GYN practice and there are 5 OB/GYNS that they're probably on the same system and sharing the information, that's not what we were defining the care team as. The care team is really more as a consumer would define it, which is well, I have an OB/GYN but I have a cardiologist and I have a physical therapist and that's really my care team for whatever purpose. And so, if there is something that changes that is significant about my care from a cardiologist I want to be able to designate that, that change automatically gets sent to my primary care provider so that they can decide do they integrate that into the record or not, but everybody, you know, has the most up to date information.

The second concept is that it would allow me to go in as a patient and one time say, or not one time only, but, you know, on demand say I'm about to go see an ophthalmologist and I'd like a copy of my summary sent to that person.

**Judy Faulkner – EPIC Systems – Founder**

I think the way you're saying it sounds like is that, it's not saying these are the only ones. It's saying send them to these and there could be lots of others that are sent in the course of taking care of that patient that maybe you might need to qualify that it's additional specific in addition to those.

The next one was on B, some folks have been concerned about things like as per Surgeon General being fairly detailed and complex, and that might not be the right way to do it. So, maybe it's sort of like the blue button, it can be a choice but not necessarily that it has to be just that.

The second thing is I'm not sure what 10% have the ability to do that means. For example, weight, some of the things that we have looked at on those is not the problem technologically to do it but some of the costs to do it have been quite expensive. And so, when you say 10%, does that mean they could if they wanted to and could afford it? That's different, because where we're finding the problem is on the cost.

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

So, I think the word here...well first of all, I think this has to be clarified. There has to be more detail so that people can react to it as you're pointing out. And the other is the word provide is the same as we had provide for clinical summaries, it's the capability is there, not necessarily that you have to force people to do such and such or in your case pay for such and such.

**Judy Faulkner – EPIC Systems – Founder**

Okay, so as long as that's clear. The next thing is on translation and where was that, 4C? Where's my translation stuff? Oh, yeah, 06, the thing I just want to point out, there are lots of times the screens can be translated, the reports and headings can be translated, but if the physician enters something in English and the patient speaks Portuguese, there's no translation and so it is limited in what the translation is by necessity. You could use Google translator but I'd worry about the patient's health.

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

So, this was patient education resources, so it's not necessarily what the provider entered and it's where publicly available. So, this is specifically...

**Judy Faulkner – EPIC Systems – Founder**

It says materials must be provided. So, if you're doing a portal for example, you can provide the headings on the materials you give to the patient. So, you're thinking educational material?

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

Educational materials.

**Judy Faulkner – EPIC Systems – Founder**

Do you maybe want to say 80% of educational materials in that first one?

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

Sure, and then it's...otherwise, I read it as generic. And then the last thing I had here was on 09, which is capability to query research enrollment systems. It says explore.

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

Right. Explore is it's less developed. We're trying to figure out how we can cue up...for people interested in participating in clinical trials, how can we make them aware of relevant ones.

**Judy Faulkner – EPIC Systems – Founder**

Yeah, it may be that you don't want to do it in that way. In other words, you may want to have instead an EHR capability to enter important enrollment criteria rather than the EHR system go out and query multiple enrollment systems. It's just how it's done. You might...

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

Judy, I'll discuss that. I think that's exactly the kind of question we want to get input on. We struggled because the original formulation of this was that the Subgroup thought that you would allow consumers to actually set their preferences for clinical trials and understand the inclusions and exclusions. But, we realized that A: there are no technical standards for that and B: it gets pretty complicated pretty quickly.

So, one simple alternative, and that's what you see on the slide, is much in the same way that today the electronic record uses the HL7 InfoButton standard to identify relevant patient education materials that are patient specific, same thing that if you could build it into the certification rule, again, not requiring necessarily it's use by the provider, but if you have EHRs that are capable of using the InfoButton standard then it's a great signal to the research community that if they are able to work with that standard then...and you'll always need some human intervention, then at least the EHR could go out and say, here are six potential trials that would be patient specific and then, you know, the clinician can help connect the patients in that way, but that's the sort of simpler first step. So, you know, input very welcome.

**Judy Faulkner – EPIC Systems – Founder**

That's really interesting, because I think there's two ways to look at it. One way is you have a patient who you'd like to put on a trial.

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

Right.

**Judy Faulkner – EPIC Systems – Founder**

How could you go out and look at different things that might be available for that patient. And the other is you have trials that your organization might be doing, how do you find the proper patient who matches those trials?

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

Right.

**Judy Faulkner – EPIC Systems – Founder**

And...

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

So, I think it's the former that this is addressing.

**Judy Faulkner – EPIC Systems – Founder**

Okay.

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

Because the latter we actually could do with like CDS rules. So, the capability is already there.

**Judy Faulkner – EPIC Systems – Founder**

Yes.

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

Okay. Well, good, this is great input. So, we'll move onto category 3 and George is going to...

**George Hripcsak – Columbia University**

Thank you and good morning, thanks for letting us present our draft. Category 3, let me...all the groups did a great job, category 3 a lot of hearings, a lot of work. A big stepping back deeply to say what really do we need next not just incremental change but followed by a fairly severe process to make this concise. So, there are four objectives in the entire category. I'd say care coordination is very important. And, so let me just remind you that the group really pared it down.

The first one was already...that first line is already eliminated. The next is on reconciliation. First of all, continuing medication reconciliation. We have it down as 50%, remember that in Stage 2 the NPRM came out at 65, we recommended dropping it to 50 and we continued the 50 to Stage 3 simply because it's one thing to set thresholds for things that you enter yourself, but things that require input from others outside we were a little more lax on the thresholds.

But, we've added two more items to the list in addition to medications, first is medication allergies. We think that's vitally important. The standards may not be 100% there but its 4 years off and it's a straightforward thing to do. The next one is the problems and this is a simple, a first start in simple reconciliation of problems and just realize that this is a draft that's going out for public comment. We realize that this might be a challenging one and we kind of put them in order of medication, allergies, problems on purpose.

And these two that the second and third that we put in allergies and problems we asked for just 10% at this early stage. And then off to Stage 4, because there's even less standards is contraindications. Here, Paul talked about it, but contraindications means anything that doesn't fit under allergies of the patient and we heard this in hearings...that need to be avoid for that patient but don't strictly fall under medication allergy.

Okay, next on summery of care, first of all the thresholds...so this is continuing of the previous summary of care objective, specifically on the thresholds we left it...well, we continued the paper version, the paper or electronic version at 65% which is where it was suggested in the NPRM, but we upped the electronic by 2016 from 10% to 30%, that was a change there. And in addition, we specified certain fields.

For transitions...okay, let me explain for a second. We have the word site transitions. Now, a transition of site of care as opposed to setting of care and the important thing here is that we mean this to be a big transition. So, for example, going from the patient...within a hospital, going from the floor to the ICU is not the big change we're talking about, but if you're going from one...even if it's in the hospital, you're going from one site to a distance geographic site that would be an important transition that requires more oversight. So, that's what we're talking about here when we say site transitions.

And there are four items listed here, first one, the concise narrative and support of care transitions, setting specific goals, instructions for care during the transition and care team members involved during that transition. These are four things that would be these site transitions that would be required.

And then for referrals, which are also under subjective, only the first one would be required, because that's basically saying the reason for the referral, we think that is reasonable and the others would be included only as deemed necessary by the relevant professional.

Okay, I printed so small that I've got to flip back and forth between my super glasses and my regular progressive glasses. Thank you. Next is care plan. Now, in the care summary we've seen some elements of the care plan. Remember the care summary is a summary of a lot of other things including the patient's personal demographics, etcetera. This objective, this new objective that we proposed for Stage 3 is to bring in the concept of a longitudinal care plan as a separate entity that can become a structured document over time whether it's Stage 3 or Stage 4, I don't know yet, but can become a thing that is maintained.

And as you can see we have, for each transition of care, provide the care plan information including the following elements as applicable. As applicable is an important thing as we wrestled with putting this in, in Stage 3. So, this is a list of items that we think may be important in the care plan, the longitudinal care plan and this is going to be a common period. So, we're flexible on what exactly the elements need to be and this is a first list to get the thinking going. We expect that this will change after the comment period, but we emphasize that the as applicable means that not every transition will require every one of these elements. That's for transitions of site of care.

And then for the referrals we simply say that you don't have to necessarily, for a simple referral, say you're just referring someone to the dentist, you don't have to generate a longitudinal care plan necessarily, but if there is a care plan it would be good electronically, since it's no extra work for you, to have that sent to the provider that you're referring to in the same way you would send the referral and that because this is just beginning we're starting with 10% threshold.

And, the fourth objective for Stage 3 is about closing the loop and basically when a referral occurs the provider who is referred to acknowledge receipt of the external referral information and then provides referral results back to the requesting provider. And, so this is linked to the order entry requirement that Paul talked about earlier. And again, our threshold of 10% is low at this point because we're just starting with this.

The next two are for Stage 4 and actually related to previous objectives, first is to maintain an up-to-date interdisciplinary problem list inclusive of versioning and supportive collaborative care. In other words, the real problem list is going to be a lot more complex than simple reconciliation and we recognize that. We recognize that's its difficult and we see that it's something that's often Stage 4 but we want comments on it now.

And then the next row is medication reconciliation, receiving a data feed from PBM. So, in other words, gathering more data so we can do a more reasonable medication reconciliation. And the last two have already been moved as of the NPRM into the care summary. And that's it. Comments?

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

I have some comments, George, great work, you know, this is really important to the VA because of connect and exchange, and Direct. So, I have one question...I have a few questions, on number one, eliminate for Stage 3 in favor of use cases, are they in here and I just didn't see them?

**George Hripcsak – Columbia University**

The use cases are that HIE is required for reconciliation.

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

Oh, okay, so that's what you've done is just...

**George Hripcsak – Columbia University**

And for referrals or that and that's actually done as of Stage 2.

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

Okay, great. The other thing is, I think our concern as we have a perspective in terms of at least connect and using exchange that way is that the community is lagging a little behind in terms of the ability to engage in at least exchange. Obviously, there's some more information going on in Direct. So, I'm just wondering, given what you know about the current landscape and I realize we're talking 4 years out, Paul, so I don't want to minimize that it's a long time, whether you've taken that into account and I'm sure you have. But, I think that that's...obviously we would like to see acceleration in the marketplace around this for many reasons. I'm wondering if...do you think the incentive is enough with it being in meaningful use?

**George Hripcsak – Columbia University**

So, a couple of things. I think that...remember, this is our fourth to last presentation of this draft followed by more presentations after the NPRM. So, we do see a path. If we set it too easy it's hard to make it harder along the drafting process, whereas if things don't go...you know, it's easy to cut it back than to add more a year from now. We've set the thresholds to be...you know, we've tried for mostly 10% and that will be adjusted further, but in a lot of places you heard me say 10% for exactly that reason because we don't know how many people will be, you know, with a telephone on the other side listening to this, you know, figuratively speaking.

And, finally I think you can imagine amazing things in care coordination and we've pared it down to this list in effect for that reason. Now, we may have to see whether this is still feasible, but this is an enormously pared down list from the kinds of things we'd like to do in transitions of care by 2016.

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

Yeah, I think it goes back to Marc's earlier comment about are we...do we know enough out there right now to be doing informed decision-making about where we should go and if I had to choose the 4 or 5 things that Marc said were critical, this is, in my opinion, really critical and we need to just emphasize it, so, thank you.

**George Hripcsak – Columbia University**

Okay. Christine?

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

I think on a similar note, one of the things that I thought the Workgroup was talking about was with respect to item 2, wait a minute, nope, sorry, item 3, you've got 30% of summary of care records sent electronically and one of the things that, you know, we've really struggled with over the trajectory of meaningful use is trying to figure out, and particularly in Stage 2, how do we really drive exchange and how do we support the maintenance of that exchange among those who are capable of sending and receiving, and so we had a talked a lot about things like well are there other ways to look at the environment and see what's happening with Direct or what's happening with state-based information exchanges or even Direct, you know, meaningful user to meaningful user, to see if it is still appropriate to continue that construct, which is an older construct or should we shift our mindset in the way that we're encouraging exchange.

And, so I thought that the workgroup was going to have a broader discussion or encourage it, I don't know if it's in the RFC or get IE Workgroup opinion, but to really figure out with input from HHS where is the market now, where is it going and where is it likely to be in two years and is this the right construct or can we advance it in a different way?

**George Hripcsak – Columbia University**

Well, one thing I want to emphasize is that we're trying to stay away from, first of all how it should be implementing because it's so far off and we don't know how it's going to go.

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

Right.

**George Hripcsak – Columbia University**

So, these are the functional requirements of what we want to happen clinically, in other words, you want this clinician to be connected to that clinician for this patient. So, that's what we're saying, we're not saying that that would be implemented via Direct because that's one directory between the two. HIE, however, as it unfolds should support that function.

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

Yeah, I'm not necessarily...I am definitely not trying to prescribe the process. What, I'm saying is a 30% threshold the right way to continue to drive exchange when Stage 2 was really supposed to be the era of information exchange and I don't think we hit that mark, at least in the NPRM because of where the environment is, right? So you can't construct a new threshold and measure that will or won't drive exchange unless you understand where the information exchange marketplace is, those two examples I used being but two examples, but we talked for instance about the fact that CMS reports on the meaningful use website the name, NPI address, everything of every provider who has successfully attested to meaningful use

If we were to think about Stage 3 two years from now and the possibility of actually having a provider directory so that I know if...and my EHR can automatically tell me without additional workflow steps I'm transmitting to another meaningful user so I can do that electronically and the threshold we're doing that should be much higher than 30% as an example.

**George Hripcsak – Columbia University**

I'm not sure how sensitive the market really is to the threshold we've picked for these recommendations and I'm afraid that if we go too high it will, not a backlash, but it'll...you know, have an unintended consequence of pushing people away from meaningful use rather than driving HIE forward. I think once you're at 30% you kind of have to have real...I mean, 30% is much bigger than 10%, it really means you're almost there. Say, like 30% versus 50%, versus 65% are roughly the same number, 90% is a different number, 10 is a different number and there's stuff in between.

How we ended up at 30 is usually because it's a committee effort and so you pick a number that everyone feels comfortable with. I think there are people that if you start at 50 people wean it down toward 30 or whatever, but I think that a 30 versus a 60 is not going to change the market. But, I think what we'll do is we're going to get comments back on the request for comments from the public and that may make us shift up or down.

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

Right, all I'm suggesting is it's not necessarily about the number or...it's more about the construct and that what I think is needed is a conversation about the environment for exchange and what makes sense and how to do that and then a relook at that, that's all I'm saying.

**George Hripcsak – Columbia University**

Okay.

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

I'm not suggesting that I know the way, I'm saying let's think about the broader exchange environment and have that as one input into this piece.

**George Hripcsak – Columbia University**

Okay.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

Yeah, so, I'll weigh in on that, you know, this is precisely when I made my comment earlier about where do we push and where do we follow, this is exactly one of those spaces, you know, I mentioned quality measures as an example when I made the comment, but this is really as important of a one and as difficult of a one.

You know, the only area where we've seen significant exchange happening is in ePrescribing and that's because it's been around the longest, you know, if we go and look at the health information exchange, the verb, and how we're actually doing in the country it's not pretty, you know, we haven't made the kind of strides. So, the question now is do we push it? And you're pushing it I think right now with what's in there and I'm thinking we have to push it too, but this is an area where we probably need to get good public comment.

I think everybody's identified the importance of having the information ubiquitously available in all venues of care, but it's still lip service, it's not like...everybody is not there ready to do the work and ready to say I'm willing to pay for this, you know, I'm willing to pay for exchange, you know, so when we think about the sustainability of the exchanges that exist today, you know, it's still tenuous as well.

So, this is an area I think where I don't know if we plan a hearing, I don't know how we get more information, but I think it's really important to get more information and it is about the process. And, to Terry's point, we have to have optionality in terms of standards, there's just no question that there's not a one-size fits all for the different kinds of use cases that we talk about. So, I don't think it's the purview of this group to specify that, but I think again we have to really lean to the Standards Committee to give us some guidance in that area.

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

We definitely want to open it to comment of the kind Christine mentioned, like we had talked about the meaningful user to meaningful user, and just give people some options and get their feedback because people want to do the right thing too, but we just don't know what people, if they thought about it, what would be the most expedient way to trade with their clinical trading partners which is the goal and we can't be limiting, we can't be prescribing, but how do we...so it's well worth us putting it out in a way that solicits that kind of feedback.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

One other comment. I love where you're going with the care plan stuff. So, you know, I think, again more public comment and more vetting of those ideas, but you're listing of the things for the care plan is a really, really good start.

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

Thank you. Gayle?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Thank you, Paul. I want to chime in on the exchange and true care coordination depends on exchange of data and you've got to be able to do that. I really think we are a long way from making it happen and I know I'm working with our...we're trying to set up a local HIE down with the South Florida Rec and the difficulties are huge, but I think there is the ability to do it. By the time we get the Stage 3 we've got to have in place an infrastructure.

So, we're at the critical timeframe right now and I would encourage the Meaningful Use Workgroup or perhaps the Policy Committee as a whole to hold a public hearing on this and bring together the people who are out there struggling, hear from them directly what their problems are. I can tell you I go around the State of Florida and all over the Southeast and I hear exactly what's going on, and if you brought all those people into the same room and you heard from them, it would be a revelation to this committee, they would be shocked at the difficulties out there and how far away we are from exchange.

**George Hripcsak – Columbia University**

Yeah, I think the hearing is a good idea, I actually had already written down hearing for after the RFC, but maybe that's waiting too long, we've got to have it sooner.

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

And we want to also not only be shocked, but I hope we can solicit some proposed solutions.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

I do agree and there are solutions out there and they're not necessarily the ones we're envisioning right now. So, I think we need to really hear from the people in the trenches and see what they're doing.

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

Great things to talk about. Steve?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Steve Posnack, you got me? All right, good. So, I'm just...we've been through this twice now, right? And so I'm wondering if at this juncture it's more important, maybe this will be slightly rhetorical, slightly advice, that the percentages not be part of what's put forward because it's a little bit distracting and I think takes away from the discussion about the policy that you're trying to accomplish.

And I think through the request for comment and other processes where we get public input you'll get a better sense of what a real percentage might be if people agree with the policy, because I think at the end of the day having been through, you know, I would say, the rulemaking process twice now, seemed to me, there are a lot of other tangible factors and assumptions that go into the eventual percentage, you know, who has broadband in a particular area, that then creates a particular limitation for how many people could fall into, you know, whose percentages are what, and so there are a lot of different factors I think that will need to be thought through after you arrive on a policy outcome that you're looking for.

And, so, I think framing the objective for what you want the policy to accomplish might yield a better response than, and distracting is a strong word, but I think you'll get a lot of distraction in the percentage is too high, the percentage is too low, and then you won't get the comments that you want on this is feasible today, this isn't feasible today.

**George Hripcsak – Columbia University**

Steve, do you mean specifically on the new objectives or all?

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

No, I think I mean in general, that would be my advice to consider when you go out with the request for comment that the percentages not be part of that. I mean you can...I would say target that for like March and April when you actually have a good idea of what the policy is going to be.

**George Hripcsak – Columbia University**

Thank you. Terry?

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

I wanted to follow up on what Gayle said because I do think there would be a lot of dismay knowing the current state of this and I also want to remind people there is exchange with a big “E” and exchange with a little “e” so I think we could get confused here. But, George, I do like the idea of relooking where we are right now because it may be, you know, we have a few options for doing this, but perhaps there’s another novel way to advance this.

I mean we have I would say stayed tried and true some options of how we’re doing exchange. We know that there’s not good pickup in the healthcare sector out there for enumerable reasons, but maybe we need to have a fresh look at what options are as we go forward to really accelerate this, because I think, Christine’s really right, we need to have some sharp prod here and whatever we’ve done up until now isn’t it.

**George Hripcsak – Columbia University**

Okay.

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

It goes back to what Judy said, I mean it’s a hard thing that everybody wants and that’s...so how do we make that happen.

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

Well, but I think that that’s the beauty, Paul, that’s why there is a really distinct advantage on this one, everybody wants this, the consumers want it, the providers want it, the payers want it, we just got to figure out how to do it.

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

We’ve got to find out who is not wanting it I think. Okay.

**George Hripcsak – Columbia University**

Okay, other questions, okay, good. I’m going to go onto Subgroup 4, improving population and public health. Okay, the first objective is about submitting data to immunization registries, our intent was, although it may not be clear from reading this, is to continue the submission and then add to that the capability to use that, you know, there’s no sense in having everyone in the country send this centrally if no one is going to use it for clinical care, so, the idea that by Stage 3, 2016, you’re able to receive the patient’s immunization history supplied by an immunization registry or immunization information system.

And, in fact, we had a...even here we had a discussion about prioritizing and the feeling was that immunization was an important one was to push hard on and you’ll see in a second that there’s more to come on immunizations. And then pushing to Stage 4 the idea of submission of vaccine contraindications and reasons for substance refusal, again, similarly, like the other contraindications that it’s not quite ready yet and something that we can put off, but we do want comments on now. Do I want to say more, no that’s good.

Furthermore, this is...you can look at this as a second half, it’s related to the first one, its capability to receive, generate or access appropriate age, gender and immunization history-based recommendations. So, what we’re saying here is that not only have we put it centrally, not only can you review it, but we have the technology, for the last 20 years, of generating recommendations that are reasonable and the provider should be able to use that.

What we here that for 20% of the patients receiving immunizations they receive recommendations before giving that immunization. This could be implemented by putting rules in the EHR or by receiving recommendations say from the Public Health Department or by simply accessing those recommendations and then we can decide through public comment whether they have to be stored in the EHR or not, but the...so we’re trying not to prescribe how you get your recommendations and where exactly they’re generated at least at this early point in time when we’re specifying these things. So, this is basically a public health-based decision support in an area that we think is critical.

The next one is about submission to...reportable lab results and that's unchanged. The next one we came up with a new stage for it, it's called objective presented for comment, stage undetermined. We didn't call it Stage 4 because that implies that the Subgroup wanted to wait until after Stage 3. What they wanted to do is get...so they're not putting it forward as a Stage 3 definite, in other words, they're not sure whether it's feasible, they want comments but they don't want to necessarily say that it has to wait until Stage 4 and that's what this intended. And, I think 1 or 2 of Paul's could have been classified that way.

This one is the capability to use externally accessed or received knowledge to determine when a case report should be reported, in other words the Public Health Department steering the reporting of diseases back to the Health Departments about population health. And we're worried that the technology of the standards and the technology to do this may not be there yet and that's why we didn't state it as Stage 3, and by the way, in the column that says Stage 2 NPRM new for Stage 3 it should just say new not new for Stage 3 since we haven't assigned it as Stage 3, so that's just a typo.

The next is syndromic surveillance and that's no change from current requirements. The next two relate to the new registry objectives that were in the NPRM. Basically, this one is...that first one was about cancer, this is extending it or broadening it not extending it, broadening it to say electronically...the capability to electronically participate and send standardized commonly formatted reports to a mandated jurisdictional registry. In other words, pick one of the things that you're mandated to do and report that electronically from the electronic health record although the threshold is set fairly low. It's hard to discuss this at length until we see what the Stage 2 final rule says about registries, so we recognize that.

And then if I go to the next one it's really the same recommendation only it's not forced to be the mandated or jurisdictional one, but to be any registry that you want to collaborate with. We put this as objective presented for comment stage undetermined, again, for concern about the number of objectives and what's feasible and what registries that are non-jurisdictional that will have the capability to receive it in time, but this has got to be coordinated with the Stage 2 final rule. So, if the Stage 2 final rule mandates 2 then we can do 2, if it cuts down to 1 or 0 then we might cut down to the 1. Okay.

And, then the last two are here, actually it's really one for Stage 3, the first one is to electronically send standardized healthcare associated infection reports to the National Healthcare Safety Network for eligible hospitals. So, this, our understanding from our research is that this is definitely feasible because it's required and we want it be done through a mechanism through the EHR and through the standards and that's why we are including it as an objective.

The second line there, which is again one of these objective prevented for comment stage undetermined is an analogous thing for adverse event reports, but we felt that because the standards weren't there yet that we couldn't comment of what stage, so at this point it's really putting it out there for public comment and see what the reaction is and that's it for those. Comments? Judy?

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

Judy Murphy, just a quick question, George, was there any discussion, and I actually don't know if this fits more in the consumer or in the public health, was there any conversation about patient and significant other access to immunization reports? You know, we talk about providers getting access to it, but it's really been an area that has been up and coming in terms of public desire I think in the nation to have patients be able to access their immunization records themselves or again, you know, guardians.

**George Hripcsak – Columbia University**

I think we were assuming that the patients had access through patient engagement, in other words, they're accessing the medical record through view, download and transmit and that would be the mechanism to get the provider's version. And then there's the public health central registry version and that we can't mediate through the EHR so we can't do that one.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

Fair.

**George Hripcsak – Columbia University**

But if you think there's a need for a separate provision to ensure that patients can get to this information, but it's interesting, we hadn't thought of that.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

There's a bang for the buck there, but you're right you're differentiating the EHR version versus the immunization registry version and I hadn't actually, you know, made that connection myself.

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

You could talk to Todd Park in the open government initiative.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

Yes.

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

I mean, honestly that's...

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

It maybe for consideration.

**George Hripcsak – Columbia University**

Okay. Michelle?

**P. Jonathan White – Agency for Healthcare Research & Quality (AHRQ)**

Oh, sorry, Jon White, I have no nametag. Just strapping on my AHRQ helmet for a second, as you all discussed sending adverse event reports; I think my colleagues back at the ranch would like you to consider patient safety events and patient safety organizations within that context, thanks.

**George Hripcsak – Columbia University**

Okay, all right, expand that. Judy?

**Judy Faulkner – EPIC Systems – Founder**

A couple of things, one is on the immunizations, because each state can do immunizations differently in the immunization section when it says be able to take the immunizations, suppose you're Marc and you're in Utah and that someone shows up from North Dakota, what happens? What is your expectation because maybe Marc programmed it for Utah but not for every state in the country or is that the expectation?

**George Hripcsak – Columbia University**

The expectation...it's interesting the thought about moving your immunizations from your previous state to your next state, so we didn't really consider...well, Art is on the phone. Art, do you have a comment about that part?

**Arthur Davidson – Denver Public Health Department**

Sure.

**George Hripcsak – Columbia University**

Art Davidson.

**Arthur Davidson – Denver Public Health Department**

Yeah, so thank you, so Judy you're saying that the rules are different in the two states about the recommendation.

**Judy Faulkner – EPIC Systems – Founder**

The way the data is stored, formatted, collected can be different from state to state, that's run by the states.

**Arthur Davidson – Denver Public Health Department**

Well, supposedly we're driving the market to a common standard with HL7 and there are standards established from both CDC and American Immunization Registry Association, and HL7 implementation guide, and there are many states around the country that have implemented that. Indeed, there may be some variation between those, the goal is by trying to get more places to start sending, and vendors like you, start sending that we can drive those state registries to a more standard implementation.

**Judy Faulkner – EPIC Systems – Founder**

Well, just as an analogy to the lab systems, lab systems use HL7 too, but it still can take 6 months to write an interface to a lab system and that's why I don't know how to...I don't know that we have the power to say to each state you have to change it or if they have the wherewithal to make all the changes, especially if there's not a standard that is a US standard. So, I'm wondering whether at least it could address maybe that it has to be in your state or something.

**Arthur Davidson – Denver Public Health Department**

Well, maybe, Judy, is every implementation that you have of EPIC standard?

**Judy Faulkner – EPIC Systems – Founder**

What?

**George Hripcsak – Columbia University**

Is EPIC standard?

**Judy Faulkner – EPIC Systems – Founder**

No, they're not standard but we do try to work both with the immunization registries and with the lab systems but each of the lab systems are different even though they are HL7 compliant and the states are different for immunization and it may hard for...it may be hard for say the EMR that's not a national EMR, it might be more in a region to write it for every state.

**George Hripcsak – Columbia University**

So, this is a very important point, it's analogous to the previous discussion on HIE.

**Judy Faulkner – EPIC Systems – Founder**

Exactly.

**George Hripcsak – Columbia University**

How do we drive the public health arena to have a...

**Judy Faulkner – EPIC Systems – Founder**

Very analogous.

**George Hripcsak – Columbia University**

And how much can we drive it and how much do we follow it and so forth? So, I think it's another item for discussion.

**Judy Faulkner – EPIC Systems – Founder**

Right, I thought of that too.

**George Hripcsak – Columbia University**

And hopefully the public comment will also inform it.

**Judy Faulkner – EPIC Systems – Founder**

And the registries kind of fall in a similar thing as well, you know, we've talked a lot about the HIEs and they need authentication, and they need a phone book, and they need standardization of what you're sending back and forth, it's a lot of the same problem here. When you get into the registries two things I do want to alert you to and that is depending on what the registry is, some of those registries charge significant fees and some of those registries do not allow you to use the data that you're sending over to them in any similar format for anyone else, and I would just make sure that we don't require everyone to end up in situations where they are very limited with registries.

**George Hripcsak – Columbia University**

I believe in our Stage 2 comments we made that specific.

**Judy Faulkner – EPIC Systems – Founder**

Right, we did, I'm just bringing them up again.

**George Hripcsak – Columbia University**

Okay. Terry?

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

My comments are complimentary I think to what Judy just said, but I want to go back to the state of readiness out there of Public Health Departments in the states, because what we don't want to do is have an unintended adverse consequence by putting out all this different stuff and the EMR vendors don't want to be sending four different paths, one to immunization, one to registry, one to public health, not

over the same thing with all the different...and receiving. And, I wonder if we can relook at this some way so that we actually drive capacity at the State Public Health Department level.

So, I'm looking at the receiver of the data versus the EMR, which is the sender, but what I worry about is that if we rely on things like registries, cancer registries or other registries that are proprietary we're actually not helping the states or the populations improve population and public health, what we may be doing is contributing to a database that's used for multiple reasons. And I don't really know how to get that but I worry that we're side stepping that really large issue is that we need Public Health State Department IT capacity.

**George Hripcsak – Columbia University**

Remember, that one...so that's a very good point. The ways that we wanted to save registries as a concept and not just move to the referral to the state one, even though there are difficulties that we've highlighted, is that our subspecialist may not be doing immunizations, they may not be doing this, they may not be doing that, but they maybe be participating in a registry relevant to their subspecialty, we wanted to be inclusive and have their part. Now, it's not part of the government run population health monitoring but it's another form of population health that our subspecialist could participate in. So, we wanted to work it out, so we may not have it perfect but we want it to work.

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

Okay.

**George Hripcsak – Columbia University**

Gayle?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Yes, it's a dual-edged sword, you know, you want to include subspecialties and I certainly am an advocate for having measures and standards that allow them to participate, that's extremely important, but you have a very...it's a fine line we're walking here in what you can push in this element and at the state level and with state departments of health, I think there's no money out there to do what really ultimately needs to be done and it's going to take some time and I don't know if even by 2016 most departments of health in various states are going to have the wherewithal to be able to receive this information, you know, there are some there that don't receive it now electronically and I'm not sure it's going to make any...there's going to be any major changes in the state's abilities to do this.

So, presumably this is state dependent if you can't transmit, if a state can't receive it you can't transmit it. But we need to be very careful that we do not have the ability to do that, that's up to the states. Yes, you can make it out there as a goal, but we cannot enforce that.

**George Hripcsak – Columbia University**

Okay.

**Arthur Davidson – Denver Public Health Department**

George?

**George Hripcsak – Columbia University**

Yes, Art?

**Arthur Davidson – Denver Public Health Department**

I just wanted to...I agree with you, Gayle, this is Art, and I just want to make sure that you see that in almost all these it says where applicable state law and practice. So, if the practice is not such, a meaningful user would not be penalized. So, the absence of the capacity at a state would not penalize the meaningful use incentive to that provider.

**George Hripcsak – Columbia University**

On the other hand, we don't want to create incentives for states not to assemble registries just to make it easier for their doctors in the state. So, it's a complex question.

**Arthur Davidson – Denver Public Health Department**

Right, and I think, you know, back maybe to Terry's point, I think the goal is to really drive states to a more common standard themselves, you know, we talk about many different types of registries and they probably all have...their variance of a common theme is just how can I receive data and I think that's one of the things that's going on in the public health reporting initiative and ONC is how can we find a standard that's going to make it easier for many programs that are funded in very different streams to coalesce in the technology that they're trying to build.

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

Yeah, and I just had one more comment, and Art, you will recall, right, even before Stage 1 there was lots of dialogue at ONC about the public health agenda as opposed to the patient and population health agenda and obviously they've merged, but I do think we would be remiss to not try to at least embody the goal of getting public health/population health to where individual patient health is in terms of Health IT and I don't want to miss that opportunity, and while I agree with Gayle that states aren't already, I don't know what's going to make the states get ready. Obviously, financial incentives would help, but...

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

I want to chime in about that too, you know, states are struggling at this point financially and without the wherewithal to do it, there are no dollars out there. So, it takes incentive dollars, you know, this is a whole incentive program. And yes, we've given states significant dollars for exchange. I don't know whether some of those dollars can be redirected towards health, you know, population health or not, but there's a way to look at, you've got to put the dollars in place to do it.

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

So, Paul Egerman mentioned that he liked the fact that we're trying to use a different lever, the certification criteria only, I wonder if this category fits that particularly well, in other words we want the capabilities to be in the EHRs but it's far from this program to either force the providers or it's what you're saying force the State Departments to be able to do things that the resources aren't there. So, this might be one of those get the infrastructure ready but we can't pull the trigger on the folks which are within scope for EHR programs. And that's unlike the Health Information Exchange where we do have some levers but we've just got to work out how do we get those to all play, but maybe this is more in the certification criteria only. Any other comments on this last category? Well, certainly want to thank the Policy Committee for a very good discussion. Thank the Workgroup.

**George Hripcsak – Columbia University**

Do you want other comments...?

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

Yes, and thank the Workgroup, the Subgroup leads for getting us through months of preparation including listening sessions, etcetera, to get to the place where we're presenting this to you. We'll take this back and work on them. There are some areas where we want to clarify and then as I say we're going to reconcile them with the final rule that comes out before bringing it back to this group in October before the RFC.

So, it was a very orderly discussion, now I will live up to my commitment to Marc to throw out the five things that if only the world did we'd be in better shape. So, Marc, at any rate, so this is not just for Marc, but it's a broader opening up for broader comment on the stages of meaningful use and how to use this program effectively. Marc?

**Marc Probst – Intermountain Healthcare**

I'll be happy to break the ice and you're going to have to pay me for the five. You know, I'm looking at this, and you can correct me ONC or Paul, or whomever, we came up with a three stage process for meaningful use. We had a timeframe dictated to us when penalties would start being applied and, you know, we applied the incentive programs to it, but I'm going with that's not law, but that was some targets that we put forward and I'm hoping that that's the case. If it's law you obviously have to do it...

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

But 2014 and 2015 are law.

**Marc Probst – Intermountain Healthcare**

Yeah, but the three stage approach, when we implement Stage 3 does not have to be within that end of 2015, that's a goal we set, a target we set. Again, right or wrong I'm not making that, I'm just trying to put my arms around it. So, if I go back a ways, I think meaningful use has laid a tremendous foundation for electronic medical record use and it certainly raised attention, I mean the success there should not be glanced over. I mean, I think that's truly been something that's happened, we're seeing systems deployed by people that probably wouldn't have and they certainly have a lot more direction and with the RHEX and other things we've got a lot more support out there. So, I think that's terrific.

But, as I look at some of the meaningful use objectives, you know, we have things like achievable, addresses national health priorities and I just think there's a lack of evidence that we're doing those things. I think there's evidence, with \$6 billion that we're deploying systems, but I'm not sure if we're achieving those specific objective and if we go to achievable we tout the \$6 billion and we tout 50 and 20%, 50% of hospitals, which, with the glass half full that looks pretty good, with the glass half empty 50% are not achieving meaningful use and 80% of providers are not meeting meaningful use. And I think that's interesting.

What is our goal for achievable? Seventy percent, is that good when we hit 70% that's achievable or is it 100% that we talked about, Paul talked about earlier? And I don't know that we've ever laid that down, but to me 20% shouldn't be a market for achievable. We shouldn't say that we've done what we went out to do, and I don't think even 50% is on the hospitals, and I know those numbers are going to continue to grow, but again is it 75% is that when we hit that we now throw the party and say, wow we hit achievable or are we trying to do something broader for our country?

So, with all that in line, through the process we have definitely filtered out some big problems and we talked about several of them today. Interoperability remains a huge problem, our ability to exchange data and we see so many benefits for it whether it's in transitions of care or whether it's around population health management, there's just huge benefits to interoperability.

And I've mentioned it before; I go back to the Australian Railroad and the fact that there were great intentions there. There were people that needed to move large items and so they built railroads and they built them all over the country and usually it was natural resources and that type of thing, and the only reason I bring that up continually is, I've got these great pictures. I got these pictures of this huge contraption that takes a whole coal car for a train lifts it up and dumps into another train so that the train can then move down the other set of tracks that are on a different gauge that sounds just like health information exchange to me.

We build these very expensive, difficult contraptions all over the place to take data from one system and move it into another without ever addressing the underlying problem and, you know, those are things around support, there's cost, there's safety issues, there's an inability to secure things when you're continually moving them between these different standards and processes.

All this comes around to one the timing issue that I think we're trying to do things very quickly but are we exacerbating that issue of the Australian Railroad without solving the core problems around interoperability, which if we want to get to four or five things they all have to do with standards, whether they're data standards, transport standards, patient identification standards, all the things we have to change or deal with. I think those are huge issues that are out there and I would see a real opportunity.

I think we've done a lot of good. I'm really proud to be part of this committee and the things that we've done. But are we going to leave the legacy that we want to leave? Are we going to leave things better off 10 years from now? And I just really feel strongly that we aren't addressing firmly enough some of these standards. Why wouldn't there be a standard for how states receive immunization, store immunizations and use them so that we can actually help a patient that goes from state to state?

Why wouldn't there be data standards so that we can move real clinical computable data between information systems so that we can care for patients and share knowledge, and who is addressing that? I mean certainly I don't know of anyone in the government that's willing to take on this 10 or 15 year vision that will actually fix healthcare. I would love to see this committee be part of taking that step forward versus adding more requirements which I think are just building on the investment that people have made.

If we don't think the people that have bought these information systems are going to invest their...you know, are going to use that investment and expand upon it, I just think they will. I think we have an opportunity to lay down some pretty firm tracks to get us on a single gauge of railroad in healthcare technology standards that would foster innovation, would dramatically lower cost and would save lives. So, you know, now I'm preaching and maybe the whole thing was preaching, but I'm worried that we continue to lay more requirements out there versus solving the problem that's out there and we're in a unique opportunity...we have a unique opportunity to do that.

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

Okay, I'll go ahead and try to respond as a private citizen, because...and I'm going to comment on our government program. I think you mentioned 50/20, leaving out 50/80 that's 50/20 in the first of 6 year program...it's a...it's beyond 6 years, but the incentive alone is a 6 year program and it's a program in perpetuity, starting before HITECH the best available survey of comprehensive EHRs in the practice setting was at 3%, in the hospital setting it was still less than 10%. To go from 3% or less than 10% to 50 and 20% achieving something that even the 3% weren't achieving is a massive improvement in the infrastructure of providers in this country. I would certainly say that our patients are better off in quality, in safety, and even their satisfaction because of the meaningful use system that we've put in. So, in some sense...one, I want to comment that the 50/20 is extraordinary in the first year of a multiyear program.

The second is, you're talking about standards and on reaction to interoperability which we all recognize, so this FACA is set up by one piece of legislation to advise on one of the scope of that legislation and it turns out we don't have a whole lot, we certainly don't have jurisdiction over the standard setting process, but we're trying to influence it with the levers that are afforded us.

I think this was intended to be a public-private effort and I think, one it is a public-private effort in terms of the FACA Committee and I think what we do in terms of advising on the levers that are afforded us is causing, hopefully, well I know it is causing some and is it causing enough? Well, I think we actually have other venues to try to tease out what are the issues and even point out where are the opportunities in terms of collaboration, because it isn't just the government for sure, but I think the private sector has to live up to it as well, this is a Paul Tang personal opinion, and that we have some levers to press to make it in everybody's best interest or even better interest and get to the place that you described.

One, I think the program, and I really actually feel that the HHS administration of this program has been extraordinary and has accomplished extraordinary results, and want to congratulate this committee and the staff, and the folks that have made the advice that helped contribute to that. And so, that's not downplaying any of the remaining challenges you have, but I think it's within all of our...both interest and purview to be able to contribute to that which is partly regulatory and partly market-driven, but I think we can set up the country for success. So, that's sort of a personal reaction but also trying to define a little bit of what is and isn't in scope for this group and this program, which is just one piece of legislation. But, other, Judy why don't you go ahead and then...?

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

Sure, Judy Murphy, so, as a private citizen here, here, I know what you're saying and I get, you know, impatient with this stuff as well, and, you know, Paul saying we have made great strides, but is it enough? And sometimes it doesn't feel like enough to Marc's point. So, maybe the Policy Committee, now back to my normal hat, what the Policy Committee could consider doing is making a policy statement like states shouldn't be able to define their own standards and in fact we should have an national standard related to the way immunization data is stored and accessed.

We could certainly partner with the CDC or make a recommendation to the CDC who sort of has purview over that. And again, we can't just autocratically do it, but what I'm saying is make a recommendation or advise to that point and whether that's, you know, the committee feels they want to do that or need to do that, it is, I would think within your purview to be able to do that and actually I'll look to Steve Posnack maybe you want to comment on that in Jodi's absence, but certainly any kind of recommendation like that type there would be no reason why you couldn't make those. He's nodding his head, okay, good.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

I'm nodding, sorry for the people on the phone.

**Judy Murphy, RN, FACMI, FHIMSS, FAAN – Office of the National Coordinator – Deputy National Coordinator for Programs & Policy**

But, it might make sense and that would be a matter of policy I think and under the purview of this group to make that kind of recommendation.

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

That's a really interesting idea. As, Terry was talking about and Gayle, maybe the two kinds of hearings or the hearing that I heard, ideas for two hearings that I heard in the discussion, one is this whole HIE which we've certainly looked at before, but look at a lot more of the angst, but also the proposed solutions, because we've just got to get there. We thought it might, it was wishful thinking in 2009 to think we'd be in Stage 2, you know, 2012 to do this, but it's still hard and there's still room to grow.

And the other one was the state issues, which is completely out of our purview, but what Judy just invited us to do is can't we, as an advisory committee to HHS, can't we make some statement that potentially, and Terry you're part of the government, you know, could there be more private sector instigation of government action on something that is a public good? Maybe we could have a hearing on those issues. We just have to be better informed so that we, I think this invitation you just issued, Judy, of us making a recommendations about this, in response to Marc's comments, maybe that's a very useful way for us to contribute there. And then Gayle was next and then Terry.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Okay, thank you, Paul. I just want to make some very general comments about the whole thing, as we have moved from Stage 1 to Stage 2, Stage 3, I think my glass is always half full. I am a very positive person, I think we can achieve great things if we put our minds together and we have one opportunity, we have this unique HITECH money out there and I always says it's my grandchildren's money that we're spending, but I think we have this one opportunity and we have to get it right, because I don't think this is going to come around again given the financial status of this country. So, let's not waste it. I think we're on the right march.

One thing that does concern me greatly as we have moved forward from stage to stage I want to...I harp on it every time, we still have not specifically addressed the many, many providers out there who fall into specialty care categories. We have got to really make sure that at the end of this when we get to Stage 3 that we have our specialist, as well as our primary care providers, out there part of the system and that they have obtained meaningful use and that their records can be then interoperable with that PC, otherwise the system isn't going to work.

Secondly, I want to go back to this interoperability, and I totally agree with Marc, and the whole HIE concept and where we go with that. If you have standalone systems that don't talk to each other, we are never going to achieve the benefit that we want to achieve. And whether it is us making direct recommendations and I like the idea of a policy statement to the states and I think we need input from the states, you can't make those recommendations without hearing what their problems are too, so I would agree with the public hearing on that.

And get those Department of Health CEOs here and let's sit down and hear what their issues are. Also, let's...I think it's absolutely essential we hear from the people out there in the trenches who are absolutely trying to do this interoperable HIE exchange of data. We won't get the bang for our buck without it.

And then I just want to make a couple of comments on decision support. It is a very important part and it's one of the key parts of being able to have a learning healthcare system and I think that's where we all want to see this go. But, I have a little bit of fear and trepidation when we get into decision support that then tries to, where we go with, looking at how physicians, how providers respond to that and putting in then the rules and regulations that not just perhaps inform a physician to help make better decisions, but then start directing the decisions and start limiting decisions and you get down a very difficult line and a very scary line that makes people and my constituents very nervous, that you're going to have, whether it's the HMO, the healthcare system or big brother out there making decisions as to...at what age can I get dialysis, you know, if I reach 80 am I no longer eligible for a transplant? You know, who's going to limit my care? So, this is an area that really needs to be carefully thought through is how you use decision support at the end of the day.

And then of course, I assume we're going next into privacy and security. So, that will be our afternoon, but I think that's a key component we've not discussed this morning and again, absolutely very, very important as we move into Stage 3 to make sure that those privacy and security standards are there and that that patient information is absolutely protected and inviolate.

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

Let me make one comment, just so people understand the background between the...figure out what happened to a CDS intervention and it's motivated some by the work that was done at Utah, when you write guidelines or write CDS rules, like public policy, there's often times unintended consequences or you didn't think of everything. So, there was some really exemplar work that was done saying, okay, so people get together, they write a rule and because of the system, again, it was done in LDS, they got feedback on the rule, okay, the alert or the reminder.

It turns out that even with the consensus, the expert consensus of writing the rule; you're only about 50 or 60% "right." You forgot to include this stuff or you didn't realize this might happen and with the feedback you can quickly get up to 90%. So, there's two messages, one, you're out of the gate you actually don't do a really good job...it's almost like public policy. And second, you'll never hit 100%. So, the point of this feedback mechanism was to really address that question. So, I just wanted to set that, give that description or that background to why that suggestion was made. And then Terry was next and then Judy.

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

First off are we all just talking as private citizens? I'm just kidding, Judy. Secondly, I think you should give Marc a lot of money for his five things, because I think it would help us to know, but I want to follow-up on what Marc said and I actually don't think I can talk as a private citizen, Judy, I don't think you can either, so anyway.

But, I think what Marc is maybe sensing, and perhaps I'm putting words in his mouth, but I know what I'm sensing is dilution and requirements creep. I feel like I'm in a software development venture and now I have 40 things more to do and I could barely do my 20, and I wonder if the focus on five or whatever a magic number is, is really to basically say, you know, we need some core capabilities.

We need an architecture that supports it not only within the EHR but within the country and we need to do that really, really well. And, I don't want to detract from all this work, because I think it's amazing and I think I can support all of it. I think my concern is, do we have enough time, money, willpower, consensus to do all of this and not dilute the five or whatever the magic number of things that we have to do or we're never going to get where we need to go.

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

...

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

I really want to underscore that because there is not a single objective on here that I would say is wrong, bad, not worthy, it's all worthy, right? But it is the piece you own, there's only so much bandwidth and are we in danger of diluting, I like that term very much so I'm going to borrow it and re-enforce it, the things that we really need to focus on because we've got people chasing so many other things at one time.

So, just something for us to keep in mind. I mean there already was some pieces where the Meaningful Use Workgroup said, you know, we don't have to call this out as a separate measure anymore it sort of all part of another initiative and maybe a little bit of harder work on that and paying Marc for his five things might get us to make sure that we don't...we're not in danger of trying to do too much and therefore not achieving the goals that we really need to achieve.

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

Extraordinarily important comments. I think, George alluded to it, I was trying to like get these things to be pruned to the extent that anybody has magic five or...this is the time, so if you want to write us...well before we come back next October we don't really want to have an argument in October, because we want to get close to the RFC. So, now's the time for the push back and get it to us, get it to the Meaningful Use Workgroup before we bring it back to you in October, because we want it to be near final there for the RFC. We still have plenty of time. And then I think, Judy and then Christine.

**Judy Faulkner – EPIC Systems – Founder**

There was a study, I think it was done by MetroHealth in Cleveland, where they had a lot of clinical decision support alerts and they found that when they reduced them dramatically, I think it was something like they cut 90% of them out the compliance for the remaining ones was much, much higher. This has two messages, one the message about, Gayle was saying, about do we get the clinical decision support and get it right, and two just a general thing that if you figure on a few things to concentrate on you might do a better job.

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

See, Marc, this has paid off. Christine?

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

I guess I'm a little bit, not on the other side, but I think I'm in a slightly different view-point as what I'm hearing here and I get the complexity, I really do. I get the complexity of healthcare. I think that's the reason that Marc's card isn't up right now with his five things, because healthcare is complex, right? So, we've got these major categories that are all really important and all of these functionalities and there are two types in here in my view.

One is that there are a number of objectives and measures that are really supporting current care processes that people will not get rid of, right? And don't want to see go, you know, smoking status and clinical decision support. But then there are a ton of actually new things that are really designed to support providers in delivering care in a different way that is reflective of the new models of care that we think are all coming down the pike, right? That was our number one criteria in doing this.

So, I think if there were five things...well I would say two things, one is we'd know what they are by now and number two is Congress would not have written a rule that said meaningful use, they would have just said, you know, EHR adoption.

So, I think this is really for me, different in that respect and one of the tools that I think we did use effectively in this go around was identifying a number of things that could go just in the certification rule so that it didn't create this perceived burden on providers. But, I really want to challenge us to think about whether...if we're going to be in the mode of creating parsimony then let's think about removing some of the standard of care pieces, right? The things that we know...and the functionalities that we know that the people need, want and are going to use anyway.

But, things like patient-generated health data, things like care coordination and information exchange, that's not where to go. So, I just wanted to share a slightly different view and the complexity of healthcare, and really coming from a perspective that patients are really ready for people to do this in a very different way.

And when I look out into the world and I see and hear a lot of reports, and you all have heard my own experiences, where patients aren't actually getting care that's any different because the EHR isn't being used in a different way. So, Stage 3, you know, last piece of the incentive, right? That's a really great time to think about driving truly different care delivery.

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

Good point. Marc?

**Marc Probst – Intermountain Healthcare**

I agree, actually a lot with what Christine just said. I mean, I really think focusing on those things that we can make a difference with that we wouldn't do normally is a good way of looking at things and I really appreciate Deven and Terry for putting the right words in my mouth.

If you look at the objectives though for Stage 3 and however we approach this moving forward, I do think we need to get some broad, whether it's five things, you know, it certainly isn't 56, things that we need to focus on. I think we need to get policy statements on them and move them forward, because I think we can make a difference that the 56 things or if you take all of meaningful use and add it together their scratching the surface of the benefits that electronic medical records can provide people in healthcare, you know, they're very small incremental steps and, you know, I agree with this bundling effect, we have to go build the software, we have to test it, we have to implement it, I mean there's all those things that make it different.

But, the real difference is that electronic health records can do, electronic data can do so far exceed what we're asking for or putting within our objectives and those are the things that I think why I go back to if we can get these foundational pieces right we're going to have a huge impact on healthcare. And that's kind of where I'm going from.

The other thing I want to say, Paul, because, you lectured me a little at the beginning of your talk, appropriately so, I do think meaningful use has done, we have done some amazing things. Going from 3% to where we are today was a huge leap and I don't think we're there. I mean I don't think 50% is where it stops and I can tell you 23 hospitals that will be doing it next year, because I happen to run those, you know, I can tell you they have 1000 physician.

So, I know there's more coming, but is it really achievable by everyone and are we doing the measurements, are we learning, are we growing through the process and are we really laying the foundation that can achieve what we really could achieve if we do this appropriately, as Gayle said. So, that was my comment.

**George Hripcsak – Columbia University**

This is George, just a quick comment. I feel like the process has been pretty good and actually this has been very helpful to hear the comments, I think, you know, if we do infrastructure then we get killed because we're not linking it to use cases and then, you know, and then nothing happens there and if we do just uses then it's empty because you can't do anything, and this is not a bad group that we've assembled, the Policy Committee and the subcommittees of people from both sides to work together to get there.

I think the...and then when we veer too far, say if you take HIE and we've gotten too divorced from the infrastructure we're going to pull it back with the hearing. So, I think we've got a pretty good process and I think if you look what the third category of that Subgroup did, those four objectives is pretty parsimonious, like I think it's around the right place where we should be, at least at this stage in drafting. I think we're pretty close to the right amount of functional requirement and then...but as you said we have to work a little more on the infrastructure right now and that's why we're pulling this hearing, that I think everyone...whether they wanted the threshold to go up from 30 or down from 30, everyone agreed that we needed the hearing next. So, I think it's a pretty good process.

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

Good, so let me...so in closing off this section let me put before you some of the guiding principles we used and get any comments there, because what I would say is we reapply these again, as we planned to as a filter, to try to get to the next stage of reducing and just getting the critical few. And to support new model of care, we're not just electronifying current process, we're trying to get out of silos, it's got to align. The pull is going to be the new CMS and payer programs, that's not what we do. We're getting the electronic infrastructure in place.

The second is addressing the national health priorities, we don't set them, but we've got to use...we apply that in our exemplar approach. So, we do exemplars to illustrate both the functionality and the use of it. The third is broad applicability. The fourth is not to beat a dead horse, if it's topped out and the market is driving it we don't need to get involved and that's part of Marc's statement.

And the fifth it's achievable, meaning we can't force, whether it's the health department, we can't force what isn't there, because that doesn't make anybody happy. Everybody's got to benefit from this and achieve their local goals. So any comments on those principles as a filter to go back and keep honing the precious few resources we have to get the right place? Judy?

**Judy Faulkner – EPIC Systems – Founder**

We could do all of that and kill the physicians with lack of productivity, should that be in there too?

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

Yeah, dead physicians are not part of the achievement. You know, what so maybe there's another one called feasibility that's in there.

**Judy Faulkner – EPIC Systems – Founder**

...

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

Yeah. Okay.

**Marc Probst – Intermountain Healthcare**

Paul, how do you measure against those? You know, that we're achieving those objectives.

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

We try to...so in fact we created a matrix that has those as columns and we checked off whether it met those things and that was one of the tools we used to try to prune, believe it or not, there were more than what we just presented here.

**Marc Probst – Intermountain Healthcare**

No, no, is that gut feel or is it...

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

It's the...it was some of the group that's working with it.

**Marc Probst – Intermountain Healthcare**

Okay.

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

I would hope that this group, the Policy Committee, challenge you to use the same filter and we can provide you the matrix that has those columns and you judge yourself, but now is the time to send us your comments so that we use that to shape what we present next so that it incorporates that. So, that's part of the challenge, right Marc? You know, I mean, if the private sector...the private sector has to contribute too then and...

**Marc Probst – Intermountain Healthcare**

Well, I even look at something like, well I don't know if it's achievable or broad applicability. I mean how many states have achieved, how many states are capable of receiving the data, I think there's three data items for Meaningful Use Stage 1, I mean how many states are there for all three and I don't know. I mean, it could be 100% but it could be 2, I just don't know.

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

So, that...you're referring to the population public health, so when we had one of our early hearings right after Stage 1 we had almost a love fest from the Public Health Departments, what they are saying is even though they weren't given extra money the fact that they were given some possibility of us being able to ship them information was music to their ears. As, Terry is pointing out now, the federal government and the state governments have to figure out how to take advantage of that, so they liked it going that far. I think that's the quandary and one of the ways we were just talking about obviously was the certification only, so we have the capability but not force people to do what they can't do. But, you have a good point. Any other last minute comments on the guiding principles? If not, I want to thank you for doing a tremendous job, we're almost literally on time in terms of the discussion and we'll adjourn for lunch until 12:45 is it? Until 12:45 when we'll resume with Deven's summary of what happened at the hearing on identity management. Thank you.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

We do hope that there is a list of restaurants or places to pick up like the Potbelly's and where they are, because we don't have food for you obviously today, but I hope at the desk right outside they'll be a list of places you could go.

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

There's no lunch in here, right? So, should we resume at 1:00 o'clock, does that make better sense?

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

I think so.

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

We'll resume at 1:00 o'clock from lunch, thanks.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Paul, would you like us to begin? I think we are still missing Christine, but other than that...yes? Okay, operator, would you open the lines please?

**Operator**

All lines are bridged.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you very much, operator. Back to you, Paul.

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

Ready? Okay. Okay, well thank you and welcome back from lunch. This afternoon we're going to hear from Deven reporting about the national strategy for trusted identity in cyberspace, which is...well, it's a new...it's new that we have to deal with it in a very reliable and robust way. It's clearly become a fabric of our society and we have to deal with it. And then we'll conclude our official meeting with the report from Joy Pritts with an update on the Chief Privacy Officer Office and conclude with public comments. But, Deven, take it away on trusted identity.

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

Okay, thank you very much, Paul. You could call this the post lunch session on Privacy and Security which maybe explains why there's fewer people in the room, but all the people who need to be here are here and that's good. So, I want to start up, we will have some recommendations to tee up for you as part of this presentation, but there's a fair amount of background that you'll have to indulge me in taking you through just so people sort of can understand where the recommendations come from, you know, as you mentioned, Paul, we had a hearing on this issue not too long ago and I actually mentioned it at our last Policy Committee Meeting, so those of us on the Tiger Team are pretty well steeped in this issue, but it has some complicated dimensions to it. So, I'll just ask your indulgence as we sort of go through a little bit of background.

I want to thank all of our Tiger Team members as well as staff from ONC, from the Office of Civil Rights as well as the folks from MITRE who provide us with support. I don't think we could be getting to this place or with any of our recommendations without them.

So, before we sort of launch into the new set of recommendations that we want to put before you today I think it's helpful to go back to where we came from which is this issue of trusted identity, which includes identity proofing and authentication of providers, is not really a new issue for the Policy Committee. In fact, we did issue some previous recommendations on this topic that are either directly relevant or indirectly relevant.

But, first being the one that we...a set of recommendations that we issued on digital certificates which said, you know, in order to exchange information between two organizations they need to be able to do so using a digital certificate, it should be issued at an entity level with, you know, some high degree of assurance that the entity is in fact who they say they are as part of this sort of machine to machine hand off of data. But, that really each entity is already responsible under the HIPAA Security Rule for credentialing its individual users.

However, with respect to individual level credentials we did recognize that when you're talking about accessing or sharing information remotely or accessing information across a network that user name and password is not sufficient and that's commonly...user name and password matches to a level of assurance for identity and credentialing that is a level 2.

And what we mean when we say level 2 is the National Institute of Standards and Technology has essentially developed sort of levels of assurance for identity and authentication that is used by the federal government to credential individuals who do business with the federal government, but it's also commonly used in the private sector, it's sort of a set of standards that has gotten into common use and username and password sort of hits you at level of assurance 3. Level of assurance 2, I'm sorry.

Level of assurance 3, which is meant for more sensitive data or more sensitive transactions commonly requires sort of a second factor beyond username and password and at the time when we initially considered this issue we could not get consensus on suggesting that the credentials of individual users within an organization would need to be at a level 3 in part because the criteria for level 3 at that particular time just looked to be a bit of a lift and not necessarily easy for organizations to do.

The other thing I want to remind folks is that as always we try to sort of confine our universe when we talk about exchange, there's a lot of data exchange going on out there. We're really talking about exchange of health information among providers for the purposes that they need to in order to meet meaningful use, it's not all exchange that happens in the world, but it's a defined category that we are particularly concerned about as a Policy Committee.

So we made those recommendations I think back in 2010 and since then the world of identity and authentication has actual made some fairly significant progress as you alluded to, Paul, before we started.

One is that other departments within the federal government have been working on a national strategy for trusted identity in cyberspace to be able to have a mechanism for individuals to essentially be authenticated in order to be able to transact business on the Internet without necessarily needing to know five or six different passwords, which, you know, for those of us who do transact business on the Internet, if you have never had to reset your password because you forgot it, my hat is off to you. It certainly hasn't happened to me.

If your somebody that doesn't use the same one or two passwords for every interaction you have on the Internet, again, my hat is off to you, but in general, having to know multiple passwords is not necessarily all that productive and username and password is not a terribly strong credential in terms of it providing a high level of assurance because it's very easy...it's very easy to break, particularly when people use not very strong passwords in order for them to actually remember the passwords.

And so, the Commerce Department has issued this National Strategy for Trusted Identity in Cyberspace and there is, even as of today, some events occurring that are intended to engage private sector stakeholders in developing a way to secure identity in cyberspace, again focusing really on at the individual level, but both for individuals like consumers but also for business purposes as well and they set out some principles and they're going to be moving forward with actually putting this into operation.

The other thing that happened is that the NIST guidance on levels of assurance and what it takes to meet certain level of assurance got updated very recently in December. And, you know, for our purposes and as I'll try to explain in a little bit more detail as we go into the presentation, the criteria for that second factor beyond username and password that's needed in order to have level of assurance 3, which is generally recommended for transactions involving more sensitive data got easier to meet, not easier in terms of making it more vulnerable, but utilizing technology that people are using ubiquitously like cell phones.

So, for example, like a one-time password that comes onto your cell phone can be the second factor, the additional token that you demonstrate in order to authenticate yourself. So, given those two important developments which were not present during our initial deliberations on this issue, we thought it made sense to number one, have a hearing to understand a little bit more fully what had happened and where these developments were in the pipeline and what did that necessarily mean for what we were trying to achieve in healthcare, which is really trusted exchange is the end goal.

And there is a background, there's a slide that shows you we have a sort of set of backup slides, but it is in your packet, that shows you who testified. We had folks from the private sector, we had folks from the government to illuminate us on what was going on and of course all the testimony is available online for folks who want to know.

So, I think ultimately what we were trying to figure out is that given that we couldn't quite get to a recommendation that would say individual credentials at level of assurance 3 really ought to be at least the baseline that we're aiming at. We did spend a fair amount of time in the hearing drilling down on what does it mean to be at level of assurance or LOA 3 per the new NIST document and of course, as I mentioned, it requires, you know, at least two factors on the authentication side but it's also fairly robust with respect to identity and, you know, seeing, you know, who that person is through either in person or form of reliable government issued photo identification that is then verified. So, really on both prongs of the credentialing equation it's both, you know, identity, can you prove who you're telling me you are and then how do we authenticate that in future transactions.

And the criteria that NIST uses to sort of judge which factors, which types of technologies are acceptable for getting a level of assurance to 3, it can't be vulnerable to man in the middle attacks, phishing or decoy websites, or divulge the authentication key. And, I'm desperately hoping that you don't ask me what I a man in the middle attack is because I'm not sure that I fully understand it, but I think the overarching point to keep in mind is what you're seeking is a high level of assurance that the person on the other end of your exchange transaction or who is seeking data from you, or seeking to access data from your EHR system is in fact who they say they are and you can count on that in terms of sort of granting them access to your data.

So, here are a few key points and observations that really came out of our hearing. First of all is that with respect to the HIPAA Security Rule, you know, certainly there is an obligation on health care entities to appropriately credential their users, but there's no minimum standard. And, the lack of that sort of minimum standard in terms of network exchange could potentially be problematic.

The current state-of-the-art is the use of passwords and about 5% of the breaches that were reported under HIPAA are associated with unauthorized use in the network and so can at least arguably be traced back to failure of username and password to be able to protect the identity or authentication of that data, it's not a high number. Many more of the breaches that we've seen reported are due to lost or stolen devices that are not encrypted and sometimes it is not even clear that if the data is protected by username and password that the person who took the equipment that had the data on it actually was breached because we don't know where it went.

But I think the other thing to keep in mind is that the breaches that we do have reports on are the, you know, massive breaches of data, right? More than 5000 records as opposed to the breaches that are smaller that may in fact be picked up by unauthorized use of credentials or sharing of usernames and passwords where a person wasn't authorized to get the data but actually did because they were using somebody else's password or they breached a password, like that would show up in...not in the big reports that come into the Office for Civil Rights, but the reports that only have to be filed annually of potentially smaller breaches. So, just something to keep in mind.

You know, we don't have as much evidence as we would like to have about the extent of this problem, but suffice it to say it's one sort of weak link and as we sort of expand the universe of exchange and really provide incentives for people to share with external entities and not just among themselves, you know, we need to make sure that the foundation for trust in terms of the credentialing aspect of this is really there.

And, as I mentioned earlier, again, the update to the NIST, it used to 800-63, now its 800-63-1 really do open the door for the use of technologies that people use on a daily basis to be able to provide that second factor of authentication which was a concern that we had before.

Another observation that we noted was that, you know, again this NSTIC initiative, this initiative to create, you know, trusted identities in cyberspace where the credential is issued at an individual level is really on the move and could be quite an important development in terms of our need to ensure trusted identity in the healthcare space.

So, again, it calls really for an ecosystem of identity and online environment where, you know, entities are able to trust each other because there are agreed-upon standards that people follow in terms of issuing credentials that the public and business entities, and healthcare entities ideally could then be able to rely on.

You know, they've set up some principles about sort of how data that's used to credential can be subsequently used from a privacy and security stand-point. It's not clear what this will cost, but we also heard testimony from some of the commercial vendors who are developing identity solutions that, you know, that they're offering these credentials at quite a reasonable cost and in fact, one of the entities testifying, Verizon, is essentially giving the credentials...I mean it's not charging for the credential, it's free in terms of out-of-pocket cost.

Again, there really does appear to be momentum building for a shared identity, again, the cost of digital certificates is dropping. DEA, we already know is requiring a high, in fact beyond level of assurance 3, because they're very specific about what that sort of additional assurance token can be, you know, that's already going to be required, it's in an interim final rule for prescribing of controlled substances. So, already individual providers who prescribe controlled substances are going to have to have an individual credential that meets that level.

CMS is planning to move, you know, again we had Tony Trenkle testifying, as early as next year to requiring contracted to providers to using high-level of assurance identity proofing and authentication when they are conducting business with Medicare. And the VA is also using high assurance with their internal providers and looking how to expand that to external providers as well. So, there's movement going on to thinking about this issue as the trust issue as not being sufficiently resolved when you are just relying on username and password level of assurance 2.

And, so what we did was look to one, whether we would and under what circumstances would we recommend a baseline of level of assurance 3, per NIST standards, for individual credentialing and if we wanted to get there is there a pathway for getting there, because that's not generally where the industry that we focus on is today. Username and password is still the way that most people handle these transactions.

So, just to lay out sort of how we scoped the discussion and the parameters that we placed around it, our focus was on trusted identity, which is about identity proofing and authentication. This doesn't answer the full question of whether you have the right to access data. So, just having some assurance that the person on the other end of the transaction is who you say they are is not...you know, doesn't necessarily mean that you have the right to access data, but it answers one significant part of the question which is do I have assurance that you are who you say you are when you're asking me for data about this patient.

So, you know, we often veer...in our discussions about this often veered into territory where it was like, well, you know, access would depend on whether we knew they had a treatment relationship with the patient or whether they...you know, we knew that they were a licensed professional and the fact is, is that you can't solve all of those issues just through identity, but you can and should solve at least the identity issue. So, we tried very hard to keep our discussions focused on that.

We also said we're still going to stick to the exchange transactions that are needed to meet meaningful use, exchanges for treatment, exchanges with public health, quality reporting to CMS not the entire universe of exchange. And, so really the question is are you who you claim to be with a sufficient level of assurance based on the purpose for which you're asking for data or exchanging data.

So, finally, here we are at our recommendations. And we recommend that the Office of the National Coordinator move to individual user level credentials meeting a baseline level of assurance 3 for what we'll call riskier exchange transactions and ideally getting to that point by Meaningful Use Stage 3, although, as we talked about in the last conversation Meaningful Use Stage 3 feels far and yet is so close, but we wanted a pathway to getting to where so many other important aspects of both our economy as well as healthcare are moving now.

What is a riskier transaction and we started to engage in this conversation. What we considered to be lower...maybe not low risk but certainly lower risk activity, on-site access to the EHR for your system. We don't necessarily think ONC needs to place...needs to necessarily move the bar higher, in part because they are sort of other indicia of security that are present when you're using a system that's on-site on your premises in your facility where there are tons of people around looking at who's accessing the computer.

Again, it isn't perfect and there's certainly are lots of folks who would say you ought to move to a baseline of level of assurance 3 for all of these transactions and the NIST framework, if you read it, since you are talking about access to sensitive data, you would probably conclude that it ought to be level of assurance 3 for any access, but since it does require, you know, that sort second credential whether we want to go so far as to say that that would be required even for internal access within your own system, we were not prepared to go there.

Having said that, when you talk about sort of riskier exchange transactions where you don't have as many of the indicia of other security measures that can be helpful in sort of knowing that you're not getting somebody unauthorized, you know, trying to access the system that's, you know, a person using somebody else's credentials or logging into an open system. You know, remote access, access across a network, access across NwHIN where it's a query type, looking for data from another institution, wireless access, more and more transactions are taking place using mobile devices in healthcare, you know, those are the sets of transactions where you really want to be focusing on in terms of moving to a baseline credential of level of assurance 3.

And here's where we made an attempt to try to lay out sort of some of the scenarios in terms of sort of their perceived level of risk, you could call these use cases, you could call them exchange scenarios. And, we didn't have as much time in our Tiger Team deliberations to really populate this chart robustly and go through these in a fair level of detail, but based on the discussion we did have this is probably where we would have landed in terms of what are the sort of riskier exchange transactions where we would ask for a higher baseline level of assurance, of course when we say baseline it means, you know, there is actually a level 4 that institutions can go to, but we think we're, you know, bringing the baseline up from level 2 to level 3 for riskier transactions is what makes sense as an initial step

Again, access via a local computer or terminal within a secured area to yes, it's a local terminal, but it's actually in a publically accessible area. I think based on our discussions we would have landed probably still at username or password because it's still within the facility. We were very focused on is it within the facility, are you trying to exchange data, again across networks making a query to another network or you're at home and you're trying to access your own system, but, you know, maybe you're trying to do so over a line that's less secure or using wireless.

So, on premises wireless access we didn't really have a chance to discuss that, but certainly, you know, off premises when you are trying to access the data would be another issue. I mean, this is one where frankly, we probably could go into more detail about what these scenarios would look like on the one hand, on the other hand, I think if we, as a Policy Committee, agree that there are some riskier transactions that movement to level 3 makes sense, I think we could have, you know, invite more dialogue on what we mean when we see riskier transactions. Certainly ePrescribing at the bottom, you know, is already up above level of assurance 3 because the DEA has already laid the marker down on that one.

Now, given that this recommendation we already admit needs to be staged, you know, one thing we also recognized is that you could have sort of an interim step of getting to full NIST compliance level of assurance 3 and that would be the stage that we made up called 2.5, which is essentially going ahead and requiring that second factor for authentication but still allowing organizations to do the identity proofing of their own users in the way that they do without requiring the additional steps that need to be taken on the identity side in order to satisfy level 3, per the NIST equation, and for folks who want to see the differences in what's required between level 2 and 3 we have some backup slides and we can go there, but they are certainly in your packet, they're part of the slides that available to the general public if you want to take a look at them.

The other thing we wanted to make clear is that this is, you know, we started off by calling this about trusted identity of providers in cyberspace, but there are a lot of individual users of EHRs who have the right to access data in their roles within an institution but they might not be physicians. So, certainly when you consider this issue you have to think about a user credential that is going to apply to any user, you know, who has the authority to be able to access data, but legally and per their own institutional policies.

We continue to think that it would be helpful for, as ONC works on this issue, to keep abreast of what's going on with the NSTIC initiative since they are just now launching the work that's going to be needed to be much more...to get from the level of principles, which is where they are, to the level of how does this work operationally, who's going to issue these credentials, are we going to credential the credentialors, what's the process for doing all of this. That work is going to begin in earnest actually in like two weeks in a meeting in Chicago and we ought to continue to be kind of tapped into that effort and see where it's going and see the extent to which we can leverage it, because obviously if there is a sort of national system of credentialing and we can tie into that for healthcare credentials we should. No reason to reinvent the wheel.

I think that the big open question is how quickly is that initiative going to actually be completed and is it going to be completed in time to facilitate trusted identity of provider users in the Nationwide Health Information Network, you know, we already would like to be exchanging data among disparate organizations more often than we currently are and we're trying to really push hard on those issues and we may be in a period of time where the work on identity and authentication is lagging a little bit behind. On the other hand, there already are institutions that issue credentials at a higher level.

We also always want to be mindful of the impact of recommendations like this on workflow. You know, I think it makes sense to sort of ask industry to step up in terms of creating a more secure and more trusted environment and that the status quo is not enough for the long-term, that's actually quoting Dr. Mostashari before our hearing, the status quo isn't good enough, username and password is a very weak way of dealing with identity when we're trying to create a network in particular. On the other hand, when it becomes really difficult for providers to be able to access data to do the jobs they need to do, people create workarounds, you know, we always have to keep those twin aims in mind, right? We do need to create a trusted exchange, we also need to make sure providers can do the work they need to do and it's a balance and it's a give-and-take and we need to be mindful of both of those things as we move forward.

We also think it would be helpful actually if the really smart cryptographers at NIST who do the changes to 800-63-1 were to do some more specific thinking about the healthcare space and what the unique needs are in the healthcare space so that, you know, as they continue to iterate on that document as they always do because innovation is happening rapidly in this field that, you know, that there's some...it's our idea, I don't know if NIST would agree, that, you know, some focused attention to what is unique about healthcare and how that could inform future iterations of 800-63-1.

So, that might be yet another example of the Policy Committee maybe using its bully pulpit to say to another administrative entity that we don't directly advise, hey, you know, good work over there, but, you know, healthcare, as always, is a little bit different in many ways and we might need some special attention. So, that in a nutshell is where we are headed.

You know, to summarize, we're asking for approval of a recommendation to move to a baseline of level of assurance 3 for individual credentials at some point in the near future, we targeted Meaningful Use Stage 3. I think if that timeline feels tight for folks I think we can talk about how to get there.

One of the ways that we've suggested to getting there would be to allow entities not to necessarily have to meet the full NIST criteria on the identity proofing side, but to sort of focus on the authentication aspects of it first, in part because we really are seeking to focus on the riskier network exchange transactions, organizations know who their users are maybe the more important thing to focus on first is how that credential can be authenticated to the outside world. So, I'll stop and I already see 10 cards up so that's good.

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

Good, thank you. Let's give Steve the first.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

Yeah, I get priority over the members of the committee first.

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

Well, since you write the rules, I think...

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

I'll continue my joke, so ONC has some questions given that I'm the designated representative now. So, I understand the why, because, you know, from my background already. I think the how is some critical clarity that might be missing from the recommendations, because, you know, just reading, and this is the beauty of slides, right? So, I mean, just reading them in the slides without any additional text it's not clear to me how ONC would implement that recommendation and I'll kind of just tease this out a little bit.

So, for the DEA example it's not two factor authentication for the entire system, it's in the use case of at the point in time when you go to ePrescriber controlled substance then you need to invoke kind of this two facts, you know, well for them two factor is level 3.

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

Yeah.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

So, in the how the...I tried to, because I'm in, you know, rule-mode at this point, translating that into an EHR technology capability that would support level 3 oriented authentication for particular, like you're saying, you know, riskier, for lack of a better word, when particular exchange transactions occur and so that would be a capability that would need to be present in EHR technology that would be available for, you know, for lack of a better word, two factor to be used at the point in time when that exchange where to occur as opposed to a general statement that we need to apply level 3, because I don't know how it needs to be applied.

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

Right, right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

The other one just with remote access and I don't know if this is a clarification, maybe you guys discussed this as part of the group, as you consider more and more EHR technology going to the cloud, the premises on which axis occurs isn't brick-and-mortar as it may be considered for some. So the access is anywhere and in that case that's just going to be...it's always remote.

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

Right.

**Steve Posnack – Office of the National Coordinator for Health Information Technology – Policy Analyst**

So, I didn't know if, you know, in that case again, the how would be anyone that signs up with a cloud-based EHR technology would always have to have, you know, greater than level 3 and that might be the right policy outcome that you want, but it's kind of the, you know, applying this down the road and how we implement if for the future.

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

Right, you know, I think it's a really good question, you know, sometimes when you pull up these recommendations and articulate them it feels like enough of a list to get people to accept the premise that this is where we ought to land and then you think about sort of well what are the tools for getting there, right? So the systems have to be able to accommodate the additional factor, but there are sort of multiple ways that you can do that in the NIST framework, it doesn't have to be sort of one-size-fits-all, it's just have the capability to be able to authenticate at that higher level.

There's, you know, if we weren't out of the RFI comment period, for example, one could say since you really are focusing on transactions across a network a condition of trusted exchange could be developed that would ask for entities to credential their individual level users at LOA 3 for those users who are involved in exchanging data across a network. So, that might be another way to do it.

You know, another way to shoot at it is if there's a desire for some policy unity on this would be to take a look at the HIPAA Security Rule and say, you know, in these certain transactions we're going to ask you to, you know, either through guidance or through some specific rule-making to do something different. So, I think there are sort of multiple ways to get at this, but I do think you're right, like the how is a big question. I'm not sure how much we should be sort of dictating that or whether it's enough for us, at least at the first blush to say we think it's a good idea to move to this, but we also think that the government would be really well served for us to dive down into some more of these details like what are the riskier exchange transactions.

For example, is it the case that in cloud instances we would say LOA 3 across the board? Like, you know, where...I think we can do some additional work on this, but I don't want to go down that road if the committee isn't where the Tiger Team is in terms of the need to move there for certain riskier transactions.

**Marc Probst – Intermountain Healthcare**

That was great, thank you very much and I think there's five, no I'm just kidding.

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

I'm not paying you for those too.

**Marc Probst – Intermountain Healthcare**

Exactly, as you went through the hearing, you know, there's a certain overhead associated with this and some of it can be the actual transactional, you know, signing in and that type of thing, but did you talk at all about the overhead of managing? So, at LOA 2, there's a certain management requirement, you know, to provide passwords to go to understand what did you call it, identify proofing, identity proofing that type of thing that you do. At 3 my guess is it's more of a burden, you know, for the organization, did you measure that, and I'm not looking for a number, but did you talk about that and what that impact might be, because, you know, every organization that provisions out, you know, passwords and that type of thing is going to have to deal with it.

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

Right, we didn't get enough testimony on that and that's one of the reasons why, I mean maybe this language isn't quite as strong on this slide because it really focuses on workflow as opposed to, you know, sort of thinking from a resource perspective. I would say that certainly with respect to identity proofing there are extra steps that you need to take to verify someone's government issued ID. So, at level of assurance 2, if they give you the government issued ID and it's not expired you can rely on it and credential that person. In LOA 3 there's an additional step that you need to take, which is one of the reasons why we said you could phase this in to through what we're calling 2.5, which is the second token, the additional token on authentication but identity proofing in the same way that you do it today.

In terms of what's the burden of that additional token I think it probably depends on what the token is that you're using and the extent to which your system gives you strong capabilities to be able to do that fairly easily. So, if you've got, for example, you decide that your token is going to be this sort of one time password on the mobile device, it's not without work to sort of make sure that you have people's mobile device, mobile numbers so that the credential can be sent and to have them present the device so you can attach it to the right person.

So, you know, there certainly is some work that needs to be done, but it's also...and of course, credentials shouldn't last forever, right? You have to refresh them. But once you do that once it should last for some period of time, but again it isn't without...I don't think we got a lot of really good information on that, but it seemed to us that the level of trust that we would need in order to allow for exchange across a network where it suggested that it made sense to move to level of assurance 3, but to do so in a staged way recognizing that people would need to keep up with it. So, it's a tradeoff.

**Marc Probst – Intermountain Healthcare**

Yeah, I clearly see that the end you're trying to...we're trying to get to is absolutely correct. I just think there is going to be an overhead that we're going to impose everyone has to realize that and it would be nice to just get an idea on what that's going to ultimately be because we are going to have to assume it.

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

Right, I mean, again, the questions of cost were asked of the credential panel, the private sector credential panel that we had and again, you know, they ranged from, you know, super cheap, under \$20 to getting it free. Verizon was the one who said free. So, you know, in some respects if there's a...if there are vendors out there who are making these services available for a relatively low-cost that should help. On the other hand, I think we don't have that robust of a marketplace yet for credentialing that we can know with assurance what those end level costs, but hopefully some of the NSTIC process will work that out. Joy?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Yeah, if I could jump in here minute? One of the problems in getting kind of a handle on the cost with this is that the models, the business models vary so dramatically and how people intend to provide these credentials. So, with the one model that Deven was referring to they provide the credential for free but impose a cost on the verifying party, the recipient party. So there's a cost there, but it's hard to know who's going to bear it. So, it's a little bit difficult because the models, you know, in the market are really vastly different.

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

Good point, thanks. Okay, Jon and Judy and then I have a question.

**P. Jonathan White – Agency for Healthcare Research & Quality (AHRQ)**

Thanks. I'm just going to offer two quick pieces of advice, one to the committee and one to my federal colleagues. To the committee, having sat next to Steve through the DEA thing, there was a very clear use case that drove ePrescribing controlled substances, you know, and it was brought to us by with people with guns which is diversion, you know, that's our thing, you know, they don't care that people in pain get the medicines that they need, they're trying to prevention diversion.

For the Policy Committee you should, as Deven mentioned, the actual work that she needs to do is what is that case that drives this and that's where you can help clarify things for us is, you know, you need this to be able to do that. So, that's the friendly advice for you all.

For Steve and my colleagues back at home, agree with you. You've got certain tools in your toolbox, right, to be able to address this issue. I think while they're doing their homework we can do our homework not just in terms of what we can do, but who we can work with, right? I think there are other initiatives out there. I think working with professional associations I think, you know, might be a good way to think about it. We don't necessarily have to do it all, right? And, I think there are places...connections that can be made. So, thanks.

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

Great, Judy?

### **Judy Faulkner – EPIC Systems – Founder**

Yes, commenting a little bit on some of the discussion that we had on the committee and then also on the slides. Five percent of reported HIPAA breaks, breaches are unauthorized use. My own experience, and I think David McCallie said the same thing for Cerner, is that the unauthorized breaches are people accessing authorized people to the system but accessing records they're not supposed to access. I, and I think David had the same experience, have never known of someone from the outside getting in and breaking into the system. So, if you look at the billions of accesses and the number of break-ins, I think...I'm not aware of any, don't think he was, and so I think that might really take some study to say what really are there out there.

The other thing I wanted to do is do a little math on what if it took five extra seconds. Now, if it's the telephone with a number that's going to take you longer, especially if it's one of those kind that each time you have unique number that takes extra time, you've got put in this... look it up and put it in accurately, other ways too, but if you assume 5 seconds and then you assume that you do it 50 times so you're doctor going into different hospital rooms or you're a practitioner seeing 25-30 patients in a day, plus you're answering phone calls, you're responding to portal questions, etcetera, etcetera.

So 50 times a day, that is a 150 seconds or 4.2 minutes, 500,000 practicing doctors in the US, if you multiply that out that's the equivalent of 3700 doctors a day. Now, if you add the nurses to that, because they have to do that too, there's about 5 times as many nurses as doctors, that's RNs, so you get 18,000 people a day is the equivalent of doing this. And so that's where I think that we have to figure out where are the breaches, where are the real risks of breaches, what is the history of those risks and how do we appropriately use it so that we put that effort where it's really needed and don't put it where it isn't needed.

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

So, a couple of things on that, one is that an unauthorized access to a record by somebody who in fact is credentialed but is getting into the wrong record is in fact partially addressed by better identity, because people are sharing credentials all over the place in healthcare.

### **Judy Faulkner – EPIC Systems – Founder**

No, but what I...

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

Which is really...you can actually do better provisioning of records, role-based access controls if you have an ability to more precisely credential your individual users and that's what...I mean, this figure was...you know, I'll turn to Joy, because we initially had a figure in terms of sort of breaches nationwide, not healthcare data, breaches due to the use of low authentication thresholds of just username and password are extremely high, extremely high and it's the reason why most other industries are moving well away from that and instead moving towards more trusted authentication credentials.

And, I'm not disagreeing with the need to sort of understand where the risks are where we would deliberately want to say for these transactions in the way the DEA said with respect to controlled substances, for these transactions these are the ones that we want to focus on, but some of the examples that you raised in terms of your timing Judy are the ones where people are accessing data in rooms within one institution where we recognize that the higher level of authentication wouldn't necessarily be...that wouldn't necessarily be where we need to focus. And also, that assumes that people have to reenter that credential with every single access which isn't necessarily required in order to meet LOA 3, so...

### **Judy Faulkner – EPIC Systems – Founder**

Let me find out a little bit more about what you're saying there. My experience is, so you login, your Dr. Deven McGraw, you login, you're a family practice doctor of an internist, you login and we know who you are, but you access a famous person's record. If you logged in with the third identifier, we still know who you are, what's different? So, I'm not understanding.

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

Yes, right, well...

**Judy Faulkner – EPIC Systems – Founder**

In either case even with just the...if you didn't take that additional authentication, in either case, it's possible to figure out what roles you're allowed to have and not have. So I don't know why you're saying there's a difference there.

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

No, with the circumstance that I was talking about, so you have a physician accessing a...you have somebody who has authorization to enter the system generally and isn't prohibited such as through role-based access control from being able to access a famous person's record. So, that's clearly an example of a breach. The situation I'm talking about is where people share IDs and passwords, physician has access, but co-physician does not, but other physicians doesn't want to re-log onto the system so uses the same credential and, you know, while he's in there he decides wants to check out why Beyoncé was in the hospital, right? So, that's what I'm talking about.

Again, it's not...it doesn't answer all of the inappropriate access numbers, but it's one piece of the equation which is being able to know that you've got a unique user and that person has, you know, a higher-level credential that you can then use to create better role-based access control. You know, I don't know why the famous person thing made me think about this point that we didn't raise on the slide, but people at the hearing made the point that healthcare fraud is not resolved by better identity, but it sure helps. Knowing that the person who's actually billing for the service is who they say they are, again, not 100% of the fraud that goes on out there, but certainly in terms of sort of being able to ferret out fraud, it helps. It's just one piece.

**Judy Faulkner – EPIC Systems – Founder**

I guess the point is given the impact that it can make and my experience is that re-authentication is done very often as go from room to room it's redone.

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

Yeah, it doesn't necessarily need too, but I've heard about that too.

**Judy Faulkner – EPIC Systems – Founder**

Yeah, it typically is though. That, I think it's very important to figure out what each kind is. So, how much is there of borrowing versus how much is there from someone from the outside coming in and then it can be more targeted given that it has an overhead that can be significant, it could be more targeted to exactly those things that are going wrong the most.

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

On that point, Judy, unfortunately, I think the higher unauthorized access is on the inside rather than the external hacking. So the idea is to get better identity so for example, the sharing wouldn't happen as often if you had two factors because the other person can't then use your ID and password. But we have to pay attention to what you said in terms of the cost of the overhead so it would really be targeted.

The other piece is you said it's usually an authorized person getting unauthorized access to somebody else, but there's a lot of sharing with, let's say, non-clinicians who have the access just on behalf of a clinician. So, there's a lots of identity sharing in a sense and I think that's part of the point that Deven is making. That's one problem to solve; it doesn't necessarily mean create a high burden solution. So, those are the two points and like Deven says, we have to figure out how do we balance those, but I think the identity sharing is an issue we have to deal with.

**Paul Egerman – Businessman/Entrepreneur**

And, this is Paul, sort of playing the man in the middle here, but.

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

That is Paul Egerman.

**Paul Egerman – Businessman/Entrepreneur**

The other Paul.

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

We don't allow you the level of assurance 3.

**Paul Egerman – Businessman/Entrepreneur**

I think those comments are really good that Deven just made and you just made, Dr. Tang, however, it really doesn't come across in this presentation, in other words this presentation is about identity assurance as it relates to information exchange is the way I understand the presentation and part of the justification however is this other problem which is a legitimate problem, which is the sharing of credentials. And so somehow that needs to be made clear because I think that problem is an important problem to solve and I actually think it is in terms of frequency of occurrence far more frequent right now than, you know, this issue about in effect inappropriate remote access, at least in terms of a problem, that's been where we have some level of understanding or occurrences, we have a lot of occurrences of internal sharing of passwords and I think we have a lot less of the other issue. So I...

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

Deven, is it true that this is directed mainly towards exchange or was intended to cover both?

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

Well, so the problem at the highest level that we're trying to solve is creating a trusted ecosystem for exchange among disparate healthcare providers in the Nationwide Health Information Network, right?

So, but the problem isn't necessarily in the exchange, you know, the problem of insufficient authentication and identity proofing at the user level is about whether one organization is going to trust another organization enough to send their data there or the organization who is holding the data but gets a query in from another institution to say, well, you know, Dr. Smith would like...you know, Dr. Smith from the Palo Alto Medical Foundation would like to receive data about your patient, that if we have a sort of baseline level of authentication for those types of cross entity transactions, that's one notch on the level of trust in terms of, well I know if I send it to this entity that the likelihood that it's going to get to Dr. Smith is high, because they, in fact, credential their providers for, at least for these types of transactions, at this higher-level.

So, it's a little bit of both and, we're not, you know, it's suggesting that trust, the trust we're trying to build is at an ecosystem level, but it filters down to the user level fairly frequently.

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

So, in some sense it is designed to deal with the data commerce side, because that's...

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

Yeah, that's right. I mean if we were sort of dealing with a universe where we just wanted people to exchange within their own silos, you know, probably the law we have today would be sufficient to hold us for some period of time, but now we're really talking about an exchange ecosystem that we are trying to create and a recognition that the level of assurance that works probably perfectly fine for internal access and, you know, Steve's point well taken, that when your internal is in a cloud, you know, what does that necessarily mean, isn't necessarily going to be sufficient when we're trying to build trust across a network.

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

So, let me go to my question and I think it covers what Steve mentioned so one of the cells in your matrix about exchange scenarios that you left blank was wireless.

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

Yeah.

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

What's the intent of the group? And the reason is wireless is becoming more prevalent, one of the ways to do wireless, so the way we do it is you have to be an authenticated device on the wireless network.

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

Yes.

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

And so that does almost bring it back...and I think this would address Steve's question too. Regardless of where the server is cloud or some building still not in your locale, the organization issued device has a serial number and that basically is bound to the server. So, in a sense, it seems less risky than just taking an unsecured device and accessing let's say the cloud. Was it the intent of the Workgroup to say that secure wireless where you bind these specific devices to the server would be risky or not?

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

We didn't get into that level of detail.

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

Okay.

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

I mean, I think we can and we should. I mean, that's sort of really getting down into the question that was posed by many people today like what are the specific use cases that we need to focus on for this because, you know, we had a discussion about wireless, but didn't quite, weren't able to say wireless within a secure network or wireless not using secure transmission, what would be the...you know, what's the difference between one or the other.

I mean, you know, one could argue that an authenticated device within a secure network is not that much different than an authenticated terminal sitting in a patient's room, right? Probably the same thing, but...in two calls we couldn't get to that level of detail, but we certainly can explore that more.

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

All right. Terry?

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

So, I'm going to take a different perspective here, as you know we're the feds and Jon has a CAC card I'm sure, and he hopefully is signing on with his computer with this CAC card. So, the question I was asked to pose to you from VA is and I almost hate to bring this up, did you think of jumping three and going to four? Because the DEA, because we know there's so many unsecure networks of there.

I mean the latest survey I saw at hospitals was at least...and it's interesting because I don't know why that 50% of hospitals don't have meaningful use, but I don't know how much of that is security related that LANS...I mean the estimate was 50% of the LANS out there at hospitals aren't secure, so I just wondered if you thought about that at all? I hate to even bring it up.

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

No, no, we...actually you're making me wondered whether I should have started this presentation by saying we really need to go to level 4 and then everybody would think level 3 is so much better, my mistake. We were...I mean, it's one of the reasons why...and maybe I didn't emphasize it enough, we certainly thought that as a first step that there should be a baseline requirement for level 3 which leaves open the possibility of people doing more, but doesn't necessarily require level 4.

We were advised, by at least one of the entities that gave public comment, to go to level 4 and they particularly...on the identity proofing side in particular, because so much identity proofing in healthcare is done in person, which isn't always the case for credentials in other settings, that already healthcare had sort of that advantage in terms of meeting a prong of level 4.

I think, in general though, you know, there probably were a number of folks who would have been perfectly comfortable going to level 4 and certainly the degree of sensitivity of the data if you just do a cold read of the NIST framework you would probably conclude we ought to be at level 4 given that we are level 2 today. I think in general we didn't think we could shoot that high, at least initially.

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

Can someone define the level 4 additional requirement?

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

Level 4 is additional in-person authentication and then with like the equivalent of a CAC card or personal ID verified card, but like if you're a private practitioner with admitting privileges at a hospital you probably already have been verified in person by that facility at the time you were credentialed. You probably have an ID card. So, the issue is the ID card then has more security within it.

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

Yes, it's they're typically using cards for authentication, not exclusively, but the PIV Cards are a common examples. So, you know, I think on identity we probably would've been fine with going there again because healthcare is already pretty much there. But in terms of the tokens acceptable for authentication I think we weren't quite ready to say everybody has to get, you know, is required to get this sort of level.

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

And then, my only other concern is because of ePrescribing and we know we're really pushing that and we know providers are going to want to go to narcotic ePrescribing, so I just think we need to be really clear as we move ahead that if you are at level 3 you will still not be able to meet the DEA guidance.

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

Right, yes, for anybody that needs to prescribe a controlled substance, you're going to have to meet those higher level credentialing requirements, absolutely.

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

Any other comments? Gayle? Sorry.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Yeah, just in the way of a closing comment, first of all I want to say the Tiger Team has worked very hard on a lot of these recommendations and, you know, it's a very touchy situation. But the major concern that I have and that I here again and again out there in the public is that people want to know that their health information is safe and secure, and that I'm one of those who thinks the higher levels are better, you know, I'm right up there with you, with the VA and Terry on level 4.

However, I think we have to remember that the weakest link in the chain is where everybody is on security. So, when you go from entity to entity and that's why there was such a push within the Tiger Team was to really delineate you need that higher level of exterior exchange, you know, within an entity you could perhaps go with something a little less, but once you go outside those walls you have to make sure that you are absolutely secure.

On the other hand, the people that you are exchanging with, if they know you're at a level 2, they may choose not to exchange with you because the weakest link is where everyone is. So, it's a touchy situation. And to me, yes it's going to...there's a cost, there is a cost, yes, it maybe five seconds, it may be 3 seconds and all that adds up on the aggregate across the whole system, but it's a cost we cannot afford to not pay, we've got to do it, because the public will not accept this if we don't.

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

So, Deven, let me ask you on the three recommendations, I'm going to combine 1 and 3.

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

Okay.

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

Because 3 just says clinician. So, you're saying, the recommendations that clinicians use LOA 3 for "riskier exchange" and that two as an interim way of getting there we might start with 2.5.

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

Right.

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

Are those standalone recommendations or are these things you are targeting towards Stage 3 recommendations?

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

Well, we used Stage 3 as a sort of benchmark for timing; it doesn't necessarily mean we would suggest it would be a meaningful use criterion necessarily. And in terms of your use of the word clinician, I'm comfortable with lumping those as long as we understand that...I mean we wanted to sort of hit all clinical users. So, if a clinician includes a nurse then that would be consistent with where we were.

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

And at what point then where you going to define riskier exchange? Because that seems like...

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

Well, if the committee would like us to do more work on that issue we could, you know, we drew these very rough boundaries of inside/outside, but they don't necessarily match up very well with the world and where it's going or where it already is, it just...sometimes it's about sort of this intrinsic feel and that's really not good enough for a policy. You know, if you need us...again, I didn't want us to take us down this road if in fact there wasn't an appetite to explore that among the Policy Committee if in fact you would like to hear more from us about sort of what are these riskier transactions, we are on board with the idea of going to a higher level of assurance for riskier transactions, but we'd like to know more about what some of those would be then we can go there. We have a meeting on Monday and an empty space.

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

Well, I think we do need to have that in order to have the policy filled out.

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

Okay.

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

And, so I guess this is a separate recommendation than that just goes to ONC, correct?

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

Yes.

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

Okay.

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

So, I guess what I would ask, because if folks would be more comfortable...I would like at least an indication that the Policy Committee accepts the premise that for some riskier transactions we ought to be at a baseline of level 3 for individual authentication subject to the Tiger Team coming back with a sense of what those riskier transactions are that would then be vetted by the Policy Committee definitively. Because, I don't want to have...again, I don't want to have that conversation if folks are not already on board with that.

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

I sense that people are on board. Do you want to go ahead and raise your hand for the straw poll? So, basically, I think everybody is, yes.

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

Okay, okay.

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

So thank you and we'd appreciate a little bit better definition of trust riskier requirement.

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

Okay.

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

Great, because the consequences of universal protection in the analogy would be the cost that Judy mentioned.

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

Well, I mean, I think that's right, you know, we want the degree of assurance. We want the public to trust what we're doing at the same time we still want healthcare data to flow for all the important reasons that we discuss every month when we are here.

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

Very good.

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

So, it's always a challenge.

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

Thank you very much, Deven, and to the Tiger Team. So, we'll see that back next month maybe with the riskier exchange.

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

Yes, I hope so.

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

Good. Thank you. And so for our final act we have Joy Pritts giving us an update of the Office of the Privacy Officer. Okay, the Privacy Officer has brought her...

**W**

She's a federal employee.

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

Yeah, she's a federal employee and brought her secured encrypted flash drive. So, let us know whether you want this into Stage 3, category 5? When you come back you might tell us whether you want this in Stage 3, category 5 recommendations, yeah. So, we're testing out Judy's calculation of the time overhead for security. Okay, so the password has been entered and the encrypted presentation has been loaded.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

That's right and it is a tough password too, let me tell you, it has large and small letters and numbers, and symbols, all the things that you would want in a password, because they make me do it.

**W**

The Privacy Officer?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

That's right, that's right, it plays both ways. So, I'm going to give you a little update on what ONC has been up to in the Privacy and Security Rule today. Part of what I'm going to do is update some information on some of our projects that we've talked to you about before, but also just give you some information about where privacy and security is policy-wise in the health sphere in general. So, Paul you may want to just go to sleep, because I think you've seen most of this presentation at NCVHS already.

But, onward and over, the first thing I'd like to talk about, next slide please, oh is this it? Let's see if I can...oh, there we go, okay. So, I wanted to let you know that you may have seen, you may not know about this, but you might recognize some of the guidance that was issued to one of our sets of grantees so we issued a state health information exchange privacy and security program information notice, it is called a PIN, and what that is, is it's where we tell our grantees what we would like to see in their plans for the development of their HIEs.

We issued one in March and this particular one is a standalone one that gives guidance on our expectations for privacy and security frameworks in the State Health Information Exchange Program. Those expectations are based on the fair information practices and, as you all know, a lot of the recommendations that this committee has sent over to ONC are based on those same practices. It incorporates a lot of the HIT Policy Committee's recommendations particularly those regarding informed choice to participate in Health Information Exchange with a query exchange model and strong provider authentication.

You can see that notice yourself and read it at that website; I gave you also a search term because it's much easier to find it that way than trying to type in all of those letters. But, the reason I wanted to bring this to your attention is because I want you to know that with meaningful use when you make recommendations it's easy to what happens because there's a definite rule that comes out. With some of the other recommendations that come out from the Policy Committee on privacy and security there are a number of different levers that we use in order to effectuate them and this is one that you might not be aware of, if it wasn't brought to your attention, so we'd like to thank you for your recommendations and let you know that they are being used.

We are working very closely, as Deven told you, with the Presidential Initiative on the National Strategy for Trusted Identities in Cyberspace, it's basically, I think you went into this, Deven, I missed it. Okay, so it's one-time ID proofing that could be used over various entities and we did have the Tiger Team hearing on this, the initial one was provider focused. We will also have a patient focused one because this issue on how you ID patients is one that's really developing particularly through health insurance exchanges is one avenue that is a focus. Also, through some of the requirements of the meaningful use and providing people access to their own health information so, there will be more consideration on how you ID patients discussed later this year.

As a general policy matter, we're talking about the big policy issues right now, this is not one that ONC is directly involved in, but you should know that the HITECH modifications to HIPAA, the final rule on that was sent to OMB in March. There was a notice given that there was a request for an expansion of the 90 day response period that they have.

But this rule when it's finalized will finalize a breach notification rule and the other really...it has a lot of provisions in it that extend privacy provisions and refine some of the regulations as they stand now. But one of the major ones is it extends the use of disclosure provisions of the HIPAA Privacy Rule and most of the requirements of the HIPAA Security Rule to Business Associates. So, this will be the largest expansion of HIPAA by far and away in the many years that it's been in place and it will have a large impact on entities such as cloud EHR vendors and Health Information Exchange Organizations because it makes all of them directly subject to enforcement activity.

We also worked very closely with CMS on some of the regulations that came out of the Affordable Care Act. We are attempting to make sure that our privacy and security policies are coordinated as we move forward in all of these different areas that are reforming healthcare. So, there are rules on the Accountable Care Organizations that were finalized last year and they included some of the recommendations that came from this committee about individuals having the potential to opt out as having certain of their information shared.

There's a final rule on the availability of Medicare data for performance measurement and that came out in December and those rules have very rigorous data privacy and security requirements in them that are very well aligned with the fair information practices that we have used to guide all of our work here.

And, lastly on of the...it won't be the last Affordable Care Act Reg, I'm sorry to say, but one of the...finally, on our agenda, one of the other major Affordable Care Act Regulations, a huge one is the establishment of the exchanges themselves and qualified health plans. And there are a lot of privacy and security standards that are set out in that rule as well and these are difficult because these exchanges are going to be collecting information, and processing information from a number of different agencies, from the Social Security Administration, from the Internal Revenue Service, from state agencies in all likelihood.

So, you have to have kind of broad principles set out here. There a lot of existing laws in place in this area, but there's a lot of overlap. There are areas that are not overlapping, so it's a complicated area, but there is assurance that they will be consistent with the fair information practice principles.

In addition to these really, what I would call very high level policy initiatives that we've been working on, I'm going to give you a little bit of a snapshot of where we are in our research and internal initiatives.

We reported to you before on the data segmentation for privacy initiative. Just to give you a brief reminder of that one, this is the project that builds on the PCAST vision of putting metadata tags on data. There were recommendations that came from the Standards Committee that said that we should test the privacy metadata tags, the standards for that, and this group is involved in that. They have done some work on that. The standards assessment is complete and they did report out on the standards how they thought the standards were shaping up to the Standards Committee.

The user story that the whole group decided on, this is in the S&I framework initiatives, so this is all a collaborative public-private stakeholder collaborative effort, and the use case that was decided on to pursue was related to the confidentiality of substance abuse treatment information under, particularly under 42 CFR Part 2, which I'm sure we've all heard a lot over the years.

The reason that the group chose this as the use case was because it is a rule that is fairly uniform across all 50 states, so that if they could crack it and if they could solve, you know, have some solutions that people might be able to use, it would be widely applicable. Having said that, they also wanted to address this in a way that anything that they...any solutions that they do come up with are extendable to other areas of law where the individual has the existing right under law to share some, but not all of their health information or that they must...their permission must be received in order to share particular information.

The pilot has been selected on this, it is, I believe a joint pilot by the VA and SAMHSA. And we're a little delayed in getting the pilot instituted due to the, I'll just say the federal funding cycle, but we are confident that it will happen and there is the website where you can keep yourself updated if you're really interested in following the progress of this on a more frequent basis.

We also have, in the works right now, the trial, the pilot on eConsent and this trial is, this pilot is being held out of the Western District of New York in conjunction with one of the Beacon websites and also with the New York health...with the healthy links which is the Health Information Exchange Network in that area.

And this project grew out of this committee's recommendation that individuals have meaningful choice as to whether to exchange their information through a Health Information Exchange which is query and response-based. And what the meaningful means as the individual would learn about it and that they would understand what their choices meant.

So, this project is designed to test out what does that really mean and they're creating learning materials for individuals in a couple of different formats to educate them about what participating in healthy links would mean and having them electronically choose, make their consent choices on that and then implementing it and what we're learning from this project already is that people are really interested in this.

They sent out a...I love to tell the story, I hope I'm not giving out too much in way of what they'd like to publish, but they sent out a survey to over 2000 people just to get some general information about what information people would want to know about how their information was shared and there's this category in the survey that says do you have any other comments and usually in survey data nobody fills that out, you know, the response rate is very, very low. They had over 30% of the people who responded fill...you know, write notes about what they thought the rules should be and how it should be exchanged. So, it tells you...that alone tells you that people are very interested in this. They take the time to even write their thoughts and send them to us, which is, I think really exciting to see that they care that much, enough to send us missives.

So, this project is moving along quite rapidly and we're hoping that it is on time right now and is set to conclude in March 2013 at which point we're hoping to be able to provide just some general guidance or just lessons learned to people on these are the issues that people found were interesting or they wanted to know about. We tried to use these terms, which we had tested and people understood the choices they were making or they didn't. So, there is a little component of this where there's actually a little test after the education component to see if people understood what choices they were making. So, we'll keep you posted on this one too.

We've developed fairly rapidly what I would call a mobile health portfolio. And this was done in response to what we see as a rapidly changing environment where the adoption of this technology exceeds the security that has been attached to it. And when you read the surveys that have been done by some of the associations such as HIMSS, they show, you know, 70% of providers are intending to adopt mobile technology and the next question is and how many of you have security plans in place for that and that number drops down dramatically. And, it's not only the HIMSS survey it's a couple of other surveys that were done. The numbers aren't consistent but they're all significant enough to give you great concern. So, we have focused in rapid order on this issue.

One of the things that we are doing is we are working on a mobile health good practices project with the Office for Civil Rights. We had a roundtable this spring where we gathered information about how providers were using these devices. What issues they saw, what practices that they had put in place and we also did some work on testing smartphones, tablets and other mobile devices right out of the box because that's how people are using them. And that testing showed that that was not a good idea as a general rule.

And, I think some people were surprised to see that result, because people aren't thinking that this is a consumer driven device that you are now moving into a commercial healthcare related field and perhaps you need to do more than just take it out of the box. The outcome of this project in particular is going to be some educational materials for providers in various formats. We have heard loud and clear from our providers that they really don't want a whole lot of PDFs anymore. So, we are looking for a lot of different ways of presenting the information to make it easy for them to understand and very digestible.

We are also doing an mHealth Consumer Attitude Survey which is in conjunction with the Text4Health Task Force and that should be completed in October. This is identifying and exploring attitudes and preferences of consumers with respect to privacy and security and, you know, looking at things from the consumer's perspective as to what they would be willing to use as Deven was pointing out if you make security difficult enough, people won't use it.

We also, my office in particular, has recently been assigned the SHARPS Project which is the Strategic Healthcare IT Advanced Research Projects on Security. Some of the things that they're looking at which help complete our mobile health portfolio include implantable medical devices and security, and consumer attitudes regarding privacy and remote monitoring devices, so it's a different angle of that is how do people feel about the things that are evolving such as where are you, what's your geolocation and what's the air quality where you are, and what's your heartbeat, you know, are you having asthma problems here. So, it is looking at a lot of different angles of developing area in mobile health.

In another area, a broader area we are looking at the pursuing...continuing to pursue our consumer privacy and security survey which is one that ONC has fielded for in some form surveys like this for a number of years. This was the first one I think that's going to be done in Spanish as well as English and will serve as our official baseline metric going forward from my office. We had some of our core questions that were also put into the HINTs survey and that's kind of a safeguard for us in case we are budgeted differently in future years. So we have our own safety net that I guess is kind of a little backup in recovery of our own in case we have any kind of emergencies. The intent here is to identify consumer attitudes over time and we will be launching this in August, later this year, probably August if everything goes as planned.

We're also on the programmatic side, working very closely with the privacy and security communities of practice of both the REC program and the state HIE program to learn what their needs are and to provide them with materials that they would find helpful. One of the products that we have released this year is this guide to privacy and security of health information which is based on a lot of information that had already been developed by ONC, OCR and others, but reorganized so that it is aligned with how a small healthcare provider would implement an electronic health record, so it is specifically geared towards the implementation stages and this was developed with assistance from the American Health Information Management Association as well as OCR and our own general counsel's office.

One of the other kind of fun things that we're doing is the training materials on security for small providers and we have developed the security video games for training and the kind of entertaining thing about this one is it uses avatars, but if your security is good your practice grows and if your security is bad, the badge up on the left-hand side cracks and falls apart and you end up with like no patients. So, there are real implications if you don't protect your virtual information. So, that's a snapshot of some of the things that we're doing right now and I think we have some time for questions.

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

Good, thank you very much, Joy. And as you pointed out, we see where meaningful use goes. We don't see where a lot of the work that the Tiger Teams and privacy and security goes and there's a lot of programs here and where's that being taken up, and everything from new policies to educational vehicles to get the word out so thank you. Questions or comments? Oh, Gayle?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Yeah, a couple questions. I know some of this material is available, I don't know if the avatar games are not out yet, but the manual, you know, is that out through the RECs and is it available to the general public and practices that are perhaps not eligible for REC membership?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

I believe it's on our general website at this point.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

It's on the website?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Yes and we can get you the link to it if you would like.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Did we get this electronically through a presentation?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Yes, but I don't think I included the link on this one.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Just sent it? Okay, thank you.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Maybe I should revise it and put the link in and then people would have access to that, would that help?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

I would like to see some of that.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Okay.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Yeah.

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

Other questions, comments? Deven?

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

So, the...when the PIN, the Program Information Notice, to the state HIE grantees came out that incorporated so many of the recommendations that we had done on fair information practices and meaningful consent, I think I told folks here that in fact that was a place where many of our very hard-earned recommendations were actually adopted by ONC because I was quite pleased to see it. And so, I would encourage folks who really want to read into the details to do that and the link was on one of your slides. But, now I'm sort of curious as to whether the response from the grantees to how they implemented the guidance if that's publicly available?

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Not at this point.

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

Okay.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

We're still getting...the grantees are on a cycle as to when they have to submit their plans.

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

Okay. It might be something worth pursuing because I think it's interesting to sort of see the policy choices that different entities are making even within that kind of broader framework; it's just a good source of information about what's happening in the field.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Yes.

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

Gayle?

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Yes, I'd like to add into that. Do know if we are going to do a workshop on health information exchange, some of that update on what the grantees are doing might be an appropriate time to get some of that feedback and find out if that could all be timed together because that of course is an extremely important aspect. And, I think as we get...we start standing up exchanges that are going to link into that state HIE we want to make sure they have access and implement the same policies.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Well, we don't have quite the same leverage over them at the moment, so, but we did suggest in the PIN that it might be a policy that within it they might want to broaden beyond just the grantees.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

Well, perhaps this is more appropriate if and when we have that meeting. However, to be linked to the health information, the statewide and grantee funded exchange you might require all parties to have the same policy in place in order to link.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Okay, we hear you.

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

Well, you know how states and feds may have differences of opinions.

**Gayle Harrell – Consumer Representative/Florida – Florida State Legislator**

I very well know that one.

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

But you are speaking from the state perspective...any other comments or questions? Terry?

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

Yeah, I just had one comment, Joy. From a federal perspective you may be aware that last week there was a big OMB meeting about mobile, interestingly driven by OMB to try to get some consistent guidance across the federal space for a privacy and security and I know we're really trying to figure out the privacy issues related to people downloading their own data from our system onto their device.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

You mean a citizen user?

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

Yeah, like Blue Button but not as an ASCII file, but as like very detailed, say you download your radiological images and because we're federal and then your device gets swiped and do we end up in trouble like who owns that data at that point because it's federal going to individual and because that device isn't FIPS compliant, so I think we may just have to reach out to you a little.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Yes, that issue comes up repeatedly and in some ways it befuddles me because if we gave the patient the information in paper, there's no question that they are responsible for it and they have to maintain it and protect it.

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

But, I think some of why it comes up is because it's kind of a new space and nobody knows if there needs to be a Reg or there just needs to be guidance.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Okay. We should talk more about that.

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

Yeah, we should.

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

Any final questions? Thank you very much, Joy.

**Joy Pritts – Office of the National Coordinator for Health Information Technology – Chief Privacy Officer**

Well, thank you.

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

A lot of good work. Okay, why don't we open up for public comment then, please?

## **Public Comment**

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Okay, operator, would you please open the phones for public comment and if there's anyone in the room who would like to make a public for comment, you can please come forward and sit at the desk and please identify yourself. And public comments are limited to 3 minutes. And, we'll start with the people in the room while we're letting people on the phone come forward.

**Alan Merritt- Altarum Institute**

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

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

Hi, it's Larry Wolf; I'm a Health IT Strategist at Kindred Healthcare. It was great to hear the passionate conversation this morning going on, it's really pretty inspiring and I think, yes we ought to be looking really broadly at policy levers in general and not just ones tied two meaningful use regulations. And also that we need to look carefully at what is really the minimum necessary to enable the kinds of changes we look to. I think this notion of could you get it down to 5 things is a really interesting challenge.

And, I further want to emphasize, and it's sort of taking me back to an earlier job when I was an application data architect, that if we start looking at architectural principles to the systems we're designing and a roadmap for getting to those principles it might really help to frame some of the discussion and get us to look beyond just what's achievable today and what we would actually like to achieve and what we need to do to get there. I think the risks around data conversion are really high and well documented and that's also a really big sunk cost of existing systems so moving off of one data set to another data standard really is a key thing to work through.

And, also a comment about that infamous glass that's either half-full or half-empty. There's sort of the wisecrack answer is that it is always full it's just maybe full of different things and we should try to remember that because the lives of the healthcare providers are already very full and as we're looking to take things on the lives of the organizations are very full, so looking to take things on we need to really be asking the question what are we not doing, what are we shifting our emphasis for on how we're really enabling things. Thank you.

**Darryl Roberts – Senior Policy Fellow – American Nurses Association**

Hello, I'm Darryl Roberts; I'm a Senior Policy Fellow with the American Nurses Association. The area of my comment is actually having to do with Deven's presentation. As a nurse I understand the value of limiting records access only to those persons authorized to view them, but it does not seem that LOA 3 actually does that except by association.

People that are logged in have access to anything that the system that they are logged into has and by definition they can get to anything they want to if they are authenticated users, and if you look at a lot of the cases where people have had illegal access to records that they have access to, but they are violating the HIPAA regulation of using the information inappropriately or accessing information that's not appropriate to them. It seems to me that the LOA 3 doesn't limit that in any way it only makes them think twice about it and frankly, the news stories that have hit the stands about nurses particularly accessing information they should not have access to, other providers accessing information they should not have access to would not have been prevented by LOA 3, they had ulterior motives, sometimes financial, that allowed them to overlook their fiduciary and professional responsibilities.

There are other ways that we could involve authentication without having...that would not be as time-consuming as LOA 3 seems to be. If Judy's calculations are off even by 90%, the amount of time that it takes for an individual to log into...as a nurse I would go in to...I'd have eight patients. I would be seeing those patients upwards of six and eight times a day. The devices like the iPhone, every time the phone powers down and you log back you have to log your credentials in again. My thumbs are a lot bigger than the keypad on my iPhone and 5 seconds is probably a bit short for how long it takes me to access it, that interferes with patient care. It presents an opportunity to look away from the patient when in fact the idea of being in the patient's room is to be there for the individual. Each opportunity to get into these credentials to authenticate increases the likelihood that you're going to take time away from that patient, it also causes a bit of aggravation.

One of the things I did not hear the committee talk about is possibly use of biometrics. These are things that cannot be shared. My thumbprint is attached to me and I cannot lend it to someone else. It doesn't prevent me from logging into my device and handing it to someone else but through a higher level of association I think it would limit the likelihood that I would do so.

Such a type of authentication might be considerably more expensive, but I think that the time lost associated with people forgetting passwords, having to login every time and etcetera, would be worth the additional cost. Alternatively, there would also be a considerable savings on the part of help desks which, as having run help desks in the past, I will tell you that a considerable part of a help desk workload is on password resets. I don't have to reset my thumbprint. Thank you.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

All right, we can go to people on the phone. I believe we have Julie Cantor-Weinberg.

**Julie Cantor-Weinberg – College of American Pathologists**

Yes, this is Julie Cantor-Weinberg with the College of American Pathologists. Thank you for giving me a few minutes this afternoon. I wanted to thank the committee for its good work in trying to advance the triple aim, but recognizing that we're not talking about Stage 3 puts a lot of pressures on laboratories for whom you rely on a lot of these objectives. And, also we continue to have a concern that while you're up to 20% adoption by eligible providers of meaningful use, the requirements really do not fit pathology at all, Pathologist practice in the laboratory information systems not in certified EHRs.

Most of the objectives that had been promulgated in Stage 1 and 2 and you're thinking about for Stage 3 really don't fit within our scope of practice and even when they do they're written from the perspective of the provider placing an order rather than the radiologist or pathologist receiving the order, and while we have five quality measures in PQRS, none of those have been on the table thus far. So I hope...you had some good conversations late last year on specialist. I would urge you to review those because while we're not counted in CDC surveys and uptake rates of the EHRs, we are considered eligible providers and thus eligible for incentives and penalties.

And then also, I would ask that you move slowly and cautiously on many of your objectives that rely on laboratory data. We're part of many of the S&I efforts but there's a need to proceed with caution because the LIS EHR interfaces are under strain and if you don't assure that the data moving from the LIS to the EHR is correct and appears in the right format there can be many problems with patient safety and the like. So, thank you very much and I hope you'll revisit the issue of specialists, particularly pathologist, radiologist and anesthesiologists. Thank you.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you. Tom Leary?

**Tom Leary – Healthcare Information and Management Systems Society**

Thank you very much, this is Tom Leary with HIMSS and wanted to express my appreciation for the discussion today of the numbers of meaningful users are a real testament to the work of this committee. In particular, glad to hear about the dialogue around privacy and security, and in particular we're interested in learning more about how organizations can get involved in the activity that you referenced on the OMB meeting on mobile last week.

And, finally, we want to remind the committee that National Health IT week is scheduled for September 10<sup>th</sup> through the 14<sup>th</sup> and we're hoping for over 200 organizations serving as supporters and are anticipating presidential proclamation and Senate and House proclamations, as well as some state-level proclamations this year as well. So, we're keeping the momentum going and much appreciate the work of the committee. Thank you.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you. Seth Foldy?

**Seth Foldy – Senior Advisor – Centers for Disease Control and Prevention**

Seth Foldy, Senior Advisor at CDC and I wanted to thank the committee for an excellent discussion this morning about the potential opportunities for population in public health in Stage 3. There was a lot of discussion and some of it I realize was kind of hypothetical pointing at variations in how immunization information was handled and whether or not this was proving to be a great dysfunction in Meaningful Use Stage 1.

I wanted to make sure that the group knew that considerable work has been done with the lessons from the first year of Stage 1 of Meaningful Use, work that is included the communities of practice implementation group at ONC, CDC, vendors and the Immunization Registry Association to find ways to tighten up the implementation as well as the certification to specifications for immunization reporting and the lessons learned there have actually been spread to other public-health types of reporting as well so that each of the implementation guides used in Stage 1 of Meaningful Use will soon be coming with conformance statements and other important improvements that will facilitate more uniform implementation between EHRs and the many public health agencies.

I think also that Art Davidson made a brief comment that the standards and interoperability framework public health reporting initiative is working on harmonizing the data elements that are used across a wide variety of public health reports so that any future implementations in Stage 3 of Meaningful Use may also have important ramifications for simplifying future types of public health reporting if that initiative is successful.

So I would in no way detract from the statements from those who raised the concern about how much funding is available for public health implementation because that's always an issue, but I think that it is important to know that the pressure of the meaningful use objectives is resulting in progressive and positive change towards more standardization on the public health side as well as among health-care providers.

I also do concur with those who are concerned about the adequacy of the structures for health information exchange in many ways the public health reporting objectives are some of the most aggressive forms of Health Information Exchange that are embodied in Stage 1 of Meaningful Use and public-health like other parts of the industry continue to look for clarity, a vision about the role of Health Information Exchange the protocols and of course health information exchange organizations moving into the future. So, I think that that concern is well placed and we will be very interested in participating with the committee on solutions for that.

**Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**

Thank you, Seth. Operator, are there any more people online?

**Alan Merritt- Altarum Institute**

We have no further comments.

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

Thank you and appreciate all the committee members and staff being at this latest meeting. We will see you in September; I think there's a song about that, but anyway, thank you.

## Public Comment Received During the Meeting

1. Subgroup 107: Would be good to also include food allergies.
2. Problem Lists: If the patient's HDL Cholesterol is very low, it would be a nice prompt the clinician the question if a low HDL should be placed on the problem list?
3. Subgroup 1-04: Is there clinical evidence that supports capturing "Sexual Orientation"? Is there concern about patients reporting this information as well as mandating EPs and EHs capturing it?
4. Subgroup 302: Stage 3 Recommendations: Would include Food Allergies.
5. One can agree having a public forum regarding HIEs and their issues and struggles. However, one should also include the successful HIEs whom have tackled and addressed these difficult issues.
6. Subgroup 1-05: In using SNOMED codes for the Problem List as a clinical tool to document, is there any concern with the potential for inconsistency with ICD coding used for a patient billing and how those differences are reflected in a patient's record?
7. Subgroup 1-05: Are there competency standards that direct which care providers are permitted to select an appropriate SNOMED code and document in the problem list?
8. I would urge ONC and the HIT PC to delay release of any RFC on Stage 3 of meaningful use until after the new year. The slides suggested that a request for comment on the Stage 3 meaningful use objectives would be distributed in November, with comments due by December 21. This timing is very challenging for providers, and especially physicians. We are all hoping that a large number of physicians will attest to meaningful use for the first time in 2012. For these physicians, the most likely 90-day reporting period would be October 1 – December 31, 2012. Thus, your proposed RFC window would overlap directly with their most intensive Stage 1 implementation timeframe. In addition, of course, most providers and vendors will also be digging into the soon-to-be-released Stage 2 final rules at that time, and engaging in planning their transition from Stage 1 to Stage 2. All of that while doing their primary job of caring for patients. While I understand the regulatory pressures leading to the timeline that was presented, a short delay would likely lead to a much more thoughtful and rich response that could, perhaps, lead to a more expedited process later on.
9. I would also urge you to start the RFC process with a 60-day comment period. This allows a short, but reasonable window for busy providers to take time out and consider the ramifications of the proposals and provide thoughtful feedback. Anything less than 60 days really is too short to gather input that draws on both evidence and experience. This is especially true when comment periods include national holidays.
10. Finally, I greatly appreciate the guiding principles you would forward. I would recommend that the data gathered to assess feasibility of each recommended objectives also include information on: (i) costs relative to benefit, and (ii) scalability. It is generally a long road from proof of concept in a pilot to universal implementation across all health care providers in all environments.
11. Thanks, as always, for your hard work and commitment.