

# HIT Standards Committee Transcript August 20, 2009

## Presentation

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

Good morning, everybody, and welcome to the fourth meeting of the HIT Standards Committee. Just a reminder that this is a federal advisory committee, which means it is being operated in public. The public are on the telephone and on the Web listening to the meeting.

Also, the meeting minutes will be available on the ONC Web sites within about ten days. There will be opportunity at the end of the meeting for the public to make comments here in the room, as well as dialing in on the phone line.

So with that, let me just remind the committee members both here in the room and on the phone to identify yourselves as you begin to speak. That is for the transcription purposes. Let's go around the table here and introduce ourselves. If you could just state your name, your organization, and if there's any conflict of interest (yes or no) according to the agenda. Let me begin on my right with Jodi.

**Jodi Daniel, Office of Policy & Research, Director**

Jodi Daniel, ONC.

**Liz Johnson, Tenet Healthcare**

Liz Johnson, Tenet Healthcare, no conflicts.

**John Klimek, National Council for Prescription Drug Programs, Inc.**

John Klimek, NCPDP, no conflicts.

**Karen Trudel, CMS**

Karen Trudel, CMS, no conflicts.

**Kevin Hutchinson, Prematics, Inc., CEO**

Kevin Hutchinson, Prematics, no conflicts.

**Linda Fishetti, Provider Organization of Veterans Health Administration**

Linda Fishetti, Provider Organization of Veterans Health Administration, no conflict, but I'd like to note that I'm on the board of HITSP as a Federal Representative, on the board of MEHIC as a federal liaison, and an elected member of the board of directors of HL7.

**John Derr, Golden Living LLC, Chief Technology Strategic Officer**

John Derr, Golden Living. I'm a provider. I'm also a commissioner on CCHIT, representing long-term and post-acute care.

**Sharon Terry, Genetic Alliance, President & CEO**

Sharon Terry, Genetic Alliance, no conflicts.

**Douglas Fridsma, Arizona State University**

Douglas Fridsma, Arizona State University, no conflict.

**Dixie Baker, Health & Life Sciences, Science Applications Intl. Corp., CTO**

Dixie Baker, Science Applications International, no conflicts.

**John Halamka, Harvard Medical School, Chief Information Officer**

John Halamka, Harvard Medical School. I'm on the board of Envita Health, a decision support service provider and I always say I'm part of a provider organization. So in that sense, I'm biased towards doctors and nurses.

**John Ferrelin, HCI**

Good morning. John Ferrelin, HCI. I'm a board member of ... and as well, I would note that HCI is ... organization. I think our collective bias is not only providers, but also centrally the patients. Thanks, all, for being here and all the hard work you're doing.

**Anne Castro, BlueCross BlueShield of South Carolina, Chief Design Architect**

Anne Castro, BlueCross BlueShield South Carolina, and I have no conflicts.

**Christopher Chute, Mayo Clinic, VC Data Gov. Health IT Standards**

Chris Chute, Mayo Clinic, no conflicts.

**Janet Corrigan, National Quality Forum, President and CEO**

Janet Corrigan, National Quality Forum, no conflicts. I would note I'm on the board of NEHIC as well.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Jamie Ferguson, Kaiser Permanente, no conflicts, but I'd note I'm on the board of HITSP and of WEDI.

**David McCallie, Cerner Corporation, Vice President, Medical Informatics**

David McCallie, Cerner Corporation, no conflicts.

**Judy Murphy, Aurora Healthcare, Vice President of Applications**

Judy Murphy, Aurora Healthcare, no conflicts.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Wes Rishel, Gartner, Inc., no conflicts, but I would note that I'm on the board of trustees with CCHIT.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

Lisa Carnahan, NIST, no conflicts.

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

I believe we have a few of the members on the telephone. Cita Furlani, are you present?

**Cita Furlani, National Institutes of Standards and Technology**

I'm here for a few minutes, Judy. Thank you. Thanks to Lisa for standing in for me and no conflicts.

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

Thank you. Stan Huff?

**Stan Huff, Intermountain Healthcare, Chief Medical Informatics Officer**

Yes, I'm also here. I'm with Intermountain Healthcare in Salt Lake City and the University of Utah. I have no conflicts, but I am a member of the board of HL7 and also a co-chair of the LOINC committee.

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

Thank you. Any other members on the telephone?

**Jim Walker, Geisinger Health Systems, Chief Health Information Officer**

Jim Walker, no conflicts.

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

Okay, thank you, and I'll turn it over to Dr. Perlin.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Well, thank you, Judy and good morning, everybody. Thank you so much for being here and being part of this process. It's a wonderful example of democracy in action. It's been an incredibly robust process and working through support for meaningful use and standards, the aspirations for higher-valued healthcare as part of this process.

As you may recall, I used the term that we would be a highly caffeinated group when we first met and indeed, I'm impressed. In fact, I'm impressed not only of every member of the committee and the public's energy, responsiveness. Indeed, we so much appreciate all the input that we've received. Please know, it's read, thoroughly considered, and part of the deliberations. I think we also described the challenge of having three workgroups, wondering how they would work together.

Since our last meeting, I think perhaps more than any before, there has been absolute interdigitation of effort. So as we come forward to this meeting, I think we see that coalescence of activity.

As caffeinated as many of the members of the group may be, I'm absolutely convinced that there is one member of our group who needs no caffeine, but doesn't sleep and that's my co-chair, John Halamka. The fact that he's been in Japan for the last few days, that we get correspondence during what is our daytime is testament to that. John has been a part of virtually every single call of each of the workgroups. John, I want to recognize and thank you for that.

Many of you saw a communications that Dr. David Blumenthal send yesterday describing the aspirations of technology, not as an end of itself, but importantly as a piece of improving the value of healthcare; value described as relationships between the outputs and the resources; importantly, aspects of outcomes such as safety and protectiveness and efficiency and I'd even argue compassion.

When I think back to my career, the ability to operate in an environment which had electronic health records, it's the difference between asking a patient who might be there to follow-up on a biopsy to rule out cancer why she's there today and knowing it.

So, what we do today, really, I see as fundamental to our ability to provide safer, more effective, more efficient, more compassionate care. I know that those are the attributes that drive David and the entire staff of ONC to which we're entirely grateful because it's the kind of care that we, we with our various relationships to healthcare, not only want to foster, but as consumers and family members, it's the kind of care that we want to be able to receive for ourselves, our families, our communities, our country.

Now, going from the aspirational to the very practical, as people have had a chance to review the materials in preparation for this meeting, I think we're really at a remarkable point. We're at a point where we recognize the messiness of democracy, but the transparency that's also part of the process. We're at a point where we have been considering the state of the world and how to get from the world that we have today, which really has not yet adequately embraced electronic technology as a predicate for these better attributes of healthcare to one that actually has a degree of detail that's specific enough to allow a road map to emerge for the next decade.

Indeed, when I look at the material and take myself out of this role and think about going back to a provider organization that is composed of large entities, but also interacts with the cross-section of the country - small physician practices and patients across America - I know that I can go back and say as I look at these materials that there is beginning to become definition that allows this aspiration to better care, but structures it in a way that there are some things that are very clear cut for 2011. Maybe do a little polishing in some areas and a little more ambiguity in 2013 and 2015, but there is a clarity.

I can go back and honestly say that it doesn't ask us to do things that are insurmountable. I won't tell you that it's not difficult. Change is difficult, and the environment is challenging as well, but I can go back with a clear conscience and identify that there is a clarity of direction.

Anne Castro during the very first meeting charged us; said, "Look how much else is coming down the pike over the next year." I remember you specifically identified ICD-10 as one of the big transitions in that period ahead and I remember that you implored us to great specificity for each of the years.

I think during this meeting, we will recount the debates, the way in which certain questions were resolved to help provide that degree of specificity for 2011 in particular, and some of the work that needs to be chartered for 2015, intermediate detail and the period in between.

I think we'll hear specifically from the CALDI workgroup and the ability to use technology not as an end of itself, but as a vehicle to drive through better performance in healthcare.

We'll hear from clinical operations to help provide those elements of standards with a degree specificity that helps us describe content of data, transmission of data. We'll learn from this privacy and security workgroup insights, and ... and Steve Findlay were so terrific at the outset; no how privacy and security are a barrier, but in fact how privacy and security have become facilitators; facilitators at a number of levels. Facilitators of the integrity of the information in the first place and facilitators of acceptance that ensures the requisite protection that not only would we have responsibility for, again, by virtue of our personal roles or advocacy roles from a consumer perspective, but simply what we would want and expect as, again, consumers, as family members, as members of a community. And so, let me just personally applaud and thank each of the workgroups for the heroic efforts that have gone.

So, what you're hearing is that there is a convergence. I think that really is the message here is that out of a vast sea of material, I think there is greater and greater clarity that finds applicability across a variety of context and does so with a great deal of responsibility.

The old song goes, "Aren't standards wonderful? There are so many to choose from." Indeed, that has been one of the things that has been a frustration to many because if we had different standards going from coast-to-coast, we never would have realized Intercontinental Railway.

But indeed, we are really at the precipice of being able to offer in analog, in electronic format that would allow those individuals who seek healthcare that's increasingly informed, not only when they go to the provider they usually go to, but when they seek information in their homes, or when they find themselves in other circumstances. For that, less as a professional, but specifically of a prospective patient, I say thank you.

Let me turn to my co-chair, John Halamka. I really want to thank you in particular for helping us really foster some epiphany moments. Some of these had to do both with some of the resolution of technical issues, but some framing as well, especially in terms of not trying to over-engineer those things which go on within the firewall of a particular entity, but really which need to handshake with other entities.

So, without stealing your thunder, thank you, and I'd ask you to address some of those comments.

**John Halamka, Harvard Medical School, Chief Information Officer**

Well, thanks very much. I've been doing this for four years, and I think the word "convergence" is very appropriate, and that is we've leveraged the work of HITSP, the SDO, implementation guide writers, commenters from the public and created a set of deliverables today that are quite impressive. The interdigitation among the groups is quite clear.

What you're going to see is more and more clarity and more and more constraints. When I started four years ago, there were a thousand controversies and a lot of ambiguity and now, the controversies are getting fewer and fewer. You'll see these grids we present that say, "Oh, you want to do this? Here's exactly the standards that you use to a degrees of specificity that's implementable."

Now, implementation and adoption is going to be the ongoing role of this committee, I am certain, because our measure of success should be the number of transactions using these standards that are exchanged. So as you say, there is work to do, change is hard, and I have no doubt that this committee

will have an infinite lifespan. We'll never be done, but we'll increasingly get clarity, we'll increasingly get specificity.

Some examples: Jane will talk about, for example, as you exchange the content of a message, whether it's a problem list or a medication list or a clinical summary. For each one of these exchanges for meaningful use, there's typically a document standard and a messaging standard. So, it actually provides a variety that's constrained, but yet there's enough that gets us from where we are today, where we want to be in the future, and the glide path is clear.

For each one of the vocabularies, Jamie, and really all the groups focus on how do we take what is today often free text, unstructured, but get to the transmission, that semantic interoperable transmission of highly constrained and structured vocabulary controlled information and do it in a way that's implementable.

Because again, if we say 2011, everyone is going to use highly structured, vocabulary constrained identical standards; it'll all be plug-and-play, that will be hard to achieve, but we want to get there by 2013, and we want to get even more semantic interoperability by 2015. So, you'll see vocabulary standards and a glide path clearly specified.

You made the comment about internal versus external. Let me just mention there; the work that has been done on quality and on clinical operations goes from the border of an enterprise to the border of another enterprise. It really is moved in some ways about what you do inside an organization.

However, security is a different animal. I think we all agree if we're going to protect the privacy of a patient, you can't have perfect security between organizations and a completely leaky organization itself. You need to actually ask the question; with inside the four walls of an organization, are there appropriate applications with security capabilities, good infrastructure, and business practices? So, you will see in Dixie's area we have gone inside the enterprise to make some recommendations, but the other recommendations are between enterprises.

There's also been careful thought paid into the maturity of standards. Now, one of the things we all recognize is some of the meaningful use criteria are actually quite complicated and use standards that are young, that have not been widely deployed. And so, we've taken all that into account to say, "Well, what is possible in 2011?" and then, "What will require additional testing and refinement and polish before it is going to be required?" Therefore, we offer some optionality and alternatives until then. So, each one of the presentations does include vocabulary, content, levels of maturity, this glide path I've described.

We also have tried to make some statements about certification criteria and meaningful use. Just so everyone understands, what do those terms mean exactly? Well, a certified EHR will have certain functional characteristics, and we've heard from the policy committee and its workgroups at ONC is, of course, now going to be offering those functional characteristic lists, and there will be multiple organizations that certify conformance against those.

But in addition to functional characteristics, an EHR that is certified will have to adopt the standards recommended by this body. You have to do both - the function and the standards for interoperability. And, meaningful use is the actual exchange of the data. Yes, you enter codified patient data and you measure quality, and you exchange data among organizations using some of the meaningful use data exchanges that have been specified. That's meaningful use.

So, you'll see in our presentations that we've tried to provide that, both insights - what are the standards for certification, those capabilities that a product or enterprise much have, and what are the meaningful use metrics and data exchanges for use?

So, I am quite excited as well by the quality of the work that has been done by these working groups. I look forward to the discussion today. I think members of the public, you too will be impressed.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Well, thank you, John. I'd like to acknowledge we've been joined by Dr. Aneesh Chopra, the White House Chief Technology Officer. Good morning, Aneesh. I want to recognize your support of the entire process, again, as a vehicle to improving healthcare. Would you like to offer any introductory comments?

**Aneesh Chopra, White House, Chief Technology Officer**

No. I just wanted to say thank you to the working group members. I particularly have been enjoying these conference calls that you've been convening on the security and privacy workgroup, and it's been high-quality throughout. So, kudos to the team for the work that's been done thus far.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you for your support and indeed, this is a very ... individual who- thank you for your involvement and the knowledge you share. It was an incredible legacy of what he was able to accomplish in the Commonwealth of Virginia and many insights into the sorts of opportunities, indeed even challenges that we will face.

Without further ado, let's move to our first order of business. I trust people have had an opportunity to review the minutes, and I'd ask if there any amendments, modifications, corrections that anyone would like to offer.

Again, while you look at that, I do want to note that I'm pleased that Steven Findlay from Consumers Union has joined the table as well. Good morning, Steven.

Okay. Well, hearing no comments, let's agree to consensus on the minutes. I want to thank Judy Sparrow and ... staff for really a very sensitive capturing of the deliberations at the last committee meeting. Thank you very much for all of that hard work.

Well, now, we will get an update on the Health HIT Policy Committee and it's workgroups. Another individual who I am certain has not slept for the last few months since he came to Washington is Dr. John Glaser. John, thank you for your leadership. We appreciate your helping to be the thread that connects our work on a day-to-day basis with the policy committee and the meaningful use workgroup as well.

**John Glaser, Partners HealthCare System, VP & CIO**

Thank you, Jon. It has been an energetic and time-consuming ... time. If you don't mind, I'm going to take a nap for the next 20 minutes while somebody else flips the slides.

What I thought I would do is give you an update on the discussions of the policy committee, which occurred last Friday. So, this is their August meeting. We had three presentations by three policy committee workgroups, and they also had three sets of recommendations. I'm just going to go through the recommendations that were fronted by those groups.

Also, I want to acknowledge that we had the three workgroups from this committee give an update of their activities at that meeting. So, the policy committee is reasonably up to speed on the conversations occurring here, and clearly, you'll see the specifics in more detail coming from the workgroups of this committee following me.

Let me start with the meaningful use workgroup. As you recall, in their July meeting, they presented the final set of recommendations for the definition of meaningful use for 2011 and also, their preliminary thinking on 2013 and 2015. Those recommendations were accepted by the policy committee and in the discussion of last week, they tackled two areas.

One is to realize that meaningful use is an ongoing process and as you may be aware, the definition of meaningful use increases and changes over time with a frequency of about every other year. And so, there is an 2011 definition which was recommended, but it's also time now to begin to look at 2013 and to take the preliminary ideas as they had and refine them.

Now unlike the last couple of months where all of you have worked very, very hard under remarkable short periods of time, so did they, using processes that I thought were good, but now we have the opportunity to take more time. And so, we're looking for a definition of meaningful use on 2013 to be ready approximately one year from now.

And so, they began to outline - "sketch," I think is a better term - a preliminary approach to taking on 2013. You can see the sort of rough outline that was presented today or last week, which is to conduct in Q4 some informational hearings. And so, we expect in late-October more details to be coming through. They'll invite a wide variety of organizations and individuals to come talk about 2013, their ideas of what ought to be included, etc. And so, there will be that process later on in the fall.

Early in the calendar year will be a preliminary updating based on that input for 2013 and 2015, cycling back to you all to ensure that those ideas, that we have standards or where we may have standards issues such that we make sure that we don't come out with a set of meaningful use recommendations for which the standards work is still incomplete, or at least understand if we're going to go off and do that.

And then, through the spring and the summer is continued refinement of that. We also may have, although it may be early, some early industry experience with 2011 since there will be an NPRM from CMS in December about the 2011 criteria and those will be finalized in the late-spring of next year. We may have some organizations that move earlier than that and see whether there are some particular challenges that are occurring as a result of that.

So anyway, there will be further refinements of this, and it's the right thing to do about a process. Once those processes are more refined and there are specific dates, we'll get back to you all and let you know what those look like, but this was the first set of recommendations that they had.

The second was, are you are aware, the meaningful use framework was presented as it should be, within the context of some broader national healthcare goals. At the time of the recommendations in July, the National Partnership was used as a framework. Since then, there's been some awareness and discussion of a Healthy Peoples Program, which is being led by the federal government and a set of discussions to bring the two together.

Realizing the job of the workgroup is not to set national healthcare policy, but it is to take existing policy directions and national goals and to fuse those, and to make sure that all the work that we do is conducted in light of those overall goals and with those understandings here.

They will, as you can see the third bullet here, it is to be part of the review process and the intake from advice from the industry, is to focus on some of the measures. One of the critiques, and it's a fair critique of the work that they did was that a lot of the measures are centered on primary care physicians and various specialty measures are not incorporated. It's appropriate to incorporate them in the out-years and they're going to have some discussion about how best to do that and what role and what forms those ought to be, or at least the recommendations for 2013.

I think the rest of the bullets we've talked about. Probably 18 months from now, as the industry gets more experienced with implementing meaningful use, they're planning to tackle some of the barriers and what objectives were relatively straightforward to meet, which are posing a particular challenge, is the challenge universal, etc. And so, once we get some good industry experience, they're planning to hold discussions and provide guidance to us about alterations of strategies, tactics, etc.

So, those were the two recommendations out of the meaningful use workgroup, really centered on this process, that we need to have a repeatable process. I, frankly, think one of the things that we will have to address in this committee after this initial set of recommendations today is the process you all will have on a regular go-forward basis by which we review standards, update standards, etc.

So, that is theirs. I'll just complete that and remind us of the two co-chairs who did some remarkable work on bringing this together.

Going into the certification and adoption workgroup, in the July meeting, they presented some recommendations regarding the certification process. The committee at that time approved a high-level recommendation to that, but there was concern that not enough time had been given for the committee to discuss the recommendations. And so, they were invited back and given a lot more time to enable the dialogue that's essential in the committee to looking at the recommendations, understanding them, discussing various options, etc.

So, they came back with essentially the same recommendations. There had been some refinement between the two meetings and discussed them, and these were approved both in the broad sense here. If you have the opportunity to go to the Web site and pull out the full deck, behind each of these is a set of much more specific recommendations.

But to remind you all, they had five recommendations. One is that there is a new certification process, which has sort of two core attributes, at least at the definition of the criteria. One is that the criteria focused on meaningful use and not more broadly. The second is that the certification criteria are higher level and less prescriptive and less granular. So, that was one of their recommendations.

On the other hand, while in the feature function criteria, less is more, when you get to other areas such as interoperability and security, more and more. And so, be very specific and very granular there so that we're clear about it as much as we can and as much as appropriate what we expect will get done. This in particular is where it's extraordinarily important the work that you all have done because as John Halamka mentioned in his comments, certification is both meeting the criteria and supporting the standards.

And so, the specificity, both on the interoperability side and the privacy and security side, this particular workgroup is looking forward to your all's conclusions and regarding those as essential.

They realize that if you narrow the criteria to just meaningful use, there are other pieces of the EHR, which people will be interested in. So, for example, particularly specialists. So, if you're an oncologist, the flow sheet capabilities or if you're a dermatologist, the ability to take pictures, for example.

Hence, while a meaningful use may not address those, to the degree those are non-specific meaningful use criteria, there's an anticipation and a desire for a market to respond to those, to provide advisory services both generally, but also for specialty specific products that say above and beyond the core criteria for meaningful use or other things you ought be aware of in terms of what the application can do. But also, the types of information you'd like to have, such as usability, such as support prowess on the part of a vendor and also the vendor's potential longevity in this field. So, they are contemplating additional services above and beyond the core nucleus for meaningful use purposes here.

Elaborating a little bit more on the prior recommendation, this is the second one, and that is, again, they were talking about very specific criteria and being very clear such that we do all achieve the degree of interoperability we would all like to achieve, that we do achieve the degree of quality, measures, and reporting that we'd all like to achieve and also, that we can preserve and perhaps advance the trust that patients have of the care that is delivered and the technology that we're deploying.

The first two bullets round that out a little bit and then the third is a suggestion that we have a test harness such that within these criteria, there's a common testing script that can be used across the range of organizations that might be involved in the certification process here.

There's also a change, or their recommendation is a change in the structure of the certification process and specifically, that the process of defining the criteria be separated from the process of actually doing the testing. Specifically in the detail here, they're recommending that the ONC - it's also in the law - be involved in the definition of the criteria, which is then made available to perhaps multiple organizations who would like to be certifiers. This would involve probably the designation of an accrediting organization that would accredit the certifying bodies, but let the market decide whether there are some numbers that might want to pursue this as a going concern here.

We're going to be working and have been working extensively with our colleagues from ... who are remarkably insightful and knowledgeable about this process. And so, we're in the early forms of scoping out some of the specifics that might be necessary to put in place surrounding some of the recommendations that the committee has put forward here.

The fourth one is to realize that although the bulk of the industry obtains their software, their EHRs from vendors - a number of you at the table, a number of you listening in here - there are other sources. There can be sources such as open source, and some vendors take open source and provide that. But in addition, there can be internal development. My organization in Boston engages in that, such as John Halamka, but there are others. And so, we want to make sure there's a certification path for those organizations.

And also, realizing that in a large number of organizations - clearly in the larger organizations, but perhaps in the small - no one will get all of the meaningful use capabilities from one organization. You will get pieces. An example might be the exchange portion, which is a central piece of meaningful use, might be provided by an HIE, might be provided by an interface engine. And so, your certification suite is a composite, a series of modules, and to have the certification process that permits and enables that sort of modular composition such I put together the suite. In aggregate, they have the criteria, support the standards that have been defined based on a lot of the recommendations of you all and I can obtain certification that way.

So, there's also an understanding of a variety of sources that people have and a variety of mechanisms and approaches they have to bringing together the essential set of applications and technologies needed to engage in meaningful use.

Then in the fifth one, there was a realization that standing up multiple certifiers and accrediting organizations and all that will take some time, and that there is a need for a near-term/short-term certification process. It's not clear how much time it'll take to ... over the long-term, but we ought to be prepared for a 12- to 18-month period of time regardless of what we do here. And so, what does the industry do in the near-term?

There, they have a couple of recommendations. One is to leverage the existing certification work. They are very specific in their appendix, as you will see, in that they say the recommendations will leverage CCHIT specifically in the near-term. If one were to do that, one would say there is a need for additional criteria to support what has been referred to as the meaningful use gap. In other words, features/functions that are in the meaningful use criteria, but for which certification has not occurred; an example being a lot of the public health reporting.

And also, to the degree there's a near-term process, it too has to address open source. It too has to address internal development. And so, there are a number of specific recommendations regarding what the industry should do in the near-term while this longer process is being stood up.

So, those are the five that they have - a lot of discussion, useful discussion, and these recommendations and the specific details behind them were also accepted by the policy committee at its meeting. So again, to remind all of our ... co-chairs, who did a nice job of shepherding us through.

The last set, and then I will stop and see if there are any questions or comments on anything I said, involves the HIE workgroup, which has been looking at a range of issues associated with exchange, both "exchange" the noun and "exchange" the verb as we've come to discuss in a lot of these context.

This is the only animated graph that we have here, although your seat will start shaking once we go to the recommendations part of the multi-sensational experience we provide to all of you and there will be some dry ice floating through the room too.

But, they laid out there, it was a nice piece, looking at the importance of exchange for the meaningful use approach. This is also reflected in your all's recommendations. And so, they took the meaningful use

criteria and objectives and arrayed them, this is not necessarily a complete list, and pointing to in 2011, 2013, and 2015 that there was a large set of the meaningful use objectives that will require exchange capabilities. And so, you can see the mapping that has occurred here. It's a nice way of pointing out the importance of the HIE conversation to our collective agenda.

They had their recommendations just on one slide. Their recommendations are, obviously, that - not obviously; I'll let you read the print here - is that the requirements should be neutral to technology and the architectural approach. I think there's a lot to be learned about how best to architect exchanges across a region or geography of any form, or for specific classes of transactions that might be focused on laboratory or radiology or pharmacy, etc.

They also realize as part of the modular approach that there will be piece of the HIE, which will be part of a certification process on the part of a provider who is trying to get meaningful use and to identify— They'll work with the certification workgroup about how to address those aspects of that.

And then, again, the sort of set of points here is to make sure that we are collectively aligned with the states. As you may be aware, there will be grants to the states coming out in the near-term, and to make sure that the collective efforts, both on the Medicare/Medicaid, but also the set of efforts required to put an exchange infrastructure in place are well coordinated and well aligned across the board. And again, these recommendations were made and accepted by the policy committee.

That's the end of the overview here. Let me just stop, Jon, and see if there are any questions or comments from you all.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

First, thank you very, very much for a thoughtful synthesis of all the huge amounts of work going on in parallel. Just at a very brunt level, it's notable that there are a number of parallels in the concepts that are coming through, particularly on this that's overarched in the certification - the concept of transparency, the concept of fostering innovation, but also a practicality, secure contacts note these themes, but are pervasive and will be pervasive through our discussion, particularly the concept of modularity in terms of supporting practicality or things that I know we've had discussions about in the process.

Let me open for any comments/questions that any members of the committee would like to address. Wes?

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

John, I have a couple of questions to address. And, some of these you may just choose to regard as a comment instead of answering. I'm having a difficulty understanding how the certification process achieves objective evaluation of general criteria. I know that the processes that I've seen for functional certification is that, "Well, let's do a script." The script is not specific as to the user interface or the technology that it's on, but you put in certain data and you see certain data back.

By the time you get that to the point where three doctors can agree on the script, it's pretty specific. So as I understand the direction for certification on functional conformance, let's be general; I haven't heard the objective, but I'm willing to assume that that's part of the requirement. I just am questioning how to achieve those two things at the same time.

**John Glaser, Partners HealthCare System, VP & CIO**

Well, I think it's a fair question, Wes, and be very mindful with the usual caveat that people like me ... conversations like this; this is workgroup recommendations, which have to be factored into the rule-writing process. So, I can't talk about how the federal government will do it in the rule-writing process, but I can sort of reflect conversations that occurred within the policy committee and the workgroup that went on.

If you say, listen, I want to raise them to higher levels and to be less granular, to allow innovation and to be less prescriptive for a whole bunch of good reasons—

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

I think we all understand the virtues of being general. It's—

**John Glaser, Partners HealthCare System, VP & CIO**

Yes, it creates other issues, which is how do I get a test script for something that's now more general which is a good test of that objectivity. I think the workgroup did not tackle that. I think there was awareness of solving one and perhaps creating other issues that need to be addressed.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Okay. Correspondingly, the goal of certification of components, particularly for the examples that you called out, are clearly necessary, but I am concerned that we don't portray to the physician community in particular a degree of trust in certification that we can deliver. What I mean is I would like to have a car that has the power of a Ferrari, steers like a bicycle, has the brakes of a Volvo. I'm sure that I can find a bicycle with a certified steering system and the Ferrari engine can be certified to be meaningful and so forth.

But, I get no assurance that when I put those together, I get a meaningful use out of that construct. And so, I'm worried. A knowledgeable physician, a knowledgeable hospital would understand that I'm taking on the responsibility for putting this together and achieving meaningful use. The fact that these components are certified helps me decide which components to use. But we can't, I think— I haven't heard us set the goal that says if you buy a set of certified components, you will achieve meaningful use by virtue of the individual components having been certified, and I'm worried about that.

**John Glaser, Partners HealthCare System, VP & CIO**

I would agree.... It's a fair concern, which was touched upon, and made the workgroup aware of. There was not a certain answer to that that they came up with.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

And I note with favor that it appears that the timetable you have set, or that the policy committee has set out calls for about two years from closing the definition of meaningful use criteria to their being enforced. And I think that's clearly a minimum necessary in terms of the ability of industry to respond, whether that industry is software vendors or it's do-it-yourself organizations. I'm concerned that it's not enough time around achieving interoperability -- that the ability to roll out a new standard nationwide takes more than two years. I comment that to a certain extent the HIEs that have been successful now are those that provide that adaptation between what's going on locally and one another or against standards. In fact, I could envision the time when that wasn't necessary because everybody really did the standards, but I think by that time, we'll have brought out enough new criteria on the standards that it really won't be true. So to a certain extent HIEs are the permanent interim solution for rolling out standards, and I think we should not lose track of that. I think we should certify products as meeting standards. But we shouldn't limit our definition of meaningful use to always using those standards. If you're using software that can meet the standards and some of the times you're using the standards and sometimes you're not, that ought to be enough.

**John Glaser, Partners HealthCare System, VP & CIO**

Yes, Wes, a couple of things. One is the timing of the meaningful use guide surfaced, I think we need to take a harder look at to make sure that there is enough lead time. And I think that would be the same in any of the conversations we have here – is do we allow enough time to give the industry, the vendors to respond, and technology to respond, and frankly, the adopting organizations to absorb them in a thoughtful but methodical way. The other, I think what we'll all have to collectively learn as we move along this path here is what is reasonable to expect. And realizing that can be variable by region because of exchange capabilities, etc. And I think that will probably largely be reflected in the meaningful use measures as to what degree you set a target at X versus Y, etc. Obviously this is a very new phenomenon. It's an extraordinary change that is ... we'll get better at that over time as we make best judgments at this point, but we'll get better in time of knowing how to calibrate a degree of meaningful use to the degree that that becomes an important consideration because the, while the provider might be willing, the surrounding infrastructure isn't quite there. And so we'll have to ensure we don't inadvertently

penalize people because of that. So I think that's going to be an ongoing conversation here, but also in the meaningful use workgroup about the right way to set that or recommend to CMS and the federal government write large the measures and the approach to assessing.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Thanks, I have one last comment, but I appreciate your tolerance. I have been quite, I felt that the material that Farzad brought forth about his experience getting lab results into New York City was very instructive about the other issues, the non-standards issues that are required. I see that when you talk to both the labs and Farzad and the vendor there, they all have a side of their story which has to be considered. There is a requirement to pay vendors for lab to deliver results to each physician's EMR. That creates an economic constraint on when the lab can afford to do that there is an ability of the labs just to say no, we won't do it. We're not obligated. As we look at the incentive money and the penalties later as a stick as well as a carrot, we have to be mindful that we don't necessarily have a carrot and stick over all of the players that we're counting on for meaningful use. And to a certain extent I think CMS could strengthen our stick by saying to other parties that they pay that aren't EHR vendors that they still require the use and that would be very helpful.

**John Glaser, Partners HealthCare System, VP & CIO**

I agree, Wes. ... we're exploring a bunch of different options, realizing that the high-tech is directed to the provider, but there are others who for the provider to do all the stuff we want them to do, need to be playing the game too and to see what other levers we have to address that. So I think there is a recognition that we've got to do bilateral and multiple cases, efforts in order to make this as straightforward as an efficient and as quick of a set of achievements as we'd like it to be. Do you have a question?

**Christopher Chute, Mayo Clinic, VC Data Gov. & Health IT Standards**

Yes, thank you. John, like others I think we're all deeply impressed by the carefulness and thoughtfulness that has gone into these proposals and recommendations. I remain unclear as we've discussed previously, about this boundary between certification and meaningful use. I understand particularly in some of the revised concepts that you brought forward how, when let's say metaphorically software or hardware shows up on the shipping dock, it would have some mechanism to assert or assure that it is certified. But I still see a boundary between what has become certified and what is designated as meaningfully used. I'm manifestly unclear as to how the recommendations would unfold to close that gap in a specific installation.

**John Glaser, Partners HealthCare System, VP & CIO**

Well, Chris, let's see if we can reflect a workgroup thinking. The certification intent is to the purchasing provider and say this software is capable, it's got the feature and function that make it capable of exchanging or documenting allergies, etc. So it's capable. There may be other capabilities you're interested in that go beyond meaningful use and there may be other services that provide that, but this is capable. And you say alright I bought it, it's down on the shipping dock, I know that it is capable. I have to do lots of other things if I'm going to qualify for meaningful use. I have workflow changes to make, I have training to occur, I have a bunch of stuff. I might have conversations with some of the other local providers, about how do I exchange and what the mechanisms are.

So there's a phenomenal amount of significant implementation work that has got to occur before capable turns into the actions on the part of the physicians and other care providers that lead to meaningful use. And that is in some ways no different than with the phenomenon we face today when one of your provider organizations purchases a system and has certain overall goals in mind, is the fact that they bought it let's say from Cerner and David McCauley. They still have a lot of work to do to turn it into their patient safety goals, etc. So there's clearly work that has to be done and the part of the overall ONC strategy is to make sure through the extension centers that those who don't have an internal staff to turn to – don't have a John Glaser IS Group, etc. have access to the resources necessary to take capable and put it into the reality called exchange and the reality called reporting of quality and documented care, etc. So we will have to do that and I think in particular in the federal strategy there is an awareness that the

organizations that need it the most are the smaller physician practice, the critical access hospital and not because they don't have the talent necessarily on board, can't afford the talent and in some cases might be in areas where you just can't find the talent. But also that's where the bulk of the care occurs.

And so that is who – so anyway, if there was a capability assertion that it's capable and we have to be careful here in that a certification as described by the workgroup doesn't mean that it's the most usable thing you ever did. It's capable of writing a prescription, but it might be one of the most bizarre approaches you've ever seen. It's not an assessment per se as usability. I think that will have to come through advisory services and other things and be able to take some look at to what degree you can really be more quantitative pass-fail on usability. So anyway a long way of saying it is, there's a certification to determine capability and then a fair amount of obviously implementation work on an ongoing basis to achieve meaningful use.

#### **Christopher Chute, Mayo Clinic, VC Data Gov. & Health IT Standards**

Yes, we're painfully aware of the implementation. I guess my question was unclear. I meant how can we understand the determination that a specific, say Mayo Clinic installing the Cerner system in Jacksonville, Florida, has met the meaningful use after going through all the implementation and work that you've characterized?

#### **John Glaser, Partners HealthCare System, VP & CIO**

Well, we will see there were some recommendations out of the meaningful use workgroup and some of their recommendations, and this is a sort of in the discussions with Karen and the colleagues at CMS about how do you determine realizing that the in 2011 and maybe a good chunk of attestation that I am, I attest that I am engaged in meaningful use per the definition. I know that CMS might audit that attestation, so I want to make sure that I don't engage in fraudulent activity. Clearly what we will be doing or the meaningful use workgroup will be doing in the years ahead is moving into a much more of an electronic such as the product reports. For example, the percent of prescriptions written and so that becomes an easier thing to warrant and to inspect. And similarly, as we evolve over time and the quality measures become directly submissible to the federal government and they now ... So anyway there is an evolution of approaches to asserting and verifying that you are a meaningful use and that is an active discussion within the federal government – how best to do that and the workgroup has some thoughts along the way.

#### **Christopher Chute, Mayo Clinic, VC Data Gov. & Health IT Standards**

And just briefly with my own experience, say in pay performance contracts, sometimes, for example Blue Cross of Massachusetts says demonstrate your software can do medication reconciliation. So that's straightforward, it's a certification criteria. And other times they say we won't pay you unless 90% of your encounters include medication reconciliation actually being done. Well, alas, it's challenging at the moment to do that automatically so what we do is unannounced random audits, where we review was the medication changed or a new medication prescribed and did that get reflected in the medication reconciliation. And then we attest based on random audits, we were at 93.4% at the moment. That's messy, but that's worked for us.

#### **Jonathan Perlin, Hospital Corporation of America, CMO & President**

Other comments? Terrific, John, thank you very much. Many thanks to all the work represented behind that presentation. The point again of the technology is of course improving health care and it's fitting that we start with a clinical quality workgroup progress report. I want to thank all the members of the committee not only for all the work that occurred in each of the sessions, but all of the work that occurred between and to everyone, many in this room, who provided input to the deliberations, this workgroup as well as others. So let me introduce Floyd Eisenberg and Janet Corrigan for the report of the progress of the clinical quality workgroup. I think Chris Chute's question really is a good segue because there are many of those issues that come forward. I appreciate the great clarity that surrounds a number of the metrics in terms of standards, but there are some areas where further work needs to be established or where the representation of completion of the metric itself is not immediately derivative of the use of the

performance of the action that completes that metric. So I'll turn to Janet and Floyd and thank you very much.

**Janet Corrigan, National Quality Forum, President & CEO**

Thank you, John. Yes, I'd like to also thank all the members of the clinical quality workgroup who've had numerous conference calls this week trying to kind of pull this together. And I also want to acknowledge Floyd's contributions in particular. I think it was John Walker who said at the outset that in many ways the success of our work here has had a lot to do with leveraging the work of other groups, and his role with HITEP and also with HITSP has been critical to kind of be the glue between numerous interrelated efforts that we needed to build on in a very substantial way.

There are three handouts that we're going to reference during this session. First, you should have the slides that I'll be going through, the PowerPoint slides. Second, though you have a grid, which is entitled, "Quality and Operations Workgroup Selected Measures." And then you have a second grid which is entitled, "Joint Working Groups Meaningful Use Measure Grid, Data Elements Mapped to HITEP Data Types." It's important to recognize here that you'll see that we've been working very, very closely with Jamie's workgroup, the clinical operations workgroup and ... Jamie and John's workgroup in coordinating our work and you'll find that throughout this presentation.

The clinical quality workgroup, the process that we have gone through was first to identify appropriate standardized performance measures that correspond to the HIT policy committee's 2011 measures. Second, to review those performance measures and develop guidance for measure retooling, because once again we have standardized performance measures, but they were not developed for use with electronic health records or PHRs or other HIT technology. And then third, to identify the underlying data types and elements that must be captured in EHRs and PHRs to produce the performance measures, that's the connection to the HITEP work to a great extent, and then to hand off that to the clinical operations group. And I think probably hand off is not the right term, we've kind of hand our hands tightly clasped throughout this process. So it very much has been a joint effort.

Where we're at at this point is that we essentially have a recommended set of 30 performance measures from the policy committee. We now have identified NQF-endorsed performance measures, 23 of those – 18 of them can be retooled to be produced automatically from EHRs or PHRs, 5 will require attestation in the foreseeable future. Now this doesn't address the privacy and security measures that Dixie's workgroup has been working on and she'll be speaking to it a little bit later in the day. There are seven measures that were on the original policy committee's grid for which we do not have standardized performance measures at this time. They're things like the public health surveillance data, the percent of patients with access to educational resources. So there's basically a little more than a handful here that we do not have a viable method of addressing right now. And I'm going to provide you with a little bit of an overview of some of the key issues that relate in particular to measure retooling or to phasing measures in over the next two or three years and then Floyd's going to provide you with more detailed information on the actual measure set, the data types, the data elements that correspond to them.

Our workgroup thinks it's important to consider sort of staging measures that can reflect the evolving HIT capacity. And I provided a few examples here. We have body mass index, which was one of the ones that the policy committee asked that we identify measures for. We think it would be reasonable in 2011 to have a measure that's essentially looking for whether there was documentation of BMI, but then by 2013 to up the ante a bit and be looking for the capability to actually have the BMI percentile plus demonstrating that you gave counseling if it was appropriate for that particular patient, so that would be a more complicated measure phasing in over 2011 – 2013.

With asthma medications you see a similar process in 2011. We will be looking for appropriate meds for asthma, but in 2013 the measure would become more complex and actually be looking for whether the appropriate meds were provided by stage of asthma.

On readmissions, the third example here, in 2011 we'd recommended looking for the capability to calculate readmissions to one's own facility, but by 2013 being able to calculate readmissions to more

than one facility, a small group of facilities. But by 2015 looking for that capability of calculating readmissions to any hospital or facility within the community.

There are two particular aspects that are important for calculating many of the performance measures. One of them has to do with the ability to capture diagnoses or problems listed on a problem list, and the other has to do with how we record exclusions that are often a part of the denominator of a performance measure. So we focused a good deal of attention on these two areas. When it comes to the diagnoses and the problem list, it's really the recommendation of the working group that we rely on the National Library of Medicine's SNOMED CT core subset for problem lists. And we recognize that there's going to need to be ongoing development and maintenance of the SNOMED CT. So we hope that there will be efforts underway very soon if not already to take a close look at whether or not we have the full set of problems listed there. We think it's fine for 2011, but we'll certainly need to do some checking. And then to have a mechanism in place to make sure that it evolves over time as we get more and more performance measures that really may require a more refined and extensive list of potential problems.

As we look to retooling these measures for the next few years, we think it would be wise to have alternative versions of measures and to provide the option to providers to use either version. For 2011 we would recommend that these measures be developed that use both ICD-9 and then a second version of the measure that uses SNOMED CT. Recognizing that most providers will probably not be at a point of SNOMED by 2011 and that many will be at the ICD-9, but for those that are, have more advanced capabilities and can move straight to the SNOMED CT, we wouldn't want to have to ask them to go back and use the ICD-9 one and then go back to SNOMED CT at a later date. So having two versions would probably make sense. In 2013 you see what's recommended there is that one version of measures for ICD-10, another one for SNOMED CT. But then by 2015, we would really expect that everybody would be on board with SNOMED at that point. It's also recognized that many providers will probably have internal codes that they're using and they would want to map, hopefully with expertise in SNOMED CT, map their internal codes over to SNOMED. And it's also recommended that the EHR certification criteria for 2011 require that a problem list be available within that software.

So we also provided some guidance for retooling measures that has to do with exclusions, and here once again a phased in approach. In 2011 the assumption is that exclusions would need to be by attestation and there is now a CPT2 code that indicates the provider can indicate whether there was a medical reason, a personal reason or a system reason for excluding a particular patient from the denominator. That would probably be the approach for 2011. But then in 2013 all exclusions hopefully would come from the EHR elements.

We also think it's important in the measure retooling process as these measures or new e-specifications as we say are developed we would want to encourage the measure stewards to focus on exclusions that are related to contraindications and to eliminate what is sometimes called decimal dust in the measure world, where there really is a very, very long list of exclusions to try to capture every single patient that there may not have been appropriate in that measure. We don't need quite that level of precision. And also it's important to point out that the thresholds for obtaining and ascertaining meaningful use will influence our decisions about the need for various types of exclusions, however those thresholds are set. So the sooner that we know where the thresholds are going to be set, I think it will help both in terms of measure retooling as well as other decisions for 2011-2013.

Another area that's going to be particularly challenging that our workgroup wanted to point to as important is that we really, as we move forward, want to have patient-centered measures. In the performance measurement world, measures have developed from the ground up sort of organically as we say, and they're oftentimes specific to particular sites, or particular patient populations, whether it's hospitals, nursing homes, it's home health, whether they have specific measures for children versus adults. Sometimes it's appropriate to have differences across measures, but in a lot of cases this really isn't necessary and it just adds to the noise of the system. It's not meaningful and it's harder for providers to act on it and it's harder for consumers and others to interpret the information when it is eventually publicly reported.

So another important thing here is to take advantage of the opportunity to harmonize measures and also to encourage harmonization measures, data types, data elements across all settings and to harmonize the denominators whenever possible of these measures for different age groups as well. And you'll see in the grid that's been provided to you that sometimes there are two performance measures or even three in some cases that apply to the policy committee's measure concept. Obesity is a good example where you have a specific measure for children, one for adults. We think in the measure retooling process, it should be possible to harmonize those measures and get to a fewer number.

I also want to take just a minute to also point out that we've been very much aware, John Derr is a member of our working group in this area, and we have been very much aware that the long-term care is not the specific focus of our work for 2011 at this point. But the long-term care community with John's leadership and guidance has been organizing itself to make sure that it can track with us and do as much as possible in terms of applying the measures that are eventually selected to the long-term care area. So I'd like to take just a minute, John wanted to make a couple of comments and he has been working to go through the measure grid and identify the ones that are appropriate for long-term care facilities as well.

**John Derr, Golden Living LLC, Chief Technology Strategic Officer**

Yes, thank you, Janet and thanks also to Floyd and the rest of the members of the committee. I represent what we call long-term and post-acute care services, which is home care, skilled nursing facilities, long-term hospitals, inpatient hospice and the other things where people really go from a hospital and the doctor's office into post-acute care. And as you know, we're not part of meaningful use, but we're, as Janet said, we're taking all the quality measures and working alongside that because we have the minimum data set and also the OASIS on home care, which is the outcome and assessment information set. So we do a number of these things electronically already. And in fact, we took the matrix and went through it and we, being members of the different long-term, post-acute associations, and found that there's about 13 of them which we can do with some retooling as Floyd always says. The MDS-3, which comes out next year and OASIS-C which comes out next year will be able to do some of those. So I just wanted to assure everybody that the providers and the vendors, even though we don't get incentives and we're not members of meaningful use, that we're working right along to be able to hear everything this committee's doing and also the Office of the National Coordinator so we can be ready whenever we are made part of the meaningful use.

**Janet Corrigan, National Quality Forum, President & CEO**

Thank you, John. Yes, we think that is critical because the measures really need to be patient-centered. Pain management is pain management, whether you're in the hospital or in the community or in a nursing home or you're getting home health and to the extent that we can use comparable measures, there'll be much more meaningful information down the road.

The last thing I wanted to point to before I hand this over to Floyd is that one of the key areas where we really do see a gap in measures and standards has to do with patient engagement. And our committee strongly encourages that work begin now to start to develop the measures of patient engagement and the standards so that we can be ready for 2013. We'll need measures of whether patients understand their treatment options. And we also need to do quite a bit of work on comfort care measures and methods of capturing in a standardized way, do not resuscitate, do not intubate orders. Right now we don't have a lot in that particular area.

The last point I'll make is that one of the things that we came to realize in our working group is that there's a lot of moving parts here. There's the measure stewards who develop the measures, there's NQF who does endorsement of those measures, there's the work of HITEP that continually builds the data types and data elements, standardized lists. There's all the hand-offs that had to do with the standards for the EHR and PHR world. And we think that moving forward, 2011 obviously everybody's going to run as fast as they can and nobody's going to have as much time as the really feel they need and wish they had to be able to get ready for those requirements. But if we begin now and lay out a very explicit timetable, it would be extremely helpful for 2013 and 2015. And I know efforts are already heading in that direction. And our sense is that it's going to be important to have some careful messaging around this so that everybody who is involved in this extensive enterprise understands that it's going to be rough riding for

2013. It's not going to be 100 – it's going to be rough riding for 2011, it's not going to be 100 percent smooth for 2013, but by 2015 we can probably have all of our ducks in line and really have a process that is very, very well laid out moving forward and that will be just an important thing to let everybody know. So now let me turn this to Floyd, who's going to talk a bit about the grid and more details of the data types.

**Floyd Eisenberg, Siemens Medical Solutions, Physician Consultant**

Great. Thank you, Janet and thank you to the committee. There are no specific slides, but you have two grids. One is rather large and the reason for that was there was a request for specific information on each of the measures that we were referring to. There's really not time to go through each of those measures in the full committee, although the workgroup did. And what I wanted to highlight was really the four-page spread. One thing I will comment, the committee's working on certification. Please do not certify the kind of font that I chose to make this a four-page. It is small, I apologize. But just to give you an overview of what this represents, is the HITEP, health IT expert panel, which has completed its reports July 31. The editing for formatting will be finished very shortly and be fully published on our site. Data identified for measurement data are represented in standard categories. And in your grid, you'll see that in the left-hand column so communication, a condition, diagnosis or problem, a device, a diagnostic study, a medication; then there are data types related to those. So what you will see on this grid is only those data types that are present in the measures that were reviewed for the meaningful use.

There are some data types that if you have the Excel spreadsheet, you'll see some rows are hidden. That's because those data types weren't used in these measures. They exist in the information model, but you won't get them on the printout. So communication to patient, an example is there's communication to provider and between providers, patient to provider, provider to patient and provider to provider. In this case we only had communication provider to patient, so that's all you'll see on this grid. So what that did is explained the data types and for those who are into terminology, what that means is we pre-coordinated our statement to say in the case of medication, medication administered, medication ordered, medication prescribed, are separate data types so that it makes it clear exactly what we are looking for.

The HITEP definition is listed in the third column, so the object of this is to explain what you're looking at when you see data types, when you see the definitions. Much of the definition came from the HL-7 EHR functional model. It was not newly derived by the HITEP. In some cases things were not in the functional model, and it was derived based on measures through the HITEP. You then will see a column that lists the data elements. Each of those elements is present in at least one of the measures that was selected. If you look at the larger grid for each measure, the elements required are listed there. Many are duplicate, so an active diagnosis might be present in more than one measure. To simplify, we put the active diagnoses all together into this one grid. And having done that, we then worked with the operations workgroup to look at what standards are there to represent these elements so that they could be used to transmit the information in a report on quality.

So for what you will find and I should highlight, is there are actually six areas where there was no recommendation. But only six out of the total, which actually is pretty good. And that is communication to the patient for smoking advice or counseling and that may still require attestation, somebody has to indicate that in the record in some way. But there was no specific standard found for that. Three others relate to one measure, and they were antithrombotic device related. One the device is applied, two the there's an intolerance to the device, three that it was declined or refused and the others also related to the same measure that the patients on a clinical trial, not just any trial, but specific to the thrombotic embolism. So four of these where there were not standards apply to only one measure. The sixth one was related to provider preference, medical reason for not doing something. And again, it's something that likely requires attestation, as you saw in the slides from Janet. But basically if we would eliminate the one measure, there really are only two area that had no standards.

So what you'll see as you go through this is, and I can take you through some of them, I don't know if you want to go through the entire grid, but if we take condition, diagnosis or problem, there are a number of diagnoses. The standard selected was ICD-9 or SNOMED CT for 2011, ICD-10 or SNOMED CT for 2013 and then SNOMED for 2015, although I don't have that on the grid. Past history diagnosis is still the

same diagnosis, we expect the measure stewards during the retooling to indicate where within the record it's found and how that's to be represented. So that's dependent on the measure steward retooling process. So we're giving you the terminology and the location as we can here. Again, the intolerance to device, there was no specific recommendation. Diagnostic study, again, that the study was performed with the SNOMED in the near term CPT-4 and ICD-9, ICD-10 in 2013 and then SNOMED for 2015.

You'll see a little further down encounter, which is now page 2, there were some HL-7 message-based ways of identifying the encounter. And encounters are an outpatient encounter, we have hospital admission or discharge. The measures require the time of each in order to calculate. Admission to long-term care -- some of these, discharge from long-term care or admission to were actually exclusions when I look at these measures specifically because specific discharges excluded the patient from an advice to be given at discharge. So as you look at these, you might ask where do these come from? When you look at the individual measure, it becomes a little bit clearer that these are related to inclusion or exclusion. So I can go further through this, but I think it's rather detailed and it's easier to ask for questions and discuss.

### **John Halamka, Harvard Medical School, Chief Information Officer**

Just to highlight a couple aspects of this presentation. So first the leadership that NQF and HITEP has shown in retooling the measures is remarkable. And it's taking measures that were developed by best evidence but not with an EHR in mind and now making them EHR-centric. And so that is truly a critical piece of work and they still have, of course, work to do with all of these quality metrics offering organizations but they have great momentum to do so. The convergence that has happened between this group and Jamie's group closing the gaps has been an amazing body of work over the last 30 days. Remember the last presentation that we had we said here's 24 pages of all the detailed measures. We now have a four-page grid with six lines that are blank, three of which are on one measure. I mean this is amazing. And so this is actually doable. I mean this is not, as you had said, giving our organization 24 pages of well, these standards haven't yet matured, good luck. It's here's a very clear grid of diagnosis and medication nouns and verbs and some very specific standards. Now I know one area of controversy may be SNOMED, ICD-9 and 10. Just some comments there from my own observations.

In our organization, we have a proprietary problem with some vocabulary called BI98. It was invented in 1998 and Beth Israel Deaconess used its 15,000 common free text problems to create an invented vocabulary. We know this is of course not sustainable and there's no way Floyd and Janet are going to map to BI98 and give us a set of measures specific to one institution. So we worked with the NLM over the last couple of months. It took us literally weeks of simply mapping our 15,000 legacy proprietary codes to the NLM core data set. We got 85 percent of all of our proprietary codes mapped so now its consistent with ALM core vocabulary. It wasn't a big deal, and so that's doable. We all know that ICD-9 was invented for billing, it was not invented for clinical observations. And I've probably mentioned to the committee before, there's an interesting series in the Boston Globe where I was called onto the carpet by patients for using ICD-9 to describe their problems when in fact ICD-9 was often a rule-out, not an observation. Or ICD-9 was not granular enough.

So I think the lesson that we learned and believe me, whole series of *Globe* articles, *Washington Post* articles, there's a lot on my blog about it. You can't ultimately use ICD-9 as a mechanism of symptoms and condition reporting. You need to move to SNOMED and we need to do it in a thoughtful way. It will take years. It won't be easy, but it's doable. And so this notion that they have provided measures that are sensitive to the ICD-9/10 transition but ultimately in 2015 requires SNOMED CT for accurate clinical symptoms and conditions is a very reasonable course of action, at least from one provider's viewpoint. I also recognize that there is a need and workflow to go from a clinical observation made in SNOMED to a bill. And today when you download that vocabulary from the National Library of Medicine, it includes the mapping from SNOMED to ICD-10. And so we definitely will have the glide path to get us to translation of doctor's observations to a coder's recording of a rational billing diagnosis. So I certainly applaud the work that has been done. I think the four-page grid is really a work of art and those steps that we have remaining are very minor.

### **Janet Corrigan, National Quality Forum, President & CEO**

Thank you. I just wanted to reiterate one point that John made well is that I must say I became convinced as we moved through the process that a good deal of this is doable for 2011 as well. I mean it really is nice to see as it took shape because not only were we able to work our way through to the data elements and eventually the standards, but the performance measures that have been selected here are also ones that are mature and have been in the field in use -- nearly all of them for some time. So these are areas of performance that are currently being measured by many providers and they address critical aspects of performance that have been well tested. What we had to do is retool them for the EHR, but at least we're starting with measures of performance that are mature and in use quite extensively out in the field.

**John Halamka, Harvard Medical School, Chief Information Officer**

On that point, is there a way of knowing formally or informally by survey kind of what is the market penetration of being able to produce some of these? Given your comment you just made, many do internally and so forth. Do we have a straw man or is 10 percent, 20 percent, 50 percent? How would we go about thinking about what the current market penetration rate is for the ability on some of these?

**Janet Corrigan, National Quality Forum, President & CEO**

Right now, there's a handful of these that are measures that are voluntarily reported to CMS. For those we have some information to gauge adoption of the measures. Beyond that we don't have a systematic way of knowing the extent to which measures have been used. One way that we can address many of these, though, are measures that have been developed by the PCPI of the AMA and by NCQA. And both of those measure stewards and they're the ones who have to do the lion's share of the retooling work as well. As measure stewards, they have some information, I wouldn't say it's as solid as a survey, but a good deal of anecdotal information and other information that might be able to allow us to glean how widespread the use is. The measures have been out there and tested in enough, most of them have been tested in enough environments that they're no longer measures that we view as still being in the early piloting phase. But the extent of adoption we don't have good information on.

**John Halamka, Harvard Medical School, Chief Information Officer**

Thank you.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Let me turn it back ... for comment.

**M**

I have just two comments. Fairly detailed, but it's about the 24-pager that we haven't really reviewed. The first is there's a number of measures in which it says no current measures and sort of not applicable with regard to the data types. I guess a question I have for those is that there's nothing in the recommendations column and I think that one of the things that we had talked about was when those things occur that perhaps attestation or some other mechanism of sort of addressing those meaningful use criteria would be included. And I know that things like percentage of patients with access to personal health information electronically may be something for which no standards exist, but a recommendation should be able to come from this committee in terms of how we expect in 2011 to take a look at that particular meaningful use. So I would just sort of encourage to complete that out so that we have recommendations for all of them. And if it is an attestation or if it is to develop a standard or the like, we need to start planning ahead for 2013 and 2015 if that's the case.

The other comment is again fairly detailed. It's on item 23 where it talks about all cause readmission index. One of the recommendations there in all bold is considered deletion. And one of the things that I think is important is that that particular report of a 30-day readmission rate is a really important quality indicator that I think we need to think very seriously about how we might push from 2011 towards 2013 and 2015. We've had discussions about whether 2011 should be our own facility, 2013 might be sort of local exchange and 2015 might be everyone. So I would just ask that we either, because I know that we're going to at the end of this try to approve some of these things, that we don't consider that one for deletion but actually spend some time to think about how we might get people to the meaningful exchange of information around readmission rates.

**John Halamka, Harvard Medical School, Chief Information Officer**

Okay. Can I respond to both comments. The first is that, I'll respond to the second one first. That was an inadvertent, I should have deleted "considered deletion" because in our discussion and based on Janet's slides, the intent was 2011 your own facility and to include that comment into that cell. That was an oversight. As far as the other, we did talk about adding into the recommendation and should have added attestation for 2011. It could certainly work and our intent was to look at utilization measures. So report out from the EHR that this has happened. How many times, say admit reconciliation occurred. How many times . . .

**Janet Corrigan, National Quality Forum, President & CEO**

... patients with access to patient-specific educational ....

**M**

. . . attestations have actually accessed it. So that kind – thank you – that kind of information can be a utilization measure and we look forward to creating those measures out of the system for the future. So if we can amend it to indicate that in the recommendation column.

**Janet Corrigan, National Quality Forum, President & CEO**

But there is some work to be done in trying to figure out how to specify those as measures and so I think that is a decision for the group indeed would have to require some effort to think how best to do that.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

When I see on the four-pager that they have a choice of reporting these measures using SNOMED CT, ICD-9 or ICD-10, that implies to me that they can use any of those vocabularies for reporting those measures to CMS, is that right? And if so, can CMS receive SNOMED CT and do anything with it?

**Janet Corrigan, National Quality Forum, President & CEO**

Well, yes, they would be able to report, but we can't speak to CMS capability. I'm afraid we can't speak to the CMS capability.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

I'm sorry, I didn't hear you.

**Janet Corrigan, National Quality Forum, President & CEO**

The question was whether or not we are recommending that providers be given the option of reporting many of these measures either with ICD-9 or with SNOMED and the question that Dixie posed was does CMS have the capability of receiving that information especially in the case of measures through . . .

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

And SNOMED in particular.

**Janet Corrigan, National Quality Forum, President & CEO**

Yes.

**John Halamka, Harvard Medical School, Chief Information Officer**

And if anybody would like to comment on that. And Karen Trudel, thank you for volunteering.

**Karen Trudel, CMS**

I seem the logical choice. No, we can't accept SNOMED today, but we recognize that in addition to providers and products having to change over time and evolve in terms of what will be done in terms of meaningful use, how it will be reported, we expect that we are going to have to evolve over time, too. So I think it's a partnering process that tends to move down the road.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

This is 2011 and I know CMS is pretty much overwhelmed right now with ICD-10 conversion. It seems to me for 2011, sending SNOMED CT there is going to bounce back, probably.

**Karen Trudel, CMS**

Well, okay, first of all the ICD-10 I think is on your list for 2013 because it won't be implemented until 2013. So I think what we're going to have to do is to decide the measure may provide some ability to do one or the other, but we will have to figure out how we're going to catch the ball. And if we can't actually accept measures in a certain way, we may have to look at intermediaries, we may have to look at doing attestation for a period of time. And I think some of that is still under discussion.

**John Halamka, Harvard Medical School, Chief Information Officer**

This is one of the things the committee has discussed, called the ecosystem problem, which is you have to look at both the sender and receiver and their capabilities. And I think our issue here is for example, you wish to report file surveillance, immunization and public health data. However, as a meaningful use criteria, only if there is something to receive it. And so I think your comments are quite right about intermediaries, attestation and an evolutionary path, but it would seem at least from my provider perspective reasonable to begin collecting the data in codified format as soon as you can.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Marc Overhage. I'm sorry, Aneesh, why don't you go ahead.

**Aneesh Chopra, White House, CTO**

I just wanted to sort of make it clear. This is a key reason why I stand on this committee because we have to be prepared for the recommendations that come forward. As we make deliberations internally regulatory processes understanding how our response will align is important. So this is one of my "keep me up at night" issues and I'm well aware of the issue.

**John Halamka, Harvard Medical School, Chief Information Officer**

... just have to be very sensitive to the issues of implementation and adoption. And so I know Jamie in some e-mails has discussed this whole issue as we think through now going from standards to their actual transmission, how do we get testimony, how do we hear from government and private folks. What are the barriers to doing this and how do we adjust for them I think is an important issue over our next year of work.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thanks, Marc Overhage, then Wes.

**Marc Overhage, Regenstrief, Director**

Without speculating on what CMS might choose to do or not do, one of the things just as an example they've been very flexible and innovative in the PQRI registry reporting process separate from the billing and claims submission process where I would guess there might be much more flexibility to implement and adopt new terminologies. I wouldn't be surprised if they were able to accommodate SNOMED even in that time frame.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think that's an important point. I would just dovetail on John Halamka's point about the ecosystem. I would be remiss if I didn't commend John Derr's leadership in terms of really ... of long-term care environments toward using OASIS-C and MDS-3 to really emulate some of this and we're forgetting that in addition to CMS I fully imagine that the interchange with commercial payers in a broader environment that is increasingly ready or adapting as Mark Overhage identified ways in which there are surrogates but with an intention and directionality. I think Jamie wants to jump in, Wes, if that's okay on this point before we go to the text.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

I just want to agree with Mark and as a preview of coming attractions, when I do give our workgroup report, you'll see that we are in fact recommending that the CMS PQRI registry XML specifications should be used for this measure reporting for 2011.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

... on this point or ... Okay, then we'll go to Wes and then to Steve Findlay.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Well, first off I want to say that this is the illustration of the point that Jonathan and John made at the start of the meeting about the progressive refinement and the clarification that has gone on. It's just an amazing collaboration. So anything I say that sounds the slightest bit critical is down, is decimal dust to a certain extent. Part of the trouble I had in grasping . . .

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

People are having trouble, if you could just move a little closer to the mic.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Sure. Part of the trouble now having given the compliment off mic, now I'll give the . .

**M**

Move back away.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

The thing that I had difficulty grasping as a participant on the operations side was what we have accomplished and what we have yet to accomplish. I think what we have accomplished is demonstrating that it's possible to compute these things. We have a vocabulary for expressing them, therefore we can count them. What we have yet to take off, and therefore there's no harm in not having done it, is this method of how will we transmit it, how will it be used. And if I could add, if there's any way through the bully pulpit of the federal government or HHS that we can push for not only the measures but the mechanism of submission. It is beyond CMS where it's required for meaningful use, but to be used for submission to other payers. I think we can achieve a tremendous – I think there already is a recognition by the payers that they need to use the same measures. They need also to use the same means of transmission.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Comments, Janet or Floyd?

**Floyd Eisenberg, Siemens Medical Solutions, Physician Consultant**

Well I can't comment, and this is work that has been going on in HITSP and not specific to this committee directly, but in the quality use case resolution that HITSP has been working on, we've recognized there are two missing pieces. One is the measure itself and a standard for the measure. There's actually work going on as far as making that a standard and it's invalid in HL-7 right now. The other was the export and sending the results out. And there actually is a draft standard that has been validated and approved that's going through HITSP now that drafts the quality reporting document architecture, which does still need some testing and in use but it has been used in a number of places, including the New York Public Health Department. So that is there, but we're also looking that there needs to be a message-based way to send this out, not just a document-based way. And that's going on at HITSP, but I think that's still work in progress. And to that point, as you'll hear in Jamie's presentation that he's got a very realistic view of this. The QRDA is a standard that is nascent. It's implemented in New York Public Health, but it's extraordinarily early to require it. So he said HL-7 2.31 if it's immunizations, HL-7 2.51 for some of these other measures. All very doable, very well-understood standards, but we have our eye to getting to some of these other more summary or document formats.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think there's a resonance around the point, though, that there are two challenges. One is the .... We use ..., which sometimes feels like a term of where we're really talking about a .... We have the opportunity to move patient care and we have the ... of the measures and if there's consistency and mechanisms of messaging and transmission, then it makes it that much easier across environments and accelerates the adoption. So I think that's an important point to acknowledge. Steve Findlay and then Mark, were you going to jump in, Steve?

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

Yes. John and Floyd, the seven measures that you identified where there isn't an NQF or the separate conditions or illnesses or whatever that you identified that are not – for which there are not NQF-endorsed measures. For those seven, does anyone else have endorsed measures for those? For example, PQI or any insurers or any physician groups or anybody in the system have measures for those seven. And then the question is what are you proposing actually for those seven, that they just simply be dropped. I may have missed that and I apologize if I did. But is it they would simply not be part of 2011 or 2013?

**Janet Corrigan, National Quality Forum, President & CEO**

It's a great question and let me tell you what the seven are. It's percent orders entered by physicians in CPOE, percent med or all orders entered through CPOE, so those two are clearly related, percent of patients with access to personal health information electronically, percent of patients with access to educational resources, those are clearly related, percent of all encounters for which clinical summaries are provided, percent reportable lab summaries transmitted electronically for public health purposes and then provide electronic syndromic surveillance data to public health. So the last two are public health measures. And these, we didn't limit our scan of the performance measures to NQF-endorsed measures. Only if we knew of something else out there that might be appropriate or better we would have brought it into the process. We just don't know. There may well be some measures of this nature, and there probably are in institutions that have come up with something to be able to take a look at these. So I think at this point it's a matter if there's a desire to move forward and to develop some measures in this area. It would be perhaps the next piece of work to assemble a small group and take a close look at how we could develop measures in this time frame if that's possible.

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

And would that be done at NQF? What's the proposal for the process there if the policy committee or if ONC would want to move forward with those seven?

**Floyd Eisenberg, Siemens Medical Solutions, Physician Consultant**

Well I would add a comment to that and based on my response to Doug earlier is that the recommendation now, as we discussed in our committee, would be attestation for those – that most of those elements could be handled by attestation and that we would look to certainly look to those as utilization measures directly from electronic systems and call for those measures. We endorse, we don't develop but we could do a call for those to make them directly out of electronic systems rather than attestation for the future.

**Janet Corrigan, National Quality Forum, President & CEO**

But there still is a piece of work to be done even if they're going to be done by attestation in 2011 to define the attestation mechanism. That's not entirely straightforward so I think that that would be the next step with those particular measures.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Alright. Well I think we're likely ready to call the question. Thank you for the terrific work. I think this presentation embraces three signal events. First, I cannot state it better than Wes to the degree of clarity and identification of a road map over time that converges across the work of the quality community and the informatics community is just exceptional. It's clear that there's also additional work to do so the first signal event is completion of this table. I think the second aspect and I think it really embraced by what John Derr offered is that these activities move the environment even beyond what was specified in the legislation. I want to accept your letter I know into the record of deliberations. But your intent to really move measures across the environments not specifically contemplated in the legislation, but contemplated by all at the table is critically important. And that's the second signal event. And the third we heard from John Halamaka that this will take work to move and ... and the signal is not that it will take work and adopt to, but with all due affection for my colleagues, it was a confession that the world doesn't have to map to Beth Israel, but Beth Israel will map to the rest of the world.

So thank you for a great test case in that example, because I think that's reality that all of us will face. So are we ready to accept the recommendations of the clinical quality workgroup? Any objections? Terrific, then we have consensus. Sorry, Mark, question?

**Marc Overhage, Regenstrief, Director**

Not really an objection, but as Floyd said, I think there's some, with the acknowledgement there's some clean-up things in terms of some of the terminologies and so and some of the rows that survived the careful editing.

**M**

... modifications that we discussed.

**Marc Overhage, Regenstrief, Director**

Yes. With that, also the recognition that of course our job isn't an anointing at this point, but it's really a submission of this material to the Office of the National Coordinator and a validation within that environment as well as the opportunity for public comment. Judy?

**Judy Murphy, Aurora Healthcare, Vice President of Applications**

Judy Murphy. Just one other thing. I would like to see us flush out those other seven. I think that should be part of the approval as well with the thought that we are moving ahead and looking at the seven that we don't have criteria for.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Great. And with that amendment, do we have agreement? Those two amendments? Terrific. Without objection thank you for your terrific work and it's clear in the consensus that you're not off the hook. There's much, much more work ahead both immediate and in the out years. Terrific work. Thanks very much.

**Janet Corrigan, National Quality Forum, President & CEO**

I was a little bit taken aback in John Halamka's opening comments that this committee was going to go on forever. Isn't that what you pretty much said?

**John Halamka, Harvard Medical School, Chief Information Officer**

Standards, it's a journey. But every meeting we will get more and more granular. As long as we think of it that way, we'll be . . .

**Janet Corrigan, National Quality Forum, President & CEO**

It never ends.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you very much for that terrific work. And with that, we have designed today's agenda to be especially for discussion, I know the last time some people might have thought that we were a little time pressured, we'll take the amount of time it takes to go through things, so we think we built in additional time. So let's then move ahead before we take a break to the clinical operations workgroup where I think we'll see equally heroic and effective efforts. And so we'll turn to Jamie Ferguson and John Halamka to bring us up to date on the clinical operations progress. And again I want to thank you both for terrific leadership. The members of the workgroup for just heroic efforts, and especially members of the broader community public who provided such a rich resource base of information and contributes an open and transparent process of deliberations and the ability I think to move us forward with clarity. Jamie, John, who'd like to start?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

John, I know you just got back from Japan, so I guess you're going to, if you want to stay there or join me up here, either way.

**John Halamka, Harvard Medical School, Chief Information Officer**

I'll come and join you.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Thank you. Just as an overview, I'm going to go through the recommendations that we've made at a relatively high level. I'll talk about some principles that we've discussed and some improvements that we've made in our documentation. I'll also talk about our discussions that relate to public comments that we've received, some of which you received in your packets here today. But in general, with one exception that I'll go through, our recommendations were accepted last time and we have not changed them, so we've improved our documentation but I'm not going to go through them in the same level of detail that we've just gone through the rows of the quality recommendations because we haven't changed them except for the one that I'll talk about. Let's see.

**John Halamka, Harvard Medical School, Chief Information Officer**

It's important to note as you through all the material is just as with the quality material, the remarkable convergence on a near 100% set. So when David Blumenthal asked the question for meaningful use for clinical operations, what percentage of meaningful use criteria have now standards attached. The answer is basically, 100%, very, very close.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

And that's not to say these are all the perfect standards that we would want in a perfect world, and there's certainly some maintenance that's going to be required in terms of vocabulary and some evolution of some of the standards, but we do have recommendations for everything for meaningful use for 2011. So you can see on the first slide is just a listing of our workgroup membership. In summary, we have clarified our descriptions and updated our documentation. We've received comments in our last committee meeting here and also from public comments that our recommendations were frankly hard to understand and so we think we've improved and clarified the documentation quite a bit. There is a new summary chart attached that we've reviewed in detail in the workgroup and we hope that that will be more useful and more understandable. We have recommended some additional standards for quality measure submission and we've also broken out the public health reporting of reportable labs, although that wasn't vetted in our previous recommendations.

**John Halamka, Harvard Medical School, Chief Information Officer**

So on the grid that Jamie will describe, it's very similar to the four-page grid that was used in quality and that is rather than giving the exhaustive detail, it summarizes into problems, meds, allergies, notes, reports, these sorts of things and the content as well as the vocabulary standards associated with each of those broad categories. It does not cover transmissions – that is covered in Dixie's area. So you will see actually that Dixie will provide REST, SOAP, secure transmission, all those sorts of things. This will be content and vocabulary.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Great. I've had a couple of slides in here, rather we have a couple of slides in here that address the key themes that we found in public comments as well as some of the discussions that we heard in the committee meetings. And so we've had a number of discussions obviously in the workgroup, some of them on the specific issues that relate here. We heard some comments that the recommendations that we had didn't consider innovation enough and weren't flexible enough to allow alternative innovations. But in fact the innovations that were mentioned in the comments generally were proprietary software solutions, or they would require key changes in the current legal framework for medical records, such as making personal health records legal medical records. And so that would be a substantial change that we really felt was out of scope and the fact that we can change these standards in the future through the process that we have we thought was adequate to address those concerns.

**John Halamka, Harvard Medical School, Chief Information Officer**

Obviously we embraced the personal health record and provide standards for the personal health record and where possible use EHR to EHR and EHR to PHR as identical standards, but the notion that CMS, the hospital and the doctor will no longer keep a record at their organization is probably something that

would require just a bit of regulation tweaking and therefore embrace innovation and adopt PHR is a yes. Require revision of all your regulations, not at this time.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Great. And we would also note that if that policy change were made, we believe that the standards that we're recommending could facilitate that. So we don't see any conflict there. We also heard comments to the effect that some specific standards were not recommended and in fact we had workgroup discussions on a number of alternative standards that are currently in use including the continuity of care record, e-links lab reporting and some vocabulary standards such as the most popular proprietary medication standards for vocabulary that are currently used and we felt that migrating to the standards that have already been adopted or recognized by the department by the secretary through both through HITSP and through the consolidated health informatics and other open processes that have taken place really provides the best path towards standardization and achieving the objectives that we have under the Recovery Act and for meaningful use. Do you want to further . . .

**John Halamka, Harvard Medical School, Chief Information Officer**

Right. There is also the recognition as you'll discuss that there's a path that gets us to sort of what we'll call that singular track that was the intercontinental railroad and therefore in the short term to 2011 there are exceptions that are made that say yes, there are absolutely implementations to be linked and there should be value recognized and therefore it should be allowed for 2011 but by 2013 let's get to one standard for lab transmission from labs and on the provider side be able to . . .

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

And those are some of the key considerations behind our recommendation to allow variation for 2011, but to migrate to the standards by 2013 and in general we're supporting and recommending a path very similar and analogous to what CMS did in the final rule for ICD-10, which is to set a definitive standards far enough in the future that people can actually achieve it by the date in the rule.

**John Halamka, Harvard Medical School, Chief Information Officer**

And we said this before, but just to emphasize, what we're covering in this presentation is from the border of an organization to another organization we are suggesting that within your four walls, yet if you have proprietary or legacy standards you wish to continue to use, that's okay.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Right. We heard a number of comments and received a number of e-mails and letters that basically supported our recommendations and we didn't discuss that in particular . . .

**John Halamka, Harvard Medical School, Chief Information Officer**

And just to give you an example, at Beth Israel Deaconess we happen to use the first data bank vocabulary for medications in our self-billed systems. It's unlikely we are going to rebuild all of our internally developed software to use RxNorm. With that being said, RxNorm provides a mapping that at the border can take the first data bank code and produce an RxNorm concept identifier which we would then transmit in whatever we would for meaningful use organization to organizational data exchange.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

We also heard another theme was that essentially the market should decide standards or that things that have already been implemented should be what we select. And so we found that there's a wide variety of implementations that currently exist in many different things and we do believe we have to get to standardization so we've allowed time with our 2013 recommendations, we've allowed time for those legacy implementations and the current HIT that's in place for those implementers to get value from those as they migrate towards the standards for 2013. And then we also heard on the other side of the coin that we basically either weren't fast enough or weren't strict enough in terms of allowing these variations that we are recommending for 2011.

We did hear some comments that we should not allow the kinds of variations that we're recommending for 2011, but we recognize and we had discussions in the workgroup that many IT projects just take

longer than two years. And that's true for a variety of reasons. Some of the key factors we discussed were cost effectiveness, so you may be able to pile on resources to potentially get a project done in a very accelerated time frame, but that's not cost effective and that can also be very disruptive to your operations. So allowing a longer time frame takes care of those considerations. And we felt that this was realistic. We also heard comments that we should have recommended more of the HITSP standards, but we are recommending standards that meet all of the requirements, we believe, for the 2011 meaningful use measures.

**John Halamka, Harvard Medical School, Chief Information Officer**

So an example of the 2011 allowable transition, scanning of paper documents to create an image, creation of a pdf. While as an emergency physician, I can tell you that if I received a pdf with some metadata around it, it would be a whole lot better than I have today. And so to say that we are going to get to complete structured vocabulary control documentation in 2011, as you say, from an IT perspective not realistic. So allow on the glide path the use of an image with metadata. Allow the use of a pdf and get us to 2013 where structured documentation is required.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

We did, as John has mentioned before, we did want to talk about the key concept that we're recommending standards for interoperability between enterprises. And so this is not intended, our recommendations are not intended to mandate how you capture, store or manage information within an entity or within an enterprise, but that it does apply and should apply, the recommendations should apply to the external representation of information and the exchange of information between entities. And so we believe that there are many different methods that could potentially be used to achieve this interoperability to achieve standards compliance that could include native data capture and the recommended standards and systems that only use the recommended standards. But it could also include mapping, could include external services that include and provide for the ability to continue to use internally generated coding systems and information management systems so long as you can also then generate and create and represent your information in the recommended standards and using the recommended exchange standards with other enterprises for interoperability purposes.

**John Halamka, Harvard Medical School, Chief Information Officer**

Along the way we wanted to maintain architectural neutrality and so there are different models for health information exchange. And so the model that's used in Indiana on ... and the model that's used in Massachusetts do have subtle differences. And so don't dictate architecture. If you want repositories, be they local or central, that's okay. If you want push versus pull, if you want publish and subscribe, all of those should be supported. So I think what you'll see is we got to specificity of the standards that should be used but left it such that implementations can still have variabilities that are appropriate to each community.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

I do want to take a short period to go through our key recommendations. And so these are not all of the recommendations, but these are the key items. There is an attachment, which is our new chart that we think improved documentation that has a more complete list of . . .

**John Halamka, Harvard Medical School, Chief Information Officer**

We got the font a little bit larger this way. Bigger piece of paper.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Bigger piece of paper. Not much bigger, though. So for content exchange, with one exception, our recommendations -- ... content exchange standards as well as the vocabulary standards have not changed, but we think that the new documentation will be more understandable. For structured electronic documents, we're recommending HL-7 CDA, the relevant CDA profiles, including the continuity of care document as specified by HITSP. For most clinical messaging we're recommending HL-7 version 2.5.1, again as specified by HITSP with the exception that immunization queries and vaccination updates use HL-7 version 2.3.1 in the HITSP specifications so we're agreeing with those recommendations.

**John Halamka, Harvard Medical School, Chief Information Officer**

But there is HL-7 ballot coming up I believe in January so we may get to a 2.5.1 recommendation that goes through ballot, but 2.3.1 is where we are at current.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Yes, but not in time for the current cycle of work, essentially. So then for prescriptions we're recommending NCPDP script, for ambulatory HL-7 2.5.1 within hospitals. And this is completely consistent with the current rules. For eligibility benefits and referrals, there is actually a typo on here that I'll point out. We are recommending right now the use of the X12 HIPAA transaction standards. The NCPDP standard 5.1 is not script, so that's the NCPDP telecom standard. That's my fault. I'm just so accustomed to writing NCPDP script that I put it in there. So that is a typo and that should also be removed from the next page. And we're also recommending as per the specifications of HITSP the use of the CAQH core phase one and phase two standards for the X12 transactions for eligibility.

Now the new one is the one at the bottom of the page. And so this is the only change to our recommendations, and this is therefore is the only item that we're actually recommending and requesting approval on from the committee. The next, the use of the as we said before, as Mark noted, the PQR registry specification for quality measure reporting. Currently there are approximately 70 registries across the U.S. that support this specification for reporting quality measures to CMS and we think it's practical and reasonable and can be implemented for this purpose by 2011 as we recommend. So that's the one recommendation that was not in our presentation last time that's been added. In terms of the primary vocabulary specifications that we're recommending. Again, this is not the complete list, but these are the primary standards we agreed to recommend. The complete list is attached in the handout for clinical problems and procedures. We're recommending a migration to SNOMED CT allowing of course ICD-9 currently ICD-10 in conjunction with the rule, but as Floyd mentioned, by 2015 our recommended statement of direction would be to migrate to SNOMED CT. For drugs and medication allergies, we're recommending RxNorm, again realizing that for 2011 in DC and First Data Bank and potentially others may be used currently so they should be allowed, but we want to migrate to RxNorm.

Now I do want to point out when we get to some of the quality measures, we're recommending that both for the problems and procedures as well as for drugs and medication allergies, there are just a few problems that are specifically required for quality measure reporting. There are just a few drugs that are specifically required for quality measure calculation. So we are recommending that those few items should be either mapped or be able to be represented in the recommended coding system for calculation of the measures. So that means that you may use a proprietary drug, coding or problem coding scheme or text fragments or whatever you use internally, that's fine but for purposes of quality reporting, you should be able to represent your problems in either SNOMED CT or ICD-9. And for purposes for those few drugs that are used in the quality measure reporting, you should be able to represent those in RxNorm. And that would be for 2011, so that's the only specific use of those that we recommend requiring for 2011 and it's exclusive to the quality measure reporting. Then for other allergies, more generally the unique ingredient identifier for laboratory tests, LOINC, units of measure that the uniform units of measure and again the same typo is on here with the NCPDP script being mentioned instead of the NCPDP telecom standard.

**John Halamka, Harvard Medical School, Chief Information Officer**

And all these vocabularies should be completely consistent with the ... standards that have been chosen previously and federal medication terminology standards, so if you look at the need to the FDA and other federal entities, they have said RxNorm, UNII. Did you want to make any comment on NDFRT and the gap there?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Well we have, we've noted in you'll see in there's a notes column on the right-hand side of our detailed chart and we've noted that the implementation of NDFRT is something that would have to be determined in the future.

**John Halamka, Harvard Medical School, Chief Information Officer**

Right. And NDFRT vocabulary. If you wish to describe an allergy to a class of drugs rather than an ingredient, medication or substance, NDFRT is what federal medication terminology group has selected but that is one of those early standards that has not been mapped to my knowledge to RxNorm and UNII directly and so that's still work to be done.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Now one other key concept we've mentioned this several times, but I really wanted to point it out here very specifically is we're recommending the standards for 2013 implementation. We believe that that should give meaningful users enough time to get to the recommendations. But we recognize that there has to be 2011 implementation and so we believe we have allowed for a degree of alternatives and the use of legacy and proprietary coding systems for example and unstructured documents that will allow a migration path to the standards while still being reasonable and not placing an undue burden on any implementer.

So there are some of the standards that we're recommending for 2011 that we would recommend should not be allowed for 2013 include free text, pdf and images of documents migrating then to structured documents by 2013. We're recommending the allowable use of alternative HL- 7 version 2 lab messaging. Existing implementations for 2011, but migrating to version 2.5.1 by 2013. We're recommending the use of legacy and local and proprietary coding systems should be allowed with the exception that I noted previously that for the specific list of drugs that's mentioned in the quality measures, that should be mappable to RxNorm and for the specific list of problems that's required, it should be mappable to SNOMED or ICD-9.

**John Halamka, Harvard Medical School, Chief Information Officer**

That's a really important point because Floyd, we could not persuade Floyd and Janet to map to every proprietary vocabulary that exists in the country and hence what we said was for quality measures that there are just a few data elements to report – RxNorm, IC-9, 10, or SNOMED as we've indicated and that seems reasonable to give flexibility to organizations in their glide path to use vocabularies they may already have implemented, but they will at the border. Not internally, but at the border have to translate to these few vocabularies when reporting ...

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

So even though we are recommending allowance for the use of these alternatives and existing legacy systems for 2011, it just doesn't make sense for quality reporting if you can't calculate the measures correctly. So there are a few next steps, looking forward at what's next. We do have to have a certification criteria that support the standards that are needed for meaningful use information exchange. We have not discussed certification criteria in detail in the workgroup and so I'm not making any particular recommendations other than to say that there should be certification criteria that would enable the use of these standards for that purpose.

**John Halamka, Harvard Medical School, Chief Information Officer**

Well globally what I'd said at the beginning of the meeting that the certification was going to be a functionality of the product plus the standards that are recommended by these workgroups. And therefore in some sense this becomes the certification criteria for the standards that should be baked into products.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

There are a couple of standards that we sort of wished we could have recommended, but they weren't ready and so perhaps it's work for 2013 or in an update process these can be brought into play. Floyd mentioned the QRDA as an alternative mechanism for quality measure submissions, and if CMS added that to the PQRI specifications, then it could potentially fit into our recommendations in a measured way. Also CDC has a specification called ... for public health data exchange, but I noted that the version 1 draft data dictionary for ... was just published last month and so this is not, we don't believe this is ready for recommendation but it is something to look forward to so as an alternative for reportable labs for 2011, we are recommending that the HL-7 version 2 spec that's recommended by HITSP is what should be used.

**John Halamka, Harvard Medical School, Chief Information Officer**

And just some detail on this one, Farzad Mostashari feels particularly passion about innovation in the way that public health data is reported. Traditionally if you look at the work that we did in HITSP on such things as file surveillance, public health reporting, use cases, we used deidentified or identified patient level records rather than how many patients came to your emergency department with H1N1 like systems, 7. Well ... allows that kind of very summarized, it's a number. It's doesn't have patient level rows or patient level observation or individual lab results. So there seems to be a trend, this is what we are hearing, toward reporting less data that's highly summarized as the institution so ... very likely, very important standard should be adopted but right now it's one of those category 3 to 4 kind of things we talked about. It just came out three weeks ago, and therefore probably preliminary to recommend.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

In terms of maintenance processes, we talked last time about the need for maintenance processes both in terms of vocabulary and the other standards. We recognize that as the measures are retooled for quality purposes and as new measures come into play, there will be updates that will be required to the vocabulary subset that are specified. And so there should be a process for that. And also for the content exchange; for example, updates to the PQRI registry specification will be needed for the new measures. So we'll need maintenance processes for these things. And then we look forward to working on the next batch of recommendations.

**John Halamka, Harvard Medical School, Chief Information Officer**

And then just to describe this large sheet of paper. What I hope is much clearer in this presentation format is that we've broken it down into the broad categories of data exchange, showed you the content exchange – both document and messaging, showed you the vocabulary associated with each category of data exchange and this point about architectural neutrality is very, very important. You can use whatever Web technologies you wish. You can use EHR to EHR, EHR to PHR, EHR to HIE, HIE to HIE, push/pull, publish/subscribe, all of those are consistent with this kind of category and categorization standards. And any other comments you'd like to make?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

No, I think that's it.

**John Halamka, Harvard Medical School, Chief Information Officer**

And so we certainly look forward to your comments and your input. We certainly tried to be very, very sensitive to a broad array of input in creating this matrix, incorporating public comments. I do have to just say that I am the chair of HITSP, so in some ways I am conflicted and Jamie was right in that this was a very balanced approach. HITSP standards were considered, yes, but many other standards and SDO products and implementation guides. And so we were criticized both for including too much and including too little, which hopefully means we've got it just right. So we look forward to your questions and your comments.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Let me extend the chair. Thanks to the terrific work behind the table is fabulous, especially for those who were smart enough to put a double size page for a single size page. But it's a road map. People will need to reduce the complexity in the world to minimize the complexity in implementation to really have focus on reusability of elements and suites of standards and the implications associated with that. That facilitates our ability to realize what's intended through content exchange and the vocabulary with architectural neutrality is an incredible accomplishment.

Now we have a number of people who want to comment, ask questions, so Mark Overhage is first and Dave McCallie. Steven Findlay is that from last time or is that . . . Okay. And Jodi Daniel, Kevin Hutchinson. So we'll go in that order.

**Marc Overhage, Regenstrief, Director**

I guess I have a question and then a comment. The first is related to the standard matrix. I'm just having trouble wrapping my head around, back to the ecosystem thinking about this and so the example of a chain of urgent care centers that deliver information to us in a structured format, that's a standard. It's not one of the ones that we've identified through this work. I think the implication is let me make sure I'm not missing something here. I'm probably going to keep receiving those structured data from those urgent care centers in this format because frankly I don't have any particular motivation to change and it's doing the job. So one of the challenges was that I don't have any magic answers of course, is that we're able to attack and you've got to start somewhere, a narrow space and then over time hopefully we'll see consolidation. Is that kind of consistent with how you're seeing the evolution or the workgroup's seeing the evolution?

**John Halamka, Harvard Medical School, Chief Information Officer**

Yes, Certainly we recognize that standardization goes from heterogeneity to as much homogeneity and conversions as you can imagine over time. I've said in HITSP, ideal harmonization is one. If you can go from 20 to 2 in the short term, hey that's great. So I think what we've tried to do is provide a road map that allows variation and variability but tries to get us to that single rail, that single gauge of track as much as possible by 2013. We recognize, too, that there are going to be intermediaries, there are going to be mappings, there's going to be translation that a lot of heterogeneity makes this within institutions. But what you hope is that eventually we get to as little variation as possible over the wire and the entire mapping and translation over time when we can.

**Marc Overhage, Regenstrief, Director**

So you're almost ready to run for office, John. Another couple years of practice and you'll have it down.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

I just want to say, Mark, I think that in terms of the scope aspect of your question, I think part of your question was, what about those end points – either sources or targets of information that frankly aren't covered by these provisions of the Recovery Act. And we just didn't really discuss those in that scope issue in the workgroup.

**Marc Overhage, Regenstrief, Director**

Well I think it was just the major takeaway. There's a large chunk of the healthcare ecosystem that we're not attacking or addressing or leveraging. That's okay, but I think it's important to recognize. The other brief comment that I wanted to make is there was this talk about the ..., maybe standard may be too strong a word for where it is in the process, but just to highlight for people as an example of the, and I think it's a wise choice to defer judgment on some of these things. ..., for example, is model is as we said to do some roll-up aggregated reporting. So for the State of New York, that means 1.5 million rows of data reported every day because the way this thing is designed. And so I think the pragmatic, practical implications and I think similarly, the PQRI reporting as a starting point as another example of something that's been, there are 70 folks who figured out a way to do it, made it work, that gives me a lot more confidence in something that a bunch of people in a conference room have sat down and created but not yet tried to implement in reality. And I know ... is being driven very quickly towards an attempt at reality, but some of these pragmatic issues, I think, are going to surface. So I applaud the wisdom of the group in taking their time on some of those.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

So Mark, just to turn the table a little bit, you asked the question that it's clear that not every component of the ecosystem is covered by HITEP. But in your experience and in the community, wouldn't you expect that a certain sort of snowballing effect of what you started got others to play. How do you envision that coming to fruition?

**Marc Overhage, Regenstrief, Director**

I think it's much more like John described, that we're going to see – and I think Wes alluded to this earlier – that we're going to see various kinds of adapters, intermediaries and so on almost forever, much as we have with clients. We're many years out of the HIPAA transactions, and yet we still are heavily reliant on

those transaction clearinghouses and things to bring that level of normalization. I think we're going to continue to see that.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

True, but it also implies that the information actually is communicated from among points, which we see big optimism. Okay, well thank. David McCallie?

**David McCallie, Cerner Corporation, Vice President, Medical Informatics**

Yes, David McCauley with Cerner. First, I commend you on the first fold-out pin-up at a ... meeting ever. This is a great achievement. I have two questions. One is picky and one is broad. The picky one I'll do first. And that's the recommendation for in 2011 for NCPDP script 10.x. That's pretty far beyond where Surescripts is today. Everybody that's currently certified is 8.6 or something like 8.1. Was that a conscious decision to move to 10.x which is structured vague . . .

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

That is what we discussed in the workgroup. I won't say that we spent a lot of time on that particular point because we didn't. But we did discuss and agree to recommend moving to 10.

**David McCallie, Cerner Corporation, Vice President, Medical Informatics**

Okay, well I'll register that at least one vendor is quite concerned with the implications of moving to 10 when there isn't even a certification process that you can use to validate it yet. And I don't think it's planned until even well into next year unless Surescripts has sped up their process. So maybe offline discussion. The broader question is about this notion of moving documents to the CDA format and I understand the need to have structured data for I think you referred to it as care coordination. What I wasn't clear about was what other kinds of documents are required by the 2013 timetable to be moved to a CDA format and which of the hundreds of different ways that you can interpret CDA are you implying. Is it just the top level header, is it section headers, is it structure . . .

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

So what we're focusing on is implementation of the 2011 measures. And the primary measures there are for care coordination and patient and family engagement, which has to do with transmission and exchange of summary records and giving patients encounter summaries and things of that nature. So there are just a few, only I think three or four of those measures that are covered by this recommendation. And so what we're recommending is that for 2013 when documents are used for those purposes, they should be the specified CCD or CDA template as it's been recommended by HITSP currently. But then for 2011 if you have the ability to take free text or pdf or an image of a documents and slap a CDA header on it, that that should be good enough for 2011.

**David McCallie, Cerner Corporation, Vice President, Medical Informatics**

So, and that helps a lot. So it's really those documents that are focused on this particular . . .

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

Right. It's just for those few measures where that is a requirement for 2011 meaningful use.

**David McCallie, Cerner Corporation, Vice President, Medical Informatics**

Okay, thank you. That helps a lot.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Let's go to Jodi Daniel next.

**Jodi Daniel, Office of Policy & Research, Director**

Thank you. I wanted to go back to a point maybe in your last slide, next steps about certification criteria must support the standards needed for meaningful use and information exchange. I just was hoping that you could elaborate on that and what, if you have any ideas on what that might look like and how we can make sure that we connect the standards certification, income certification criteria appropriately. Clearly the statute does talk about certified products being certified as meeting standards, so I think that's

consistent with what the statute says. I just wanted, as somebody who's going to have to figure out how to make that work in regulations, I just want to your insights into how we might think about doing that.

**John Halamka, Harvard Medical School, Chief Information Officer**

Sure. I had so many discussions with John Glaser on this point. His comment was, certification is this two-fold, functional aspect of the product which ONC will list those criteria and the standards that we all recommend of which here they are. And these are basically reflecting the meaningful use data exchanges as specified in the policy committee's definition of meaningful use. So I guess broadly one sentence would be, the certification criteria should be the capability of products to support the data exchanges required by meaningful use using these standards on this page.

**Jodi Daniel, Office of Policy & Research, Director**

Okay. And just to clarify, and this is only for when we're talking about these standards. These are for exchange of the data, not for use necessarily within an organization. Is that your affirmation?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

For exchange of the data and external representation of the information.

**Jodi Daniel, Office of Policy & Research, Director**

External representation. Okay. Thank you.

**John Halamka, Harvard Medical School, Chief Information Officer**

And so that's the quality data reporting and clinical care coordinating.

**Jodi Daniel, Office of Policy & Research, Director**

Thank you.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

And so I would include actually in that external representation would be providing the information to patients and for patient and family engagement and it's not just the clinical exchange component.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Let's go to Kevin Hutchinson and then Lisa Carnahan and then Wes, we'll come back over this way.

**Kevin Hutchinson, Prematics, Inc., CEO**

Just a couple comments and then a question, more of a process question than anything else. I think it's important to reiterate one of the public comments that are in here about the need to make sure that throughout this process, whether it's the policy committee or the standards committee and the work that we're doing both in the subgroups that we not lose track of the need for innovation. And it's something that I think that all of us in this room take very seriously finding that balance between standards allowing exchange of information and somehow restricting marketplace innovation by IT solution groups and vendors and other things. Because that is not the intent of the work that we're doing within this committee or the policy committee or anywhere else. And I think it was a well-crafted answer to the question about making sure that we're focused on the exchange of information, not necessarily focused on the actual workflow of these applications. And that is something that I get e-mails about and comments about on a regular basis of concerns that we're somehow going to dictate how things will be built and restrict innovation. And that is not the purpose of this group.

The second item was pointed out earlier that while a product may in fact be compliant with these technologies for the exchange of information, it is also okay to have third party products if a vendor chooses to use third-party products to be able to map to and exchange that information. So before we get in an uproar about we're not going to be able to implement, this company can't implement that standard, there are other options to be in compliance with that. While that company may choose to move toward native compliance, if you will, within that application. Those are just my two reporting comments.

**John Halamka, Harvard Medical School, Chief Information Officer**

That is absolutely correct. So John Glaser's institution and my institution have self-built systems and we have elected to leverage our community data exchange as the mechanism of creating standards for interoperability between organizations. Rather than build native capabilities in our own systems, we talk to a common gateway. The common gateway does the translation into these standards, and that's completely fine. We talk about certification in a sense it's certifying our self-built systems plus the healthcare information exchange as the unifier into a common format. Now I look at what your company does and you will be a module and it in fact does standards based e-prescriptions and therefore self-built modular or say a comprehensive EHR are all completely supported by the standards on this page.

**Kevin Hutchinson, Prematics, Inc., CEO**

But we may choose, as you've indicated, to use a third-party product to translate into RxNorm if we were to exchange that information versus to moving to that in that same time frame. You may choose to go to RxNorm and native as well. The process question, and I may have missed this in our initiation to the committee, but we're getting very specific on versions of these standards. In some cases, all the way down to the third decimal level and our experiences when we did that within federal legislation around NCPDP and the requirements around that were troubling because as the standard continued to evolve, in that case federal legislation, had to be amended. Now there was a little caveat in there that said so long as the standard is backward-compatible, you can implement later versions, more recent versions of that so long as it's backward compatible. But I think it's something that we should address so that there's clarity amongst the public as well. What if, by 2011, the version is now 2.7, but this calls for 2.5.1. What is the rule in place for that?

**John Halamka, Harvard Medical School, Chief Information Officer**

I think there are probably three answers to that is that certainly this notion of backward compatibility is a way out. One that John Glaser and I think Jodi has also talked about is that there's a difference in regulation between what you bake in the regulation and what you put in as guidance. And so if there are things that are going to change or we're not quite sure about, then we put them in the guidance, or you put them in the guidance section. The other recognition is that there needs to be maintenance on all of this and that this is not by any means a static document. What you'll see is that yearly or biannually there will be adjustments made as versions evolve.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Strategy & Policy**

And that's exactly what I was going to say in response is that I think I would take your comment as a vote for making the maintenance process perhaps one of our top priorities if not our top priority for the next phase of work.

**W**

Any insights from you all as far as where things would be more appropriate to put in guidance versus regulation because you think there's going to be a change over time and not something that's going to be static is helpful to us.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thanks. Great, great, great kind discussion because it really gets at sort of some of the meta discussions having about innovation and then specificity without a constraint within the need for maintenance. I think the earlier discussion as well about the immortality of this committee, and that maintenance will need to go on whether it's done here or wherever. It's inescapable. Great, great points. Let's got to Lisa Carnahan.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

Thank you. I just had a couple questions, and they're somewhat from a testing point of view. I realize it's not all about testing, as people tell me, but as we have standards, and we get to certification, there is that in between piece of testing to get the certification, and I might have missed the point. This spreadsheet is a summary of the previous spreadsheets, is that correct, or a replacement?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Yes. It's a summary of.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

It's a summary of, okay.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

With the addition of PQRI registry.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

On this spreadsheet, where it says, "as specified by HITSP," if you actually went to the other spreadsheet, you would see—

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

It lists the capabilities.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

That level ... oh—

**John Halamka, Harvard Medical School, Chief Information Officer**

The way to think about this is exactly analogous to the quality group's 24-pager versus 4-pager. This is the one-pager as compared to the extensive list of the individual capabilities by number.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

Great. Perfect. From a testing point of view, you can't just test this to this.

**John Halamka, Harvard Medical School, Chief Information Officer**

Understood.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

That's great. Then the other, just a suggestion, and as you keep going and deliberating, if you can get a little more clarity down the road on allowable alternatives. Again, from a testing perspective, you don't want the testing process to dictate requirements, right? That'd be bad. So we can't have too much ambiguity that the testing process can't handle, you know, know what in the world is allowable alternatives. You have it by example in the slides. Now maybe you have it somewhere else, but as you go forward, a little more clarity on that would be helpful as well.

**John Halamka, Harvard Medical School, Chief Information Officer**

I mean, to free text PDF an image with PDA header where the 2011....

**Lisa Carnahan, National Institute of Standards Technology, Chair**

What's in the examples on the slides is the allowable.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

That's exactly true for the unstructured documents. But, at the same time, essentially we're saying if you have a legacy HL-7 version 2 lab implementation, that's fine. Essentially we're saying, please migrate to version 2.5.1 by 2013. But I don't know how you make thousands of different variations of HL-7 version 2 lab messaging uniquely testable.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

I think that's the point. They won't be. It won't be.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Yes, and so that may be a case where attestation may be required.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

Yes.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Instead of a specific test bench.

**Lisa Carnahan, National Institute of Standards Technology, Chair**

Yes. Okay. Thank you.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Appreciate that frame of discussion. Let's go to Wes.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

John, I wanted to ask a question about something you said earlier that I would then like to tie back to this. You said that after a couple weeks, you were able to map 85% of BI-98 to this NLM, and I'm going to infer that there's implication that therefore there was a SNOMED representation of those. Is that...?

**John Halamka, Harvard Medical School, Chief Information Officer**

Right, so the NLM has produced a subset of SNOMED that is what I'll call a best practice problem list called the NLM CORE. It contains about 7,000 terms, and I think the distillation of six or seven sights. Marc, I think you contributed to that, and I know that Kaiser VA have done work with NLM in the past, so it was specifically the SNOMED CT, NLM CORE subset.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

For problems.

**John Halamka, Harvard Medical School, Chief Information Officer**

For problems.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Now you got this other 15%. Some of those you may find mappings with more work, but will you stop using that 15%? Will you stop using the data that has those 15% that you built up over the years? How will you deal with that?

**John Halamka, Harvard Medical School, Chief Information Officer**

It's a retrospective and prospective question.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Right.

**John Halamka, Harvard Medical School, Chief Information Officer**

So our plan is to map all the retrospective previous 20 years of codes that we can to SNOMED CT and, where we can't map, the 15% will be submitted as free text because I'll be honest. We have doctors who may have typed 'asbirin' allergy, you know, and it doesn't really map to anything, but that's what the doctor put in. Prospectively, we are changing the user interface to only allow entry of the SNOMED CT or NLM CORE subset as the problem list. So we'll just be limited to those 7,000 terms.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

So I assume BI-98 was a table as opposed to just a free text ... but you got to it by compiling a lot of free text, and there may be simply misspellings that constitute....

**John Halamka, Harvard Medical School, Chief Information Officer**

And that's exactly right. We did a frequency analysis of free text to create a table. And, yes, there are misspellings and colloquialisms and things like that.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Sure, sure. So this doesn't work out as an example of what I was trying to get to then, but the problem of the relationship between what you send across a boundary and what you do internally is most difficult around coding systems and the degree of granularity in the coding systems and so forth.

**John Halamka, Harvard Medical School, Chief Information Officer**

Right.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

So, to a certain extent, I think we need to understand what we are implying about what you do internally when we set up a specific coding system. If you've been coding your problems in ICD-9, you're not going to be able to send them in SNOMED. So we have the transition that you've written.

**John Halamka, Harvard Medical School, Chief Information Officer**

Right. And so we have this interesting issue. If you are using a less granular coding scheme, going to a more granular coding scheme, so you end up with things like representative NDC codes because you're just not sure what package size was dispensed.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Right.

**John Halamka, Harvard Medical School, Chief Information Officer**

You could imagine a representative SNOMED code or something of that nature where you're going from less granular to more granular.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

I think we've gotten to some representative LOINC codes through HITSP, right?

**John Halamka, Harvard Medical School, Chief Information Officer**

Yes.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Right. So that's all I had to say about that. I have a hope that....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Wes, before you go on from that, I think Chris wanted to dovetail on this theme.

**Christopher Chute, Mayo Clinic, VC Data Gov. & Health IT Standards**

Mayo was one of the people that contributed to the CORE as well, and wearing my hat as chair of ICD-11 for the World Health Organization, you have to understand that ICD, while not primarily a billing code, John, you did say that this morning. It's not exactly true. It's actually a public health code. But that being

said, it's still a categorization or a classification, and it's this whole distinction between classified data versus granularly detailed and explicit instance data. Frankly, the SNOMED CORE codes still persist at the level of a category or at the level of a classification rubric.

They are not yet, as the NLM has published them, the level of granularity and clinically detailed, grammatical sentence construction that SNOMED aspires to that I think people are expecting it to be. So it's important to recognize that as the clinical operations workgroup, which I participated, have specified is in fact for the purposes of clinical problems still a category classification layer, and we are only incrementally getting to nirvana, which would be the detailed, specific, composed, grammatical sentence about in SNOMED about what's actually going on with the patient.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Thanks for that. Did you want to respond to that?

**John Halamka, Harvard Medical School, Chief Information Officer**

I was going to say, and of course you were quite right about what the international classification of diseases was actually created for. I just simply made the statement; it has been typically used in administrative systems as a mechanism of billing.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

In the American....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thanks, Wes, for letting us take that sidebar to complete that thought. I appreciate it.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Just to add perhaps a touch of irony, it was the ICD-9 clinical modification that became a billing code, right? I have a hope that before I die, we will get to the point where if two systems are certified to interoperate, they will interoperate. I don't – I understand the very good reasons why that is not our target right now, but I think we need to be clear to the world that that is not our target. That when we say we have alternative coding measures, alternative formats, then we either say it's an alternative, but everybody must do it, or we say there are cases where two certified systems won't interoperate.

It's also true for security, but the point of what I'm saying is that I think it's also true for paradigm. And by that, in this case I mean that long list of alternatives you gave. I think it was published ... and push or shove, or whatever. I forget what it was, but something like that.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Push, pull, publish.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Yes, right. I think what HITSP has done with the Tiger Teams, the way it's been embodied in here of getting back to elemental parts of the paradigms that are important in standardizing that is a major step forward. I just don't want us to represent that we've then solved the interoperability problem with that.

**John Halamka, Harvard Medical School, Chief Information Officer**

Right. I think a couple things are true. The policy committee has emphasized the need to get much more granular about what interoperability means and to say yes, you will order, and you will receive a lab transaction. You will do e-prescribing. You will submit biosurveillance and public health data. And so I think that there will be clarity from the policy committee and the HIE working group of what you need to do

to be interoperable and, therefore, we will understand what is required and not required in 2011 and 2013. Based on the HIE working group definitions, these standards will get us to the ability to do those lab exchanges, e-prescribing exchanges, etc.

I think your point is very key because some people have said, well, wait a minute. I bought a certified system. How comes it doesn't exchange every data element for every purpose with every other system? The answer is, well, as certification was done in the past, that was actually never intended. And now there's going to be much more clarity and a much more focus on interoperability and specific transactions.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

If I could just, I think, add to it rather than disagree, what we will have done is reduce the cost and the risk of becoming interoperable by narrowing the field of differences. It would be very nice if we can get to the point where we take advantage of that, that somehow the cost to the overall system of implementing interoperable interfaces goes down. I mean, when we started out HL-7 20 years ago, we thought that everybody would be standard and, therefore, interface would be free. That didn't work out real well. But we did in fact narrow areas of disagreements on interfaces. So I would like to see us get to the point where – and I guess I'm not so much concerned about cost because it's one-time cost. But the risk of setting up an interoperable interface is reduced.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Very good. One quick follow on, and then go over to Dixie ... two quick follow-ons.

**Karen Trudel, CMS**

I promise you ... quick. What I would like to mention is, as people start planning the changes that they need to have in their organizations to support the changes that we're putting in front of people, it doesn't help when there's an out. That's going to be, I don't have to do it this year because it's not in the rules that I have to do it. So if we can keep an emphasis, if you're going to keep local codes, if you're going to keep alternatives, it's really just two more years, and you don't really have time, but people aren't going to think that way. They're going to read the regs, and they're going to say, I see nothing in here that tells me I have to actually do anything until, so I can get that off my budget year. So I just want to – the fact that it's built in that you can do alternatives is something that keeps it from happening. Thanks.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Yes. No, I think that was actually a key part of our considerations, and that's why we really are recommending that we publish now that the final rule should include definitive standards for 2013 use. And I wonder, Karen, if I can put you on the spot to talk a little bit about your deliberations on ICD-10 where you set a rule that was far enough in the future for people to implement it because that was behind a lot of our thinking.

**Karen Trudel, CMS**

Yes, I think that was exactly the point that we were trying to cut a balance between something that was doable and, when we first went out and said, well, it's 2011. The overwhelming response was, we cannot do that. And then next question was, what is a reasonable timeline without providing too much time? And yet, setting a specific date, so that people did see that there was a target, and that it had to be met. So I think that is that kind of balance.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Thanks.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

David, this was on this point?

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

Yes. It's David McCallie. A quick elaboration on Wes' point, and I think that the focus on standardizing the content of the data elements and the vocabularies used to fill those messages is the right place to start. And I also think that, in general, it's a good idea to try to maintain what you're calling technical and architectural neutrality. But at some point, interoperability at the plug and play level requires stepping up a level in specifying the next set of interconnection requirements.

If you bought a fire wire disk drive and brought it home and tried to plug it into a PC that didn't have a fire wire port, even though the file formats are completely compatible, you don't get any communication. So either everybody has to have fire wire and USB, and it has to be USB-1 and USB-2, etc. or somebody just picks, or we let the market pick, and I'm not saying which of those should happen. But at some point, we'll have to step up one level if we want to achieve Wes' dream of interoperability meaning actual interoperability.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Yes, and I would agree completely, and that is something that we discussed is that an endless list of alternatives is not useful in getting to that goal. But in fact, we believe that what we're recommending in conjunction with what you'll hear from Dixie from her workgroup gives a limited list of alternatives that still allow for architectural alternatives that can meet all the different policy objectives. So in other words, it's not anything goes, but it's, if you want to have push – as John was saying, push versus pull or central repository versus local repositories in each entity. All of those different kinds of variations can be accommodated, but it's not an endless list.

**John Halamka, Harvard Medical School, Chief Information Officer**

And I think Wes made a very important point, and that is, what we've done so far is to take the interface cost from \$10,000 to \$1,000, but not to zero. Therefore, you are absolutely right. If you're going to get us to near zero, you would have to be so prescriptive that it would probably end up dictating architecture, and we may get there eventually, but that's certainly not an area we've gone to date.

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

And the persistence of clearinghouse type entities is not necessarily a bad thing. But in the long run, that's friction in the system that it would be nice to eliminate. It's costs that we could take out.

**John Halamka, Harvard Medical School, Chief Information Officer**

I agree.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Dixie Baker.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Yes. This may be a policy committee question, but as you were talking about the CDA, it occurred to me that another clinical exchange that is certainly meaningful is claims attachments. And I was wondering whether your workgroup intends to recommend that these standards be applied to an update to the HIPAA standard for claims attachments as well.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

We did not discuss that in the workgroup. Again, I don't know, Karen, if you want to comment on the status of the work towards a final rule for claim attachments. I know you had an NPRM some time ago for

that, and if these kinds of recommendations could play into that. I believe that in HITSP, previously there was an analysis that was done in conjunction with CMS to look at the standards that were recommended in the NPRM for claims attachments versus the HITSP standards that are specified in the HITSP interoperability specifications and found no conflicts.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Just a quick comment – hu-rah. All right. If we wanted to cut a bunch of friction and gain real money out of interoperability real quickly, we either do away with claims attachments, or we make them go electronically. I mean, all of the debate about whether – I get my acronyms confused now. HIPAA claims were cost effective or not was based partly on the fact that so many claims were already being sent electronically. I mean, here we've got a Greenfield, a great chance to save a bunch of money.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Well, and also avoid ambiguity within a provider organization too. I have to provide my – I have to send in a quality measure, and for that I use SNOMED. But, oh, wait a minute, this is a claims attachment. For this one I have to use LOINC. It seems we need to bring these into alignment.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think, as we consider the action item for this, I think what I'd like to do is parse this discussion out of that, but take that as a thread, a recommendation to the Office of National Coordinator for discussion within HHS because I think ... heads nodding. There's consistency there. Let's go to Doug Fridsma, and do I see another--? Doug?

**Doug Fridsma, Arizona State University**

Thank you. I've been trying to get into the conversation for a bit here, so I'm going to go way back to the comment that Jodi made about certification because one of the recommendations here that you've described is that really what you're talking about is standards that are outside of a particular entity, and that what an organization does internally is sort of outside the purview of the standards that you're recommending.

The question I have goes back to the summary that John Glaser gave about certification process and the inclusion of certification of components so that the EHRs can be purchased from multiple sources. That would suggest that part of this would probably go within the organization as well, particularly if there's going to be certification of components.

The question I have is did you consider that in making some of your recommendations that, in some circumstances, it isn't going to be just between entities, but actually between components within an entity and whether or not the recommendation of a free text and things like that, again, going back to Wes' point. It's possible that you could be certified because you're exchanging free text. But in fact there's no integration testing that's occurring within those organizations. And, as a result, you end up with something that is less than the sum of its parts.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

We did have part of that discussion, and I would – I'm going to use an example that's not exactly what we discussed, but I think it illustrates exactly what we discussed, and that is that we decided that our scope for these interoperability standards that we're recommending for meaningful use should not apply to interfaces between all the different systems running in the basement of a hospital, but that they should apply between hospitals, between a hospital on one side of the street to a hospital on the other side of the street.

And so, I think what you're talking about is what we would call internal interoperability among the different system components within an enterprise or within an entity, and we discussed that as being out of scope for us, but I recognize that the component nature of the certification recommendations could bring that

potentially into scope for component certification where it certainly there's no reason why those internal components could not also use these standards.

**John Halamka, Harvard Medical School, Chief Information Officer**

Here's an example. Suppose there were five iPhone apps for meaningful use. I'm making this up. One is an e-prescribing app. Another is a clinical quality app. It would be the case, based on this, that as those iPhone apps sent quality measures, they would have to use the XML PQRI. But we didn't actually say, well, hey, that quality measure requires some medication information that has to be gotten from the e-prescribing app running on the iPhone. How are those two going to talk to each other? That is left to the implementation of the application writers. It was not something we specified.

**Doug Fridsma, Arizona State University**

Thanks.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Nancy Orvis.

**Nancy Orvis, U.S. Department of Defense (Health Affairs), Chief**

I just wanted to maybe ask a question for the – whether it's the future committee's direction or it will be other entities that will need to do some of the mappings or the next phase from '11 to '13. I mean, we talked a lot about how there will be ICD-9 to 10, but there will be underlying SNOMED CT for those problems in the problem list and for other kinds of procedures where SNOMED CT will be needed.

I think what Karen alluded to is a lot of organizations are looking at, well, I do the HIPAA 5010 transactions in '11 or '12, and I've got to have ICD-10 in '13. Gee, SNOMED CT is also in there. Do I go ahead and implement an ICD-10 to SNOMED CT mapping at the same time, or do I spend some time doing that? And I was curious whether we would say – is that something, an action that this committee might look at, or where would it point to, to say that we would probably be looking for good solutions or recommendations for organizations on how to proceed?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

I was going to say, my own view is that that is something that this committee should consider, and we may want to do that in conjunction with the adoption workgroup of the policy committee and really work together on recommendations per that end.

**John Halamka, Harvard Medical School, Chief Information Officer**

And I was going to say the exact same thing that as I look at the next phase of work, as we focus on implementation and adoption, we're going to learn about barriers, and it could very well be that ONC would commission work of the NLM to reduce barriers of implementation.

**Nancy Orvis, U.S. Department of Defense (Health Affairs), Chief**

Good, because I'm sure that's a question that the vendors are thinking of too because they can say I have my own proprietary inner apps. Do we spend time doing our own kind of mapping up to the information highway standards, the NHIN standards, or do we look that there'll be other solutions coming. Great.

**John Halamka, Harvard Medical School, Chief Information Officer**

Great. Just a terrific and robust discussion. I mean, there are some themes that ... perhaps the overriding one I've heard is this issue of inherent interoperability of products versus functional interoperability between entities. In the near term, one looks at the desire to advance the effectiveness of healthcare. The functional interoperability between entities really is the issue. I think Wes and others make a point that there is a more granular level of interoperability that occurs when products evolve, but there's something between here and there, and that's this issue of how fast one is able to move.

Anne's point, the concern that if there's too much generality, there's wiggle room. It may not end up at that place. On the other hand, there's the issue of the ability to actually implement and change systems from all perspectives, be it vendors or providers, clinicians, and the patient use of systems that are envisioned as well. There's that near term/far term dichotomy. The second dichotomy of generality and specificity, which we had some discussion around as well, and complicated by the recognition that Kevin Hutchinson's terrific points, but standards do evolve, and we need to make sure that there is not only a process for updating and refreshing, but backward compatibility and not walking down the wrong form, those things that are expected appropriately to evolve. Jodi's comments about how to affect that or finesse that and guidance rather than the regulation.

Then this final theme here about implementation, that this is all great in theory, but the reality is that there's a lot of lifting to do in the process, so those are the general themes that I picked up, and terrific. When I think of this, I think of my own experience with the organization. What I am really grateful for is that this essentially may constitute very much a roadmap with sufficient generality in the near term that the functional interoperability between entities is doable, and I've got some pretty good cues of where I need to go, where I need to invest, what I need to work on, and what some of the challenges will be. That really brought that to life and an excellent interchange on the issue of mapping to SNOMED from the BI-98 group.

This is really just an incredible contribution. It provides clarity and guidance, directionality, and it is, I think, as close to perfection as it can be. But it's ultimately imperfect because the standards are not complete, and there's further work to do. That is a conundrum, finally, that I don't think we'll resolve ultimately any definitive point because it will be an evolution, but that said, just absolutely fabulous work.

Is this something that we're ready to embrace as a group? I see heads nodding yes. I will take that as a motion for consensus of adoption with the commentary provided also offered as context to the Office of National Coordinator.

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

I just want to point out that we are requesting the committee's approval of the one new item in particular that we're recommending now for the first time today, which is the adoption of the CMS PQRI registry XML specification for quality measure reporting for 2011.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Great. With that taken as additional clarification, are there any objections? Terrific. Then just great work, and I think everyone has earned a biological break. It is now exactly 12:00 noon. Recognizing that the ladies room and men's room is at the far end of the hall, and there is a bandwidth challenge, let's take half an hour and reconvene precisely at 12:30.

Good afternoon, everybody. Thank you for coming back at pretty close to the appointed time. It's a really great discussion this morning and, as we move to this afternoon's discussion, I have equal confidence that it will be robust, informative, and productive, as this morning was.

And I'm stalling because Dixie Baker is coming back into the room. Dixie Baker and Steve Findlay have, with the workgroup and with tremendous public input as well, have just done equally terrific work. And, I think, in this exercise, I have never felt closer to the idea that privacy and security issues are not something you have to do, but are really tools and instruments to facilitate what you're trying to do. Dixie, for that, I am personally appreciative.

It's really been a great object lesson in how we move things forward in terms of transmitting information and protecting information in all the ways that are expected, appropriate, and facilitate the ultimate objectives. John, anything you'd like to offer, as we start this section?

**John Halamka, Harvard Medical School, Chief Information Officer**

We've said that security and privacy are foundational to all other work that we do, and so the work that Dixie and Steve are going to report on includes authorization authentication, auditing, secure transmission, all those things that really enable the organizational exchange with clear audit trails, not only for protecting privacy and confidentiality, but also for insuring that information is not modified along the way, so there are elements of data integrity. As we've already talked about, all of this is necessary within an organization, as well as between organizations, to insure privacy and to insure that good data integrity.

Like other groups, this is a journey, and so what you'll hear from Dixie is effectively at 100% of the ARRA specified privacy and security requirements now have standards associated with them for 2011, but there are going to be additional requirements in 2013 and 2015, like more granular patient consent. There will be work that needs to be done, so I think the great news is, David Blumenthal will be able to report 100% for 2011, but as I said earlier, this committee's job is not done.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Thank you. I totally agree that I think privacy and security is an absolute. It's like table stakes. It's an essential enabler for everything we're doing here because unless we make sure that the doctor has access to the information they need to make critical and solid decisions about individual's health, and unless the data are available to them, and the services are available, they won't trust any of the rest of the work that we're doing. And also, unless we assure consumers that their privacy is being protected, they won't trust the doctors with their information either, and so all of our work will be moot, so I think that this is really important that we attend to.

I want to first acknowledge the people that are on the working group and also the people who help us, like John Moehrke, who is with HITSP, and Jodi Daniel with the Office of the National Coordinator, and I really appreciate the work, the time, and effort and really some solid thinking that's gone into what we're going to be presenting to you today.

Just to give you a revamp, revisit the roadmap that we're going through, we started out by mapping what I call the ARRA-8. In the American Recovery and Reinvestment Act, it enumerates eight priority areas that should be attended to by the policy committee and the standards committee, so we looked at those eight priorities, and four of the eight had to do with privacy and security capabilities and services that were required.

Using those as our foundation, we identified the privacy and security services that were required to certify products, and we recommended standards last month. Then the next step is to recommend the privacy and security measures for enabling an enterprise. These are measures that an enterprise themselves, not the product vendor, must address in order to demonstrate that that certified product is being used meaningfully.

Today, we're going to present an update to the standards that we presented to you last month. We identified – these are minor changes. The handout that is in your materials for today's meeting includes the updated list of standards. Unfortunately, I didn't think to make it a foldout, so I definitely – the clinical operations workgroup one-upped us on that one. But you can refer to that to get all the details. In the presentation, I'll show you what the primary changes were.

This is some of the standards that are listed in your handout, and I just want to use this as kind of a background to show you the kinds of changes that we made. First of all, we added a timeline. You'll recall that last month at the committee meeting, we used the four levels of readiness that were defined by the clinical operations committee early on, and we mapped all of the standards to one of those four ratings for the readiness for use, and their adoption within the community. This month, we've identified whether we're recommending them for 2011, 2013, or 2015.

Secondly, last month – we have a column to the left that says references and cross-references. Last month, we just identified HITSP or IHE as the source reference, and we've expanded those source references to make sure that people can more easily see where the source of the standard resides.

Third, last month we recommended the use of the common criteria to prescribe levels of assurance for security services, and in thinking a little bit further about it, and also some comments from the committee, we concluded that what we really wanted to do was to recommend to the policy committees certification workgroup that they not only attend to security functionality, but they also attend to the level of assurance that is evaluated as part of this certification process. There were also two duplicates that we eliminated this time.

We added – you remember that HITSP created a number of taskforces that translated the HITSP constructs into something called capabilities, and in looking at the ARRA requirements for consumer services, we identified three HITSP capabilities that are useful in providing those consumer services. One of them is the HITSP capability 143 to manage consumer preference and consent. And then the other two are to communicate structured document, which is capability 119, and to communicate an unstructured document, which is capability 120. And we believe that both of those in the – and if you look at the capabilities, they define various topologies for each of those capabilities, and we prescribe specifically the portable media and system-to-system topologies of those capabilities for providing the consumer an electronic copy of their medical record.

We added Web services security, secure hash algorithm, which is for integrity protection, and it's used by FSL and the XDR cross-enterprise document repository. We corrected one categorization for an ASTM standard. We had it categorized as authentication. It's really a non-repudiation standard. And then there were two of them that we changed the readiness level. One was a security assertion markup language or SAML, which is really kind of a 2012 capability, but we decided to change it from 2011 to 2013 because it really hasn't been adopted by 20% or more of the enterprises out there today. Then finally, the IHE, the personnel white pages, which is basically an LDAP directory, because it's just an LDAP directory, we changed its readiness level from 2015 to 2013.

I also wanted to mention one more point. We added. This is important. We added a note that allows for the use of REST in SOA implementations, as well as SOAP. SOAP is used for messaging to access services from a client application, and that's what's prescribed by all the HITSP standards, and some of the standards actually do acknowledge REST, but because REST is being used more and more frequently, really gaining a foothold in service oriented architectures, we wanted to allow both REST and SOAP.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

That the architectures that the Amazons, the Googles, the Microsofts have proposed for data exchange, EHR to PHR, are absolutely something we want to support and encourage. Innovation is key, and so you'll see in Dixie's recommendations that absolutely embrace REST as an approach for data transmission, the content packages, the vocabulary that Jamie outlined work just fine over a REST transmission mechanism.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right. In fact, from a complexity point of view, it's less complex than a SOAP transaction, but the reason it's not listed as a standard is it uses traditional HTTP and URIs, so there's no new standard for REST. It's just a new use of those historic really Web technologies.

I wanted to comment also that the addition of the HITSP capabilities that address consumer needs were really motivated by some conversations, valuable conversations that we had with some of the CCHIT teams. I want to acknowledge their help on that.

Next, so the majority of the content that I'm going to be presenting today really focuses. Now that we have a certified product, and I as an enterprise have purchased this product, how do I demonstrate to CMS that I am using that product meaningfully, and I deserve the reimbursement?

First of all, I wanted to get some pity from you guys and give you some of the challenges that we were faced in addressing this. The only real objective that the policy committee identified was HIPAA

compliance. All applicants will be required by law to be HIPAA compliant anyway, so what more can we add? You're HIPAA compliant. We know it. There you go. You get your reimbursement. Except for the ARRA provisions, you know, those currently aren't included in HIPAA, but they need to be addressed, and ultimately they'll be part of HIPAA compliance as well.

So we thought, well, maybe we'll select a subset of the standards and implementation specifications contained in the security and privacy rules, and we'll require those to be recertified in order to get the reimbursement. But that, we were pointed to was that by doing that, we're suggesting that some of the HIPAA requirements were more important than other ones, or that we were trying to subset HIPAA, and we certainly don't want to communicate either of those messages.

We also were – we can't really prescribe new law, so we can't come up with new things entirely or new regulations, but fundamentally we recognize that meaningful use of EHR technology unquestionably brings new privacy and security risks to the provider and to consumers, and that effectively addressing these risks is critical to the ultimate objective of furthering the adoption and proliferation of interoperable EHRs and HIEs.

What you see is these are the meaningful use objectives and policy measures that were handed us by the policy committee, so this is what we had to work with is the single objective of compliance with HIPAA privacy and security rules and state laws, and they gave us three policy measures, full compliance with the privacy and security rules, conduct an update, a security risk assessment, and implement the security updates. The risk assessment is one of the HIPAA requirements, so they said you must update that security risk assessment. And then they also said that they recommended that CMS withhold meaningful use payment for any entity until any confirmed HIPAA privacy and security violations had been resolved.

What we are recommending to you today are recommendations that include three types of measures. First, there are measures that represent value that EHR adoption brings to an organization in the enterprise HIPAA compliance. An example is auditing capability. You know, they're required by law to audit accesses. Well, it is easier to audit accesses if you have an automated EHR than if you're writing it down in a log book, so that's one of those types of measures.

Secondly are measures that represent changes in an enterprise's approach to HIPAA, as a result of having adopted EHRs. EHRs bring to an organization new risks, and so we wanted to recommend some countermeasures to those new risks that they didn't have before they acquired the certified EHR. And also, this also includes configuring, now to configure the EHR, the security and privacy capabilities of the EHR product itself.

You'll recall my mentioning last month that there are certain capabilities that a product may be certified to provide, but the product vendor can't guarantee that an enterprise uses them, like encryption, like auditing. You have a product that will do that, but it's up to the enterprise to configure it so that it does encryption, and so it does auditing of actions. Then, thirdly, the measures that objectively be assessed by HHS.

The first policy measure is full compliance with HIPAA privacy and security rules. To the right are our recommendations, the recommended measures to be demonstrated to show, to enable an enterprise to show that they do in fact are fully compliant with HIPAA privacy and security. First is to update their privacy and security policies to specifically address the use of the certified EHR product in the operational environment. And we wanted to include, and those four bullets there are all from the ARRA, the new ARRA provisions. One is notification of individuals whose PHI may have been breached. Secondly, limiting disclosures to the minimum necessary or limited data sets. Third is providing an accounting of all disclosures and, finally, enabling consumers to request and receive electronic copies of their EHR.

The second measure for HIPAA compliance would be to configure the EHR system and the supporting IT infrastructure in compliance with the HIPAA privacy and security rules and guidelines, including ARRA. We recognize that the implementation line between a product and the infrastructure around it is certainly dim, and it's getting dimmer by the day, particularly in the area of service-oriented architectures. So we

wanted to include, as a demonstration measure, both the IT, supporting IT infrastructure, as well as the EHR product itself.

The second policy measure here is to conduct or update a security risk assessment and implement security updates, as necessary. So our demonstration measure is pretty much the same, except that we added, where they say update a security risk assessment, we added a privacy risk assessment as well, and implement the policy procedures and system configuration that are necessary to use the certified EHR product meaningfully.

Now these measures are on this slide, as well as the next one, and you'll notice that a number of these are the types of capabilities and types of measures that they wouldn't have had to do if they didn't have an EHR. Termination of system access of terminated work members. Until they acquire an electronic health record, they really don't have to worry about terminating the access to that system. The establishment and periodic review of accesses to assure that access is granted to those with permission, and that access is not granted to those who do not have permission. This is the minimum necessary kind of implementation in the system.

The protection against the detection and reporting of malicious software, the monitoring of that audit trail of system activity, this says the audit trail is there. We know that, and now we want you to turn the auditing on, and we want you to periodically review what is in that audit trail. Then if passwords are used for user authentication, they need a password management capability.

This is continuing in the risk management area. Screen locking and session termination after pre-established periods of activity. Secure hash function to protect the integrity of all PHI transmissions. If you talk to a physician, they will tell you that the integrity of data is absolutely essential. Not only that the data integrity be protected, but that they feel comfortable that the integrity of the data has been protected, so that's really important to the provision of quality care and safe care.

Some of our most extensive discussions had to do with encryption. And I have to tell you, I think our druthers would be that all PHI always be encrypted, whether it be inside an organization or outside, particularly in this day of wireless. If you think about HIPAA and the HIPAA standards, wireless, well, in 1996, it was hardly even heard of when HIPAA was enacted. And when the HIPAA privacy and security rules came into being, no health organization used wireless, let alone a cellular phone with a camera built in, so the days have changed.

And so what we finally agreed upon for the meaningful use measures for 2011 are the encryption of all PHI transmissions, internal or external, to an organization where the possibility of their going over unsecured wireless or cellular networks cannot be ruled out. We phrased it this way to force them to think through what's possible. Can I absolutely rule out; given the assumption that it is going to go over cellular or wireless lines, can I rule that out? Can I say that it just can't happen?

And second, the encryption of all PHI transmissions that leave a facility and travel in part over shared networks. Then, finally, the encryption of all PHI that's stored on portable devices and removable media. USB, flash drives were also unheard of when the HIPAA security rule was enacted, and that would be covered in this requirement.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

It's so important. We spent a lot of time debating. The easiest thing to say is, every transaction on every server anywhere in your enterprise must be encrypted. Now I reviewed with all of my security team. Think of the 146 applications I have running at BIDMC. Some of these are client servers. Some are very wacky proprietary protocols. The likelihood you could implement TLS with SHA AES on a lot of these is zero.

But we have a requirement in our organization that all wireless be WPA enterprise authentication. Therefore, if you open up a laptop as a clinician, you must authenticate with your credentials, and it is encrypted. Therefore, we're not going to require double encryption. The fact that you have an

infrastructure that is capable of protecting your client server transactions that are unencrypted is fine and reasonable. And, in fact, if you have a situation where you absolutely wouldn't have wireless in any way, shape, or form, whether it's cellular or WiFi or whatever because it's two servers parked in a data center with a piece of fiber between the two of them, well then that's probably sufficient too.

This notion of encryption of data at rest was also something quite controversial. Do you say that every database in the entire enterprise must have encryption at rest? Well, that's also very challenging to require in the short-term. Who knows? Maybe long-term, we'll all get there. But to say I am copying patient identified data to a USB drive that I could leave on a bus, it seemed reasonable to say, if it's going to leave the enterprise on a mobile device that it should be encrypted in some fashion so that that privacy is going to be protected. In fact, Massachusetts now has a law that does require all removable media to be encrypted as of August 1, 2009.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Thank you. The encryption at rest, absolutely we had a lot of discussion about data at rest, a lot of discussion about that.

The next slide here has conduct or update. The policy measure was to conduct or update a security risk assessment and implementation. This was the same as the last one, but these are two additional measures that we've added. One is the HIPAA security rule requires that an organization have a contingency plan, which includes the data backup plan, disaster recovery, emergency mode operations, and testing and revisions, and applications of data criticality analysis. These are all in the HIPAA security rule, and what we are requiring is that that contingency plan be updated. This addresses the whole role that security plays in continuity of service and guaranteed availability of data and critical system services when they're needed.

The next one is to identify and document data and capabilities that are minimally required in order to assure the continuity of critical data services and establish service level agreements consistent with these priorities. This sort of stretches applications and data criticality analysis. At the risk of being critical of the HIPAA security rule, it requires that enterprises perform an applications and data criticality analysis.

It requires that you identify what data are critical to you and what services are critical to you, but then it doesn't require that you do anything about it. And so, we've said that you must establish the service level agreements that are consistent with those priorities so that if your system goes down, and you can't get to the data that you need, what are the data that you absolutely require in order to continue to provide services to your patients?

This next policy measure is to recommend that CMS withhold meaningful use payment for any entity until any confirmed HIPAA privacy and security violation has been resolved. This too, we had a lot of discussion about this. Because it's not clear, and the National Coordinator's Office helped me a lot in this area of talking to the Office of Civil Rights about what they really could provide to us. It's not, well, it is pretty clear that they're not going to disclose all of the information about any investigations that they have underway.

And so what we're recommending is to the extent possible, we'll obtain confirmation from the Office of Civil Rights that any confirmed HIPAA privacy and security violations have been resolved. Then, in addition, that we obtain an affirmation from the entity that any confirmed HIPAA security or privacy violations have been resolved. This is what the quality workgroup calls attestation, and we are going to ask them to attest that all of the security and privacy violations that may have existed have been resolved.

Did you have anything more to add, Steve?

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

Yes. Just real quickly, obviously consumers care about and are focused on the entire security and privacy framework that we've developed here. But I think we all recognize that the consent management piece of this is what is really the nub of the matter for patients and consumers who are not attune to all

these details. And we had some discussions with folks about the consent management issue, and some people, some consumer groups and others are suggesting that we try to move up to 2011 on some of that.

We came to the conclusion, and I think we all broadly agree that that's unrealistic and that the measures on consent management are not ready for primetime in 2011. They are in development, and so we've got to kick that can down the road, as it were, for a while and head for 2013 on that. So this is unfortunate, in a way, because I think there'll be some focus on that. Obviously consent management is critically important. Consumer control over the part of the record that they can get access to and move to the next place, from one place to another, or have other people see it, etc., so very important.

We are also pleased to hear that the policy committee is going to be having some testimony on privacy and security in general, and with some attention to consent management, next month. So I think that promises to be a forum for our presentation of some ideas here that will advance their work and their direction to us.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Good, good. We are asking for the committee's approval of both the changes to the certification criteria that I've presented today, and the standards, and also these meaningful use measures that I've presented.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Many thanks for a very informative and thorough process, very thoughtful in terms of the pragmatics of the implementation. Wes, I automatically look to my right.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

You're the only person who has ever thought of me as standing on the right. I have several miscellaneous questions. One I hear from a colleague, and I haven't looked at it, that CMS released a pointer to the CPRI toolkit this week and said that it would be used as a criterion for evaluating security.... I don't know anything about that, but if it's actually fact and not a misinterpretation, then I would hope that we would ... there's a URL that came around in an e-mail. I can't get online, so I can't give any specifics right now. I can send you an e-mail with that....

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Yes. I wasn't aware of that. Okay.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

I have a question about REST, and it's something like this. You have pointed to a number of truly independent specifications for various kinds of certifications, and a few that seem to be based on SOAP and Web services. If in fact we are saying REST is as good as Web services, do we have those corresponding security specifications as standards for REST, or are they left to the purview of Amazon.com and Microsoft and whatever they say goes?

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

No, we still require TLS. It still has to be over TLS, and REST is used in service-oriented architecture. Both of them are used in service-oriented architecture.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

No, but that's not a standard. You specify – TLS is an encryption standard. It doesn't, but itself....

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

It's authentication, end-to-end authentication, encryption, and integrity protection over Web connection.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Is it the case that all of the things that we require by naming standards for SOAP are also covered just by saying TLS for...? I just don't know the answer. I'm not trying to corner you here.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

All the things that we – run that by me again, please.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think I can interpret the question.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Yes, thanks.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

And that is that we know that because the WS framework and SOAP does include quite a lot of standardized security protection constructs, and REST, although it does provide end-to-end data integrity protection and certificate exchange over TLS with an appropriate hash, may not have the same level of standardized tools. And, therefore, when you look at implementation of Amazon and Google, they may have their own APIs on top of TLS for some aspects of security management.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

That's exactly – yes, that's right. That's right because SOAP uses WS security for security. There is no analogous WS security for REST.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Are we saying then by saying it's okay to use REST? And I'm not trying to oppose REST. I'm just trying to make sure we understand what we're saying that it's okay to use REST and let the dominant player in the transaction define how to do the security.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

As long as the security measures for meaningful use are met, yes, in translating it into the meaningful use arena ... you're really talking about....

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

I have some difficulty of understanding how you would go about....

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

You can't bypass security by using REST. You still have to meet the security requirements.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Okay, but we don't care that every large sized company that uses REST has a different approach, and that people who want to work with all those companies will have to use the idiosyncratic approaches of those companies?

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

David, you have a clarifying...?

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

I want to jump in a little bit because I was in some of these discussions, and I would agree with Wes that it's inadequate to simply say REST can be used in place of SOAP. REST and SOAP are not at the same level of granularity. So in order to use a RESTFUL approach for interchange, additional specifications and standards would be needed compared to where we are today.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right, but he's asking whether we have – we haven't specified those additional standards.

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

Right, and we have not specified them.

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

So you could use SAML, for example, to pass trust, but if you're using a RESTFUL approach, where do you put the SAML ticket? Somebody has to specify that, and it has to be accepted if there's to be interoperability. REST is an architectural approach. SOAP is an actual protocol, and they're not the same level of granularity.

I think what we've tried to do in the committee is to say that we recognize there is a broad transition in much of what's happening on the Internet towards the RESTFUL architectural approach, and that that's not precluded by endorsement of the existing SOAP based standards, but I think additional work, HITSP or someone, would be necessary to create a RESTFUL approach that could fully replace what's covered by the SOAP defined protocols today.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Several of the HITSP constructs do already allow for REST approach.

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

But not across the board.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right, not across the board.

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

Not for a whole system.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

All I'm really saying is, first of all, I've been sort of having a peanut gallery discussion with Lisa here.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Would you separate them?

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Yes, whoever sits next to me ends up being separated from me. I don't understand. Must be something about all of them. At the level we have them listed here, these are pretty broad HITSP specifications in order to get to any kind of way of determining compliance. You probably have to be more granular in how you use the HITSP, but this is a process of refinement we're in the middle of. I don't have any problem with that.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

...so for example, IHE, XDSA is a complete end-to-end architectural specification that includes REST and includes these components. B is SOAP only, and so what you'll see, among all the HITSP secure transmission work, there are probably about ten constructs, and there is a combination of comprehensive SOAP and REST support that would enable you to have a suite of functions supporting various architectures. I wrote a blog on this, which I could circulate to the committee just to give you some more explanation of all of the possibilities.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Yes. My biggest concern is that, I mean, the problem I always have about standards is we get more interoperability from the 800-pound gorilla than we do from a monkey fight, but the only way to have reasonable governance is to have a monkey fight. I just don't want us to be unknowingly saying the 800-pound gorillas are going to get to the finals. If we make a decision through policy and everybody else that we want, you know, we want to say you can do this with Microsoft and Amazon, following their standards. That's fine. But I wanted that to be an explicit statement, not something that's extracted from one of the details of a footnote on page seven.

Then the big question I have, in looking at the – I have a comment. I think, looking at all of the things that have been said about security, your examples, your four examples in the slide are really well chosen.

They're really important stuff. Have you discussed yet how this would be evaluated through determining meaningful use compliances in small practices?

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Absolutely. We've thought about small practices all the way through.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Can you help me understand how you think that would work, because to me when I look at those, right now—

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Where do you think it wouldn't work? What do you think would not work?

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Well, would you go into each practice and say – would you have an inspector go in and say, "Show us your policy for dealing with terminated employees"?

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

I don't think you're going to go into a large hospital and ask them to show you. Of course, that's not our job. That's ... policy....

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Okay. Well, all right, so help me understand what you see the mechanism for determining that something complies, just validates its incentive payment by meeting the meaningful use requirement for security for employee termination. How would that be determined?

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Now this is not this committee's job. This really is the policy committee's job, I think, on the certification side of things. But I suspect, I can't envision CMS going out to every hospital and every provider organization and saying, "Show us your policy, and show us your termination practices." I think it will be through attestation. I think there will be – over time, there will be forms that will evolve that will be available on the Web, just like there are today. There are forms for the HIPAA compliance available on the Web.

When a small, single, physician practice wants to develop a security policy, they go on the Web. They download a template, and they do that. That's the way they do their security policy. I think that that would be the same as what will happen here is that there will be standard – just attesting that that's what they've done.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Okay, so....

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

CMS, Karen, do you have...? I mean, how do you envision it? Do you think CMS is going to have a measure, you know, meaningful use police go out and make sure they've...?

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Go ahead. Answer that, Karen.

**Karen Trudel, CMS**

There are a number of different ways in the statute that meaningful use can be demonstrated, and attestation is one of them, and various other reporting mechanisms are available as well.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Just a practical note is that physician and working provider organization, a lot of things aren't necessarily things that are actively sought. Some things come up when there's a problem, and that's not the best

way to find them. Others, there's the deeming status of hospitals through joint commission and other entities, similarly for physician offices. So it would seem that this is something that would evolve, but what's really important in this train of discussion to me is that it is the practicality of the questions about the reality of adoption and implementation. What are the pragmatics going to look like? Later, those are questions that we're going to have to address in more detail.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Actually, the real answer to that is that the only – going back to what the policy committee gave us. The only real measure for meaningful use in privacy and security is HIPAA compliance, and that's the work of the Office of Civil Rights to enforce HIPAA compliance, so really that's what it all comes down to is how is OCR going to enforce HIPAA compliance.

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

And how the regulations specify that will be issued on this, specify ARRA compliance.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I appreciate that as a clarifying discussion. Thank you for that, and that is ultimately the authority of that and the ARRA-8 that are specifically enumerated. Marc Overhage – David, did you have another point, or was that your point? Okay. Marc?

**Marc Overhage, Regenstrief, Director**

At the right of another clarifying discussion, I'm going to cover Wes' ears, but I have my little tally sheet here. There were 14 times where we said "architecture neutral" this morning – one of the John's. XDR arguably is not an architecture neutral approach, and yet it's on our list. How'd the workgroup reconcile that?

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

XDA is on our list as well.

**Marc Overhage, Regenstrief, Director**

Yes, so how do we reconcile those two recommended? The policy says architecture neutral, and yet we're promoting a particular architecture.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I can make a first comment on that. That is that basically what we said was TLS with bilateral certificate exchange, and it could be entity-to-entity, EHR-to-PHR, HIE-to-HIE. You could go community-to-community, so it's XDR and Aetna are just basic transport mechanisms with certificates, not XDS, which implies a document registry and other things. XVA is cross community exchange, and so either of these are fine.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right.

**Marc Overhage, Regenstrief, Director**

Either/or.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Either/or, yes.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Yes, right, that's why I brought up the XD. Right.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Again, to the comment that Wes made about publish or perish. One of the things we tried to say is we just want to insure the data integrity of stuff, as it goes over the wire from place-to-place, and however you want to architect that topology, you should be able to. So we wanted to try to list the collection of standards that would enable push, pull, publish, subscribe, etc., and it's your implementation, either/or.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

In fact, that's why we went to the technical standards level on this.

**Marc Overhage, Regenstrief, Director**

So the key takeaway for me from this is, when I look at the grid, my first instinct is to say all the things in 2011, I must do.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

No.

**Marc Overhage, Regenstrief, Director**

And the answer is no. You must do – and it's not clear from the grid anyway which subset you have to do, but it's sort of like one from column A and one from column B.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

That's a really good point. Yes. SAML and XACML is another example where you could pick. Yes. We should try to make that clearer. Yes.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Other questions? Doug?

**Doug Fridsma, Arizona State University**

Just one real quick question: On some of these, so if we take a look at access control, there's four different recommendations, and I guess the clarifying here is that at least one of those has to be used. There's a bunch of these, though, that don't have anything listed in 2011, so was the discussion about sort of what we're supposed to do in 2011, or is that something that's outside of the purview? Some of the recommendations for the services that are supported don't start until 2013.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Well, the services supported are the criteria, so you have to provide RBAC by 2011. But the HL-7 version 3 RBAC permissions catalog is not required until 2013. It's kind of like a different way of saying what Jamie said with the options in 2011. There are options in the early years, but the services must be provided. Access control is required in 2011. Well, access control is a requirement of HIPAA, so it's required today, but the standards that we've specified are not required in 2011. Audit is another HIPAA requirement, so it's required today, but the standard isn't. ATNA is not required until 2013.

**Doug Fridsma, Arizona State University**

I guess the assumption then is that anything that's not listed in 2011, you would do sort of what people normally do, not necessarily standardized in some fashion?

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right, it would be proprietary, but it's still, everything on here is a HIPAA requirement or ARRA....

**Doug Fridsma, Arizona State University**

Sure.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

They are HIPAA requirements, so the function that is a HIPAA standard, but you have more flexibility in how you implement it in 2011.

**Doug Fridsma, Arizona State University**

So implicit is that if the service that's – service is supported, access control is required by 2011, and nothing is listed there, the expectation is that for 2011, you need to support those services, but they can do it in a proprietary way or however they'd like.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

That's right.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

And what I might recommend is let's take a look at Jamie did, and that is, if we break this into access control, audit authentication, and just simply say 2011 either/or and proprietary is allowed. But as of 2013, proprietary is no longer allowed.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Yes.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

It's the exact same material, just presented in your format.

**Doug Fridsma, Arizona State University**

That would be helpful.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Okay. That's a good comment.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Nancy Orvis?

**Nancy Orvis, U.S. Department of Defense (Health Affairs), Chief**

Yes. You could clarify that also by saying, as you said, required HIPAA functions, and then you could say you're going to have here are the options for the recommendations, so that everybody knows you've got to do some kind of access control, whether it's manual or proprietary at this point. But you will know then that because these are required by HIPAA, then eventually these standards will start coming into play. I think that would help that end user that you're saying, like security for dummies. You know, you'd start from, I've got to do this, whether it's some form or fashion. And then, oh, by the way, then these standards are going to come into play. I think that....

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Yes, what's really in this column, 2011 column is the standard that is in the security rule, so we could come up with exactly that. Here's the standard today, and here's – yes.

**Nancy Orvis, U.S. Department of Defense (Health Affairs), Chief**

It's a requirement, then you can do it this way or this, and then you will be mandated to do it by then.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Right. That's a good point. Yes.

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

John Halamka has promised to actually contract with the dummy people and write....

**John Halamka, Harvard Medical School, Chief Information Officer**

No problem. You got it.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Jodi Daniel.

**Jodi Daniel, Office of Policy & Research, Director**

...follow up on this, and going back to the conversation we had earlier with Jamie and John about the standards and certification criteria. Let me see if this makes sense in my way of thinking of this from a non-technical perspective that say you didn't have a standard that you were recommending for audit. Audit would still be required, say, as a certification criteria. But there wouldn't necessary be a standard tied to it. If there is a standard for audit that you're recommending for 2011, then there's both a certification criteria. The product has to be able to support audit functionality, and it must use the standard.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

That's exactly right. In fact, in developing our criteria and the standards for the certification, we looked at the CCHIT work. And if you look at their criteria, that's exactly what they are. They're not standards based. They're saying, here's what we're going to attest to. This is the capability you must have. That is the capability criterion, and then the standards are over and above that, more detail.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Go ahead, Nancy.

**Nancy Orvis, U.S. Department of Defense (Health Affairs), Chief**

I think what our discussion has brought up a really good point that I could see from various agencies and folks who have worked on the EHR system functional model for years saying that we already know that CMS will require that vendors and other organizations meet certain kinds of care setting profiles, and these access control, audit authentication are a part of required functions for an EHR system to do. And I think, if we can get to that point and eventually, as we go through evolution over the years, we'll say, okay. You have an EHR. You've got to do these four things no matter what. And as we find other things that we still have not attached standards to, we're still coming back to that universal set of functions for EHRs.

Does that make sense? Therefore, that would be how we could eventually chart and look at the next priorities and look at gaps and whatever. I still really want to keep using that functional model because we spent two years, and a lot of the folks in this room helped do that. But it is also where we're saying that for ambulatory or long-term care, whatever, you're going to say you're certifying a profile. I have to have. This is required in this care setting or it's an option. Okay. I think that would help us in our way ahead for this committee.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

That kind of practical experience is very helpful in framing the dialog. Thank you for that. Wes?

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Thanks. This comment is not specific to security. I think it applies equally to interoperability, and it reflects a lot of experience I've had over many years. You haven't specified the standard until you specify how to test it. If you do, and we had a great laboratory for showing this in the last few years under that old administration where HITSP was on a firm deadline to get out certain specifications. And at least two efforts that I was involved in, after they were out and delivered to the secretary, attempted to put them into play. One was the NHIN trial implementations, and the other was CCHIT for certification.

In both cases, I think we found it was a great starting point, but there were substantial clarifications needed. There were substantial. There were occasional things that might have been done differently. There's just no way to know, no matter how hard you work on a product or how much time you have from the written deliverable. I'm afraid we're in danger of making of the same mistake here of disconnecting the production of the standard from putting it into place and testing it, and it's a serious concern.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think your point is well taken. I'd like to come back to that after this discussion because I think it has incredible ramifications for the practicality of the real world implementation. There simply is a difference between theory and practice. In this sense, we're a bit of a dry lab. We need to learn from the web lab

where these are used, what part of the wet lab actually being how to test it, both theoretically or conceptually, as well as in the practical environment. Let's come back...

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

The real web lab is how to use it.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

That's right.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

But how to test it is just sort of an intermediate point along the way.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Exactly. It gets to this whole point that we've emphasized over and over today is the need for implementation and adoption and being able to make incremental refinements based on what's learned in the real world, and I think we need to think about how best to do that, as a committee. Recognized that just as you've heard from clinical quality and clinical operations that this is a glide path, and that it starts with a set of HIPAA required functions and then incrementally adopt standards, knowing that we will allow proprietary in the short-term. It will also provide additional functions.

For example, let's talk about consent. We all feel very strongly about consent. Consents are in here, recognizing that there are proprietary mechanisms for opt in and opt out today. And then in 2013, a basic consent, which includes electronic consent document exchange, so at least there is a mechanism for saying the patient signed this and agreed to this or that, but going forward after that, highly granular.

You might imagine that I don't want to share my medication list with you. Or I want to share three of my medications, but not other two with you, doesn't exist really in the standards world. Much work needs to be done. It's a gap. Consumer preferences is something that I know ONC feels quite strongly about, so I think you will see that as additional work to be done.

I think the spirit of what's being presented today is this is a roadmap. It is a set of requirements that align well with HIPAA, and it will be reformatted in a way that you can understand what are the either/or choices, and what are the options that were on the glide path.

**Steve Findlay, Consumers Union, Senior Healthcare Policy Analyst**

Well said.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Doug, were you--?

**Doug Fridsma, Arizona State University**

I was going to follow up on Wes' comment, but if we're going to table that and come back, then I'll comment....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Well, is it directly related to the privacy and security aspects or more broadly?

**Doug Fridsma, Arizona State University**

More broadly, kind of related to how we could feedback from the operational kind of implementation and certification back into the standards....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Let's hold on that and come to that a little bit later in the discussion. Thanks. Any other points of clarification, questions, discussion around the terrific work that the privacy and security group have done? Understanding the practicality that both Nancy introduced, the reformatting that John has described using what we'll now call the Jamie format as the iteration. Are we at a point where we accept...?

**Jamie Ferguson, Kaiser Permanente, Executive Director HIT Standard & Policy**

Large piece of paper.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Yes....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Are we at a point where we are at a consensus for accepting these recommendations moving forward? Are there any objections? Okay. Terrific. Again, let me thank you for that, and we look forward to that iteration in that format, which really provides clarity of the roadmap. Terrific work. Thanks.

You heard a theme that arose, particularly in this last discussion, but my notes through the course of the day that there is this sort of wet lab, dry lab piece, and to use Wes' terminology, the intermediate stopping point may be the certification. But beyond the certification for the moment, I think there really is the difference between what we intend to work at a conceptual basis and the experience of what is working.

For example, Janet Corrigan was queried, well, who is actually using these quality data today if we surveyed that. That would seem to be something that is not only important and potentially knowable, but actually knowable. A number of people on the committee said, okay. Doesn't part of our charter include implementation guidance? I think we're at a sort of transition point in the work of the committee. We've obviously been operating with certain, very tight parameters, as specified by the legislation itself in terms of providing information, material recommendations to the Office of the National Coordinator. But it's also been said, there's a lot of maintenance work that will go on, and so I see an evolution of the work on the three workgroups, as has been identified in terms of the 2013, 2015, and even some of the loose ends, the more modest for 2011.

The piece that we haven't yet tackled is the other piece of the legislation, the implementation guidance, which is part of the purview of this. To my mind, it seems that this is a missing link here, so I wanted to open it up for thoughts. One possibility is chartering a workgroup to really being to bring that sort of insight back to informing the other activities. Aneesh?

**Aneesh Chopra, White House, CTO**

Jon, that was a very thoughtful summary of the work of the committee. I just want to say upfront, this is essentially the same dichotomy in my service to the President, so we have long-term policy recommendations, but then we have practical announcements when they President said on Monday that I want to reduce the benefits backlog at the VA, and I want to find strategies that get it done now, not in some future budget.

And you saw in April of this year when the President stood and celebrated the fact that Secretary Shinseki and Secretary Gates committed to a lifetime electronic record that was not really a 2013 or a 2095 or whatever vision. It said, let's get this going. And I can tell you the sentiment of the on the ground folks, and I don't want to speak for Linda or Nancy, but their teams are hard at work daily, weekly, you know, so this notion that implementation guidance may be the right time for this committee to provide thought leadership is an exceptional one, and I would strongly encourage and endorse this brain power assembled to provide that kind of guidance, and would like to simply echo the fact that now is the right time. This is a very, very heavy lift for these committees to be celebrated, but to then be rewarded by the fact that now let's get onto the work of implementation guidance. And so, your notion of a working group, I would strongly encourage and recommend. I think you for your suggestion of that and the great work of the group.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you very much for that, Aneesh. There's been lots of discussion about privacy and security. Nancy was being very – I think you were being very circumspect and thoughtful when you said, well, we've kind of been doing some of this. Those are the sorts of things that I think need to inform the future discussions.

Does this sound like a pretty reasonable approach to everybody in terms of informing the next phase? I see a number of heads nodding on that, so a motion for it that we charter a working group to examine adoption and provide implementation guidance. Okay. Any objections? Great.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

I have a request ... Lisa and Wes have mentioned a couple times today about – correctly – the need to be very, very specific in order for organizations to truly be interoperable. If you get very, very specific, then you really have limited innovation, and you have limited change. Yes, you'll be interoperable, but you'll be doing exactly the same thing forever and ever and ever. And I think that when we speak about implementation, there needs to be – it needs to be thought through in terms of a feedback loop and how we maintain versioning over time, as the standards evolve. Versioning of our requirements, as we move forward, and as they do implementation and learn and learn. It can't be just, here's how you can implement it next week. It's got to be dynamic over time.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Terrific point. Thank you very much. Doug Fridsma?

**Doug Fridsma, Arizona State University**

This is the time I can now add my comment that I had before. I just want to echo what Dixie said, and that is, I think there is this tension between sort of getting it perfect and kind of getting it out there. I think we recognize that, and the way that we can kind of mitigate the problem of getting it out there and then actually being locked into – if we had set up standards for programming 20 years ago, we would all be writing in Cobalt, and that's probably not where we'd want to be.

But I guess the issue then is that what we need to begin working on as a committee is developing the processes by which we can provide feedback so that we make our recommendations. We assess how well we did in providing good guidance, implementable standards and things like that, and then make sure that those things feed back into the standards development efforts.

Other standards organizations have proposed standards that are not implementable, and it becomes really hard then to kind of move that process forward. I don't want this group to fall into that problem, and so we need to make sure then when we write guidance statements, and we assess how well we accomplished our job that when there are gaps or things that we haven't done right, that gets fed back into HITSP or it gets fed back into this committee where we can actually then make modifications and recommendations that allow us to continue to move the process forward. It's part of the standards maintenance process to make sure that what gets implemented gets evaluated, and that evaluation feeds back into the generation of new and better standards.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Terrific guidance. I've been purposely somewhat circumspect because I look forward to the committee helping to really flush out ... sort of de novo work. Their de novo work will inform initial observations, but also how it feeds back in an iterative process. Great points. Kevin Hutchinson.

**Kevin Hutchinson, Prematics, Inc., CEO**

This is actually in connection with what Dixie and Doug were talking about in the sense that these implementation guides, and I brought this up at, I think, the last meeting or the meeting before about how the importance of now taking these standards and putting them into these implementation guides. I would strongly encourage us to – we already have two working groups that most of these members were split between these two working groups. If we start a third working group, that we look at reaching out to other individuals that may not be committee members, but who have real world experience on what it takes to implement these kinds of standards or creating that documentation and approach to implementation because I think this committee appreciates it, but it's a lot more complex to take the standard and then build the guidance of how to implement that than one would expect.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think a terrific advice. Fortunately, the FACA process follows going more broadly for expertise in the workgroups. It's a terrific idea. Let's check down at the end, Wes?

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

I'm not sure whether we're talking about implementation guidance or implementation guides. Guides are documents. I think guide documents are great. I love documents. I spent my life on documents, but it's the process that I'm concerned about.

I think many of the things that we're referring to now as standards were originally written as implementation guides to interpret other standards that were looser. I'm not saying we don't need yet another level of granularity of implementation guidance, but I'm more concerned about the process we have talked about of refining what we think the actual standards should be. I mean, avoid the semantics about what's the standard and what's implementation guide. But refining how we really get to interoperability, how much we expect, how much we test, how much we certify.

I'd like to know before I vote what I'm voting for. If it's producing new documents called implementation guides, I'd have a different vote than if it's ... yes. Okay.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think we're really seeking to inform this process by real world experience, understanding where the pratfalls are and the opportunities exist to accelerate and corroborate what should be there and what the timing might be.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

I can give that a big hu-rah, and I'm glad because I was trying to figure out how to say hu-rah backwards a minute ago. Ah-ruh, I think it comes out. I am also concerned to respond to some comments that Dixie made, which is this implication that there is either standardization or innovation, but you don't get both, which is effectively what she said.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

That wasn't....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I'm not so sure I heard that.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

All right.

**Dixie Baker, Science Applications Intl. Corp., CTO, Health & Life Sciences**

Take it back.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

First off, I think we wouldn't have the Internet without some standardization.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Great example.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

We wouldn't have – we know from the history of the Internet that a major, multinational, multimillion-dollar effort to replace TC/PIP failed because of what I call frozen interface syndrome. We know that once we set standards, they become self-perpetuating. However, the things that ISO ... was supposed to meet were met within the TC/PIP community. It just took longer. We know that there are ways, if we think about it, to set up standards for healthcare interoperability that have the growth mechanism built in that

don't require you to replace them, to upgrade them, and I think that should be an important focus of this new committee that you're talking about.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Well said, and I think that's a fundamental thread of tension that you need enough clarity so that you can innovate within that framework. On the other hand, how do you keep that framework from becoming inherently limiting? I appreciate your ... that. Nancy?

**Nancy Orvis, U.S. Department of Defense (Health Affairs), Chief**

I wanted to endorse the clarification of what we're actually going to vote on too because I wasn't originally advocating that we had to start writing implementation guides in this group. I think one way to phrase the discussion would be this group could investigate ways that implementation advice can be developed in the future, and then come back with some – because we could also reach out directly to HITSP or to the SDOs or to various other groups to help do this, and not necessarily take the direct responsibility, but to help advise. So maybe investigate the best way to give implementation help. I mean, we could even set up a wiki and have everybody do their own advice and sign on and say here's my thoughts.

**Wes Rishel, Gartner, Inc., Vice President & Distinguished Analyst**

Yes. Terrific points. I tried not to be overly limiting in terms of this group because I think the group should have the opportunity to deliberate how they get real world reconnaissance to inform acceleration of adoption, and so it's not – there are others who can write specific guides, but this really is informing the process of implementation and adoption with an aim toward accelerating it and informing this process and the rationale behind standard, identification of standards, the timing of standards, and the refreshing of standards would be the way I would envision the feedback to this group.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

As an example, suppose that in the discussion we had this morning of SNOMED, ICD-9, and ICD-10 crosswalks that this committee, this workgroup, heard that. If you only had a completely standardized dictionary that did X, Y, and Z with those three vocabularies, life would be grand. Then that working group could recommend ONC, please commission NLM or some other group to create such a thing that would be very helpful to the implementation of these standards.

Another example, it may be that there is some ambiguity and some aspects of security, and that if only there was implementation guidance with much more granular detail, life would be easier. Well, would it be that working group or our committee who creates the implementation guidance? No. It would be the SDOs or HITSP or IHE or some group that is quite comfortable with the creation and maintenance of implementation guides that would take on such an activity.

But this group would be very important to monitor, is implementation happening? Are the standards we selected realistic? Do there need to be changes made or clarifications or other work products created? David, and then Janet.

**David McCallie, Cerner Corporation, Vice President of Medical Informatics**

It's David McCallie. We've got sort of two interdigitating threads here, and I'm going to skip back to the standards innovation thread that Wes just left behind and just add the additional thought that architecture can also be both inhibiting or facilitating innovation, so the Internet works because there were well chosen, perhaps brilliant, perhaps lucky – I don't know what history is going to judge – standards around HTML and HTTP. But there were also some architectural assumptions around a distributed model, etc. that in fact made it take off: DNS, a variety of other things that I would call architecture were critical.

As we approach health information exchange, I think we have a relative Greenfield of opportunity to be really thoughtful and careful about getting those standards and the minimum necessary architecture correct to see innovation flourish in that space in between our institutions. And I think, as we go forward, and health reform begins to address some of the cost issues, that's mostly going to happen in between our existing organizations. That's going to happen in the care coordination space, in the community, medical homes, etc. The opportunity is to get the standards right to see a flourishing environment for

innovation in HIT, and I think that's – we should really be careful not to over-specify, and not to under-specify to let that flourish.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Well said. Did you want to say something? Janet Corrigan?

**W**

Right along the same lines, I think there are a couple of groups that have done an awful lot of work in this area that I think we could benefit from, and it might be worth reaching out to them and even getting a couple of papers prepared before our next meeting. Clearly NIFT has done a lot of work in this area and are familiar with standards setting and innovation in virtually every sector of the economy. It would be worth looking elsewhere to see how this has been handled there.

The other group that's thought about this is at the National Academy of Sciences, and CTSG is the acronym. I think it's Computer Technology and Standards Group, or whatever. One could commission from them a workshop and a background paper precisely on these issues, just to take a look, scan the environment, see how it's done elsewhere, and then come forward with a set of recommendations ... at least learn from other sectors and other countries, frankly.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Appreciate the suggestions, and I think ... Office of the National Coordinator will have some work to do in terms of some framing, helping to frame what this process will – how it will evolve. Thank you very much for that. We'll take Linda Fischetti.

**Linda Fischetti, VHA, Chief Health Informatics Officer**

Thank you, Jon. I'm not like Wes. I'm okay with a little bit more ambiguity, so I would like to support this idea and possibly the way that we can phrase this is to send this adoption group off, as them to do an environmental assessment, see if there are existing resources that we can leverage. If there are not existing resources, then where would be the appropriate organizational entities to stand that up? And also look at adoption of standards related to those who have not yet adopted EHRs, those who have adopted EHRs five to ten years ago, and are dealing with legacy systems, which is very different, and also consumers as well to make sure that we get the consumer opinion captured in this.

I do support the idea of this workgroup. I think we should time limit them and have them come back with, do they have airspace to function in, or will they be redundant with systems that are already out there? At which point they can just shut down, and we'll have a place from which we can consume the same information.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you very much. Well framed. Kevin, did you?

**Kevin Hutchinson, Prematics, Inc., CEO**

I'm good now.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Okay.

**Kevin Hutchinson, Prematics, Inc., CEO**

Great minds think alike.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

I think that as so well said that, in essence, that really is a motion to frame it. I don't think I could do it justice by repeating it, but we have consensus around the way Linda framed – terrific. Any objections? Great. I think the other thread that we also want to refer to the Office of the National Coordinator is the general guidance of this committee that there is a sweet spot between too great stringency and specification and adequate specification and deviation too far to either side would hinder innovation, and I

think that is the fundamental challenge of this process, so I appreciate the just incredibly thoughtful discussion around that.

Before we go to a public comment period, are there any other issues that anyone would like to move forward for the good of the order? John Halamka?

**John Halamka, Harvard Medical School, Chief Information Officer**

I think it's been a remarkable day, and the quality of the presentations are extremely high. They interdigitated so very well, and I feel like we, in the next several months, will continue to refine and enhance and educate and now work on implementation and constantly gain feedback from our environment so that the work products continue to be very, very useful in the next two years, as EHRs and interoperability and HIE are being implemented, and really look forward to now going beyond what was the get the basics right, and now begin the polishing.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Well said. I cannot adequately express my appreciation, and that's not just to the people at the table, but all the people in the workgroups. I should have tallied up the number of person hours that have been invested. Thanks to the Office of the National Coordinator, David Blumenthal, as I think people know, is traveling with the secretary today and, in fact, speaking about health information technology, and the concept of innovation.

**Aneesh Chopra, White House, CTO**

The release of the money....

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Yes. Aneesh, why don't you bring us up to date on that?

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

\$1.2 million, I think, was just announced today, and he's traveling also with Vice President Biden, who made the announcement.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Terrific, terrific, and so congratulate that work and appreciate.

**Aneesh Chopra, White House, CTO**

Yes. Today was the day we launched the announcement for the state based HIE components, as well as the RITECs.

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

The regional extension centers.

**Aneesh Chopra, White House, CTO**

Yes. Forgive me for acronyms.

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

That's okay.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

So it is a landmark, a banner day in many ways, and I think the other word or maybe the theme of the day is convergence, so when policy and the practicalities get together, this is a very exciting moment. Let us then stop here and adjourn. Much work ahead, much accomplished, and as we segue to public comment, two things. First, many thanks for all of the input that has been a terrific resource to the workgroups and committees deliberations, it's just been extremely helpful. And ask for anybody either online or who is in the room to please feel free to make a statement, but limit to two minutes. If you'd

identify yourself and your organization, that would be most helpful, so let us then move to public comment period. Thanks very much to all of your hard work and diligence.

**David Tao, Siemens Health Services, Interoperability Champion**

Hello. David Tao from Siemens. I also volunteer with CCHIT and HITSP. I commend the committees and both policy and standards for how clarity has been increasingly raised at each meeting. There is one area, maybe two brief areas I'd like to comment on.

One is that speaking, I think, for a lot of people, they're concerned about is there a clear signal that they can really go forward with this, as has been approved today, as well as the policy committee, in light of the fact that these recommendations to ONC, and then there's also the CMS rulemaking process. Concern about if we go with this, how much could change for one way or the other over a several month period that could throw everyone out of whack if they start developing. Can there be assurances given that this is really definitive guidance for vendors and hospitals and providers to go forward based on this? How much wiggle room is there still left, and how long would that be?

The second is, I look forward to the Dixie and Jamie format all combined in two big pieces of paper. Would it be correct to say, and my interpretation would be that if you look down the 2011 columns of both of those, that those would be the certification criteria, not the final testable scripts, but the certification criteria for products that would get started later this year perhaps with the preliminary certification per the certification workgroup recommendation? And that would be my assumption based on what I've heard. If that's not correct, it would be helpful to have some clarification from the committee as to whether those are really the certification criteria, with the only details left to be how you test it. Thank you.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Jodi Daniel?

**Jodi Daniel, Office of Policy & Research, Director**

Yes. Let me make some statements to that regard. The recommendations that come out of the policy committee and this committee, the standards committee, are recommendations from an advisory committee to HHS, so they are not HHS policy, but they are advice to us on policies that we should adopt. We, both CMS and ONC, will be going through rulemaking. CMS will be doing rulemaking on the incentives program, including defining meaningful use for qualifying for those incentives, and ONC will be developing regulations on standards and certification criteria. Both of those are anticipated to be released in December of this year.

The standards and certification criteria that ONC will be releasing in regulation will be interim final, which means that they are final when they are published in December, although we will be accepting comment on them and may make some refinements if we feel that it's necessary based on comments. At this point, we will be looking very closely at the input from this committee. There's been a lot of amazing and incredible amount of time and effort put into the thinking here, and we are both expected to by our statute, as well as intend to look very carefully at the recommendations coming out of this group and giving a lot of credibility to those recommendations.

Will the policies that come out of HHS be identical to what you see here? I can't say whether they will or will not. I can say that we will be looking very closely at them, and we'll likely explain if we do not go with recommendations, with a particular recommendation that comes out of this group because of all of the work that's gone into it and the input that we've received. I can't advise what folks should do as far as development. That's a business decision. I would say that we will look at the committee recommendations very carefully, and that our final – HHS's policy on this will be released in December.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thanks.

**Dmitry Orlov**

Can I speak?

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Yes. Please. Yes. Good afternoon.

**Dmitry Orlov**

My name is Dmitry Orlov. I represent myself. I'm a professional ... information ... information technology, and applications in particular for medical needs. But my remarks are basically based on common sense, and I appeal to common sense of all of you. So I need to make five points very shortly.

Number one, the most dangerous for any innovation, new technology progress is over-standardization and over-certification, and you must be very careful not to create barriers for real innovation in your activities. What is necessary to certify, it's ... certify professional level of doctors, and unfortunately no one speaks about this because, of course, information technology is very important. But the most important is doctors in healthcare, and it's absolutely necessary to recertify medical specialists, professionals each five years, especially for rural areas.

Point number two, I am not sure that it's necessary to standardize each EHR because each meeting of physician with patient is creative art. You cannot standardize how to write novels or create poems. It's ridiculous from my point of view, from common sense point of view. Whatever doctors need to say, he must say without any restriction. He is a professional. We trust him because they are certified professionals.

Number three; I don't see any specificity in privacy or security for medical point of view. We trust financial transactions. It's no problem at all. You create problems with nothing. It's no medical specificity because if you have digital information technology ... available to secure and to protect ... President with Afghanistan on a secure line. What's the problem?

Number four; unfortunately, I don't listen anything about telemedicine, and its information ... health information technology, and it's maybe the most important information technology. Without telemedicine, you never achieve the highest level of medical care for everyone independent of presidents, financial status, and all this stuff.

And finally, my fifth point is very simple. Will all due respect to all of you, I don't understand why among you know representative of NIH and Drug and Food Administration. If you try to standardize ... medical care, how can you do this without the voice of these organizations? Thank you very much.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you for your comments.

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

There's one person on the phone.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Let's take a call on the phone. Is there one on the phone?

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

There's one on the phone.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

We'll do that before we do the next ... tee up the phone. Go ahead if there's a caller who had a question. Okay.

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

Move on.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you....

**Ardee Kazerian, ICSA Labs (Verizon Business)**

I'm Ardee Kazerian. I'm with ICSA Labs, which is an independent division of Verizon Business, and first off want to thank you guys for doing such great work, so we've been following your progress, and you guys have done a lot in a really short amount of time. I also want to let you know that ICSA Labs has been actually certifying thousands of products over the last 20 years, and the reason why I'm here is because we're actually looking to possibly do some certification in this area, so that was it.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you very much for your comments. Are there other comments that were on the phone? Okay. Well, again, many thanks to everyone who stayed through a very long meeting. I hope that the deliberations were useful to all in the room. They certainly were to me and thank all members of the committee again. We are adjourned.

**John Halamka, Harvard Medical School, Chief Information Officer**

Extraordinary work.

**Jonathan Perlin, Hospital Corporation of America, CMO & President**

Thank you.

## **Public Comment: HIT Standards Committee Meeting August 20, 2009**

1. It's good to have architecture neutrality for internal usage. However for the interoperability, communicating with labs ... have open source implementations be provided so there can be used or help other implementers on exact implementations -As an example - java provides both specifications and reference implementations
2. Will CMS be ready for 2013 to use SNOMED CT only? Standards Committee slide says that starting in 2015, only SNOMED CT is allowed. Why go through all the upgrade to 5010 and ICD-10 if ICD-10 will not be accepted after 2015? And just to make it clear, in 2013 and 2014, both SNOMED CT and ICD-10 are allowed. Starting in 2015, only SNOMED CT is permitted. Is this correct?
3. Does exchange mean the physical exchange or is a mechanism for viewing clinical data from other EMRs/PHRs/systems be sufficient?
4. Why are PDF and free text NOT ALLOWED past 2013? These are still useful to communicate data that is not otherwise profiled. I certainly can understand why they would not be recognized toward meaningful use, but to forbid them seems extreme.
5. For the MU Grid element of Medication Dispensed - is this the date the pharmacist filled the prescription or date that patient picked up the prescription (in the ambulatory setting)? If a patient does not pick up a filled Rx, how will this be factored into the data set?
6. In the grid for data elements, medication administered is mapped to data type SCRIPT or HL7. Both of those are messages for data interchange, not data as a mechanism to record the administration of medication. Please explain how you think this might be used.
7. When NPPs make home or RCF visits, they must bill under their own NPI which precludes attaching a PQRI Measure to the supervising physician (since they are not seeing patients without "in the building" supervision required for "incident to" billing; hence the system does not

attribute the PQRI Measure to the physician (as I found participating in the MCMP Demo). How can physicians using NPPs in a medical group that makes home visits capture data on their patients seen by NPPs and billed under the NPP NPI?

8. Will specialists like Optometrists or Ophthalmologists be required to incorporate documentation of measures like BMI, immunizations, and evaluation of Asthma?
9. Comment to HIE WG: Much work has been done with IERs, to include the use of domain-based ontologies, services and smart agents that could really assist in developing "core" exchange requirements/templates. I can be of assistance in speaking to much of this.
10. Vice President Joe Biden and Secretary Sebelius will also be making a major announcement regarding the availability of grants worth nearly \$1.2 billion to help hospitals and health care providers implement and use electronic health records. I am a business that would like to get a list of who is applying for and receiving money, so I can approach them and see if I can help them implement their EMR system. How do I get that information?
11. Please consider in-home settings for Quality Measure denominator qualification: e.g. Med Reconciliation Measure 24 is restricted to post discharge encounters "in the office"
12. Self attestation seems to be a viable way to augment the qualifying process of MU. There is not much time to calibrate how every EP would provide electronic proof.
13. What is our Health IT Architecture? How do National, States, Local, Providers and Regional exchanges fit into this architecture? What aspects are common elements in this HIT architecture, what are different?
14. Will HIIPA compliance also be validating all of the HIT Privacy and Security Standards? Seemed to me that HIIPA is much focused security aspect. How will HIT Standards committee ensure that enterprises adopt and use the recommended right standards?
15. What is the process and procedure for termination is that answer Policy, process and procedure all three to comply the security?
16. Meaningful use regarding security--universal symmetric encryption of PHI "at rest" has significant practical challenges wrt. key management. However, protecting the integrity of all PHI "at rest" using one-way secure hash functions does not have the same challenges and should be a required demonstration of "meaningful use".
17. It seems that Certification is only focused on HIT Vendor Products. Certification is assuming that most enterprises will be buying HIT certified products. There are several potential gaps in this assumption: Most enterprises may build or customize solutions internally due to many factors. Even when certified products are purchased, these might be customized or configured different or some features may not be used at all. It seems that focus should be on irrespective of whether enterprise are using purchased products or custom solutions.
18. Most enterprises and organizations build systems rather than buy. What is the national HIT strategy for organizations that build systems to be exchange HIT data interoperability. Seems that this is a key aspect that needs to be addressed otherwise, many organizations may not use or adopt the new approved HIT standards.
19. How can HIT technology architecture neutrality be fully achieved through a combination of HIT standards, interoperability specifications. What are minimum architectural requirements?

20. HIT Standards committee has made great progress on Interoperability. This is very key aspect fro HIT systems. Many organizations, programs, groups have not even begin the process of understanding and identification of interoperable HIT constructs, specifications and standards.
21. What standards are recommended for interoperability of exchanging evidence based order sets?
22. My question is, from my research i gathered that CMS will be the oversight regarding incentive disbursement for EHR adaptors who met the "meaningful use" criteria. By law when is CMS required to release the guidelines for "meaningful use"? How would the delayed release impact the timeline set forth by President Obama's administration?