

HIT Standards Committee Transcript September 15, 2009

Participants

John Halamka, Chief Information Officer, Harvard Medical School
Jonathan Perlin, CMO & President, Hospital Corporation of America
Sharon Terry, President & CEO, Genetic Alliance
John Klimek, VP Industry Information Technology, NCPDP
Karen Trudel, Deputy Director, Office E-Health Standards & Services, CMS
David Kates, Vice President Product Management, Prematics, Inc.
Judy Murphy, Vice President of Applications, Aurora Healthcare
Stan Huff, Chief Medical Informatics Officer, Intermountain Healthcare
Elizabeth Johnson, VP Applied Clinical Informatics, Tenet Healthcare
Doug Fridsma, Assoc. Prof. Dept. Biomedical Informatics, Arizona State
John Derr, Chief Technology Strategic Officer, Golden Living LLC
Linda Fischetti, Chief Health Informatics Officer, VHA
Jamie Ferguson, Executive Director HIT Strategy & Policy, Kaiser Permanente
Janet Corrigan, President & CEO, National Quality Forum
Christopher Chute, VC Data Gov. & Health IT Standards, Mayo Clinic
David McCallie, Vice President of Medical Informatics, Cerner Corporation
Marc Overhage, Director, Regenstrief
Anne Castro, Chief Design Architect, BlueCross BlueShield South Carolina
Wes Rishel, Vice President & Distinguished Analyst, Gartner, Inc.
Jim Walker, Chief Health Information Officer, Geisinger Health Systems
Floyd Eisenberg, Physician Consultant, Siemens Medical Solutions
Aneesh Chopra, CTO, White House
Gina Perez, Executive Director, Delaware Health Information Network
Lee Jones, Program Manager, HITSP
Jodi Daniel, Director Office of Policy & Research, ONC
Judy Sparrow, Office of the National Coordinator

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the fifth meeting of the HIT Standards Committee. Just a reminder, this is a federal advisory committee, which means it's being held in the public, and it's being broadcast over the Internet. Committee members, just make sure that you include your name as you speak for proper attribution in the minutes. The public will be invited to make comments at the close of the meeting.

And, in fact, it's a little bit different today. We're asking for the first 15 minutes of public comment on the meeting today, and then we're going to take about 20 to 30 minutes for any comment you might have, you in the room or on the telephone, comments on the recommendations from the standards committee from last August, from August 20th, and this is per the ARRA, the American Recovery and Reinvestment Act. The act states that we need to provide for public input on the recommendations from the standards committee. With that, I will ask each member in the room to introduce yourself, your name, and your organization, and if you see that you've got any conflict, yes or no, on the agenda today, and I'll begin with Sharon Terry.

Sharon Terry - Genetic Alliance - President & CEO

Sharon Terry, Genetic Alliance, no conflict.

John Klimek - NCPDP - VP Industry Information Technology

John Klimek, NCPDP, no conflicts.

Karen Trudel - CMS - Deputy Director, Office E-Health Standards & Services

Karen Trudel, CMS, no conflicts.

David Kates - Prematics, Inc. - Vice President Product Management

David Kates, Prematics, no conflicts.

Judy Murphy - Aurora Healthcare - Vice President of Applications

Judy Murphy, Aurora Healthcare, no conflicts.

Stan Huff - Intermountain Healthcare - Chief Medical Informatics Officer

Stan Huff with Intermountain Healthcare and the University of Utah. I have no financial conflict, but I'm closely aligned with HL-7 and with LOINC.

Elizabeth Johnson - Tenet Healthcare - VP Applied Clinical Informatics

Liz Johnson, Tenet Healthcare, no conflicts.

Doug Fridsma - Arizona State - Assoc. Prof. Dept. Biomedical Informatics

Doug Fridsma, Arizona State University, no conflicts.

John Derr - Golden Living LLC - Chief Technology Strategic Officer

John Derr, Golden Living, I am a commissioner with CCHIT as well.

Linda Fischetti - VHA - Chief Health Informatics Officer

Linda Fischetti, Veterans Health Administration, no conflicts. I'm on an elected board of directors on HL-7 and a federal liaison to HITSP board.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Jamie Ferguson, Kaiser Permanente, HITSP board, but no conflicts.

Janet Corrigan - National Quality Forum - President & CEO

Janet Corrigan, National Quality Forum, no conflicts.

John Halamka - Harvard Medical School - Chief Information Officer

John Halamka, Harvard Medical School, no financial conflicts. I do serve on the board of Envita Health and I do belong to a provider organization.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Jon Perlin, Hospital Corporation of America, I have no conflicts. I would note that I am faculty at Vanderbilt University and board member of National eHealth Collaborative.

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

Christopher Chute, Mayo Clinic, I am on the board of CDISC, can chair the board of bridge, no conflicts.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

David McCallie, Cerner Corporation, an HIT vendor company.

Marc Overhage - Regenstrief - Director

Marc Overhage, Regenstrief Institute and Indiana Health Information Exchange, no conflicts.

Anne Castro - BlueCross BlueShield South Carolina - Chief Design Architect

Anne Castro, BlueCross BlueShield of South Carolina, no conflicts.

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

Wes Rishel, Gartner, no financial conflicts. I'm a trustee of CCHIT.

Jim Walker - Geisinger Health Systems - Chief Health Information Officer

Jim Walker, Geisinger Health System, no conflict.

Jodi Daniel - ONC - Director Office of Policy & Research

Jodi Daniel, ONC.

Judy Sparrow - Office of the National Coordinator - Executive Director

And do we have any members on the telephone line, please? Okay. With that, I'll turn it over to Dr. Perlin.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thank you very much, Judy, and good morning, everybody. Thank you so much for your participation. As we start, I want to reflect on some of the progress to date. But first and foremost, acknowledge the participation broadly. We received a great deal of public comments in terms of letters on a variety of topics, and those are much appreciated. Please know that Judy Sparrow absolutely assures that those get to all the committee members for their review. They become part of the record and part of the consideration, so we very much appreciate that input.

We thank, as well, the members of the committee and the workgroup for the continuing efforts. It's been, in some ways, a very fast summer, but in others, a very long summer. A lot has been accomplished, and I think it was very nice to culminate some of the prior work and the transmittal letter to David Blumenthal, Dr. David Blumenthal, and his capacity as the national coordinator for health information technology. In short, that transmittal memo described simply what we had approved at our last meeting, and that was discussed in this foray, and so that is in the hands of the national coordinator for their consideration, consistent with really the direction provided in statute by the HITECH portion of the American Recovery and Reinvestment Act.

Today, as we move into the agenda that we have some work to do in and around the three workgroups – clinical operations, clinical quality, and privacy and security – that is refining and accretive to the work done thus far. But this meeting really should be the beginning of a change in tenor from speaking and refining simply what we've done to really be getting, particularly in the second half of the meeting after the break, to probing and understanding the way in which we can be most effective in terms of providing guidance and input around implementation.

One of the themes that's been really driven home to John Halamka and myself over this period of time is that that sort of guidance doesn't accrue from the committee. It accrues from real world experience. We understand and appreciate and agree that this next phase of our really promulgating information around implementation specification really has to be based in that experiential framework of what has worked in order to realize the ultimate objectives of this entire effort. Not simply promulgating health information technology, but promulgating health information technology as an underpinning for more effective, safer, and higher value healthcare, and so that really will be the thrust of our transition and look forward to the committee's input, to input n testimony that I know we will seek in the future on implementation, and indeed the public comment on implementation.

This really is, for those who have felt a heavy lift of the past few months, that is absolutely true. Your efforts are greatly appreciated, but this is not the beginning of the end, as Churchill said. It is the end of the beginning, and a transition really to consideration of how we can collectively be effective, rational,

supportive, and motivated in terms of translating not only standards, but the opportunity of moments to advance technologies in the support of improved healthcare.

With that, let me invite my co-chair, John Halamka, for introductory comments. Again, thanks to all for your hard work, your participation, especially to the broader community who provides comments. As always, as Judy identified in this meeting, and in all of the fora that are part of and should be part of this deliberative process.

John Halamka - Harvard Medical School - Chief Information Officer

Thank you, and good morning, everybody. I think the key theme of today's meeting is implementation guidance. What we tried to do over the success of meetings, the HIT Standards Committee, is get more and more constraints, more and more granular. So we started off with naming some standards, some base standards, and it's just not sufficient for implementation to occur, for interoperability to occur by just naming a standard, saying, oh, we'll use HL-7 this or NCPDP that.

You need to have the guidance to say how. What vocabulary and code sets? How do you constrain it? How do you insure there's enough guidance that two vendors creating a product can create interoperability without a huge amount of expense or customization? You'll see each of the workgroups has diligently tried to be as specific as possible.

So in the quality workgroup, you'll see there are 29 measures of which 2 are privacy and security, 10 are more about meaningful use measures and to how a product, an EHR is actually implemented, and 17 you'll hear about are quality measures that are being retooled to be EHR specific, so some excellent, very specific work there. And Floyd will present a taxonomy for how you get quality data exchanged, and this is really interesting work because when you get to actual implementation, think about this. You might have a provider with an EHR, and there might be a health information exchange in a community, and there might be a quality registry function, whether that's a company or a community effort. And then there's CMS.

Oh, wait a minute. It isn't just a provider sending a spreadsheet to CMS. It's actually the data transmission that might occur among all these stakeholders, and there may be different standards. It may be patient identified, line item data from the EHR to a registry. But then it may be rolled up, numerators and denominators that go from a registry, through reporting to CMS. So we need to think through all that complexity, so you hear about some of that.

Privacy and security, unfortunately, Dixie's person antivirus software has failed, and she can't be here today, so you'll hear from David McCallie. You'll see some very significant implementation guidance around some of these privacy and security constructs, and I think the important thing that was done from your advice last meeting was to be extremely clear in putting these matrices together. What are the ands and what are the ors because, I think, Marc, you made the comment. Wait a minute. I'm looking at this list, and you've given me 27 things. I need to do all 27 of them, or can I do just one? And so you'll now see there are two matrices to be presented: one that includes the name standards, one that includes the implementation guidance, and real clarity as to the ands and the ors and all the options for implementers.

Then we'll have a conversation that will include Jamie presenting the work of clinical operations, but also Lee Jones from HITSP talking about how some of the implementation guidance has been developed over the last many years at HITSP and then incorporated into some of the clinical operations workgroup deliverable. So you'll see there what are the specific functions and then what are the named standards, and what's the implementation guidance and 2011, 2013, and 2015 milestones.

One of the challenges, and David Blumenthal has said this to us before. You can't have an escalator that moves too fast because otherwise people will fall off. And so I think one of the challenges and so much work has been done by the operations committee is providing enough granular implementation guidance that shows you how to get on the escalator and how to have a glide path that is smooth because this does allow, early on, some optionality saying, although directionally we want to go to perfection, here is what you can do along the way to get there, and to provide the clarity of how that's going to happen, but

still foster interoperability. It's been tough, so I think what you'll see in Jamie's work, although the named standards haven't changed significantly, the implementation guidance has doubled in volume, so there'll be some enhanced clarity there.

Then we will talk about some next steps. I mean, this afternoon, after our break, I think it's very important that we keep an agenda going forward that doesn't lose momentum. As you've said, this isn't just, oh, we're done. Here's a nice stack, and now let us polish. In fact, what we need to do is go beyond this, especially, for example, in areas of consumer consent. I mean, there are gaps for 2013 and 2015, and we need to keep an eye on all of the things that we will want to do next, and we will be getting all of your input after the break so that we keep an agenda going and keep this very engaged committee, so I look forward to the day.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thank you, John, for that more detailed overview, and ... my thanks to Dave McCallie for stepping in for Dixie, and so to follow up with your metaphor, let's hope she reboots successfully.

John Halamka - Harvard Medical School - Chief Information Officer

Yes

Jonathan Perlin - Hospital Corporation of America - CMO & President

So much for strained IT metaphors. We have the minutes. I trust everyone had a chance to review them, and let me thank the national coordinator for what I think is very sensitive and thoughtful summary of our last meeting. Any amendments, clarifications, or recommended changes? By consensus, we'll consider those minutes approved, and we'll move into the first order of new business for the meeting, and that is to discuss meaningful use quality measures. I appreciate Janet Corrigan and Floyd Eisenberg's discussion of this topic.

Janet Corrigan - National Quality Forum - President & CEO

Thank you, Jon. The clinical quality workgroup has a relatively short report today. Since the last meeting, we had an opportunity to update the measure grid, and you have a new copy of that distributed to you today, which essentially reflects the various edits and issues that were raised at the last meeting, as well as those raised in public comment, and I think a careful double checking back to the policy committee's measures and a variety of clarifying issues.

What you find there is that at this point, we essentially, the policy committee had a recommended set of 29 measures. In fact, if we could go to the first slide, please, 29 measures, and 17 of those – thank you, Floyd. Seventeen of those measures are performance measures that are NQF endorsed and will need to be retooled with specifications developed for electronic health records. About ten of those measures are measures of EHR utilization. Those are things like percent of patients with access to PHRs and percent of orders entered through CPOE. Those are ones that there's going to have to be some form of attestation during the 2011 period. Then there are two measures that are coming from the privacy and security workgroup, so that's pretty much where we are.

Now we anticipate that the measure retooling will begin on or about September 21st, we're told. Once there's been a little bit more vetting of these particular measures, we expect that HHS will move forward with the measure retooling, so those measures have been respecified by the end of the year.

The quality workgroup also spent some time on an issue that essentially, I think, bubbled up in Jamie's workgroup that had to do with the measure submission workflow, and essentially that is what John was referring to in his opening comment. How does the data, whether that is individual patient level data, or whether it's summary data, the data that is needed that are needed to calculate the quality measures and to report out on them, how does that flow from the EHR to whatever entity or entities are involved in that process.

Its meeting on last Thursday, our conference call of the quality workgroup, we began to kick this issue around a little bit, and I think made some substantial progress. Doug and Marc were both very engaged

in that discussion, along with Floyd and myself. And then there was a small rump group that was formed that had a conference call on Friday that include individuals from both the operations and the quality workgroup to begin to think through a framework for how to tee up this issue for discussion by the standards committee today. And Floyd is going to speak to a diagram that was developed by that group as a way to help get everybody on the same page, so we can discuss this in more detail at this point.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Sure. Thank you. Actually, I want to give credit to some of the commenter's to the HITSP ISO-6, the quality, interoperability specification where the comments indicated that it wasn't very clear on what the workflow is. It's all there, but it was hard to read. And that's where this drawing actually started.

On Friday afternoon, 1:00 to 3:00, we then pulled it into our small rump group for this committee and modified somewhat and simplified it. So the object is thinking about what is the flow of data and what is the interoperable component, which is what this committee needs to be looking at. The first piece is the measure being sent to the EHR. We're not asking for the measure to be incorporated in the EHR, but just sent so that it could be read and understood.

And you'll see each of these arrows – and I'm sorry, some of them are a little faint on the slide – are numbered, so the first is transporting the measure. The next piece is that the EHR – there may be many more than one EHR – takes that and does something with it to capture data in the clinical workflow. That data is then used by a data collection assistant in order to pull together all the data on each patient to make sure that everything is there related to the measure.

For that purpose, if these data collection assistant might be a registry, might be a health information exchange, and might be an external database, third party vendor. There are other options. It also might be incorporated in the EHR. So if you'll see, a lot of different boxes on this drawing, the first transaction only occurs in interoperability if in fact that data collection assistant is a separate entity. Otherwise it's part of the EHR and occurs within the same system.

The next step is that some organizations, specifically CMS and the joint commission, certify processing entities to verify the data are correct and prepare the data for submission to the receiver, to CMS. That processing entity then needs the patient level data to be able to verify it, make sure it's correct, ask questions about it, and make sure that that is in the proper format to then submit to the receiver. So you'll see transactions three is the data specific to a quality measure is sent to the processing entity. That specific data formatted, as required by the receiver, is sent to the receiver. Sometimes at the patient level, sometimes a very summary data, meaning how many are in the denominator, how many in the numerator, how many exclusions, how many exceptions, what is your overall performance percentage wise or what is the average time if it's a continuous variable. For instance, what's your average wait time in the emergency department?

But the processing entity could also be part of the same as the data collection assistant, and in that case there's no transaction between them. It's one organization. The same might actually be true of the EHR, the data collection assistant and the processing entity. So the reason for trying to draw the different types of architectures is when multiple components are in one architecture, the transmission standard isn't something that is in the committee's purview, as I understand it. When they're separate, it is. So we do have to understand what the transport is for each of these different items within the flow.

So what our intent was is to pass this back to the committee and have a discussion since this was a small group. It wasn't the full quality workgroup or operations workgroup, but a small number from each, to look at the standard selected and help to guide for a roadmap.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thank you. Thank you very much for those comments. I'm sure each of us, as we're processing this diagram, we're thinking about, in our frames of reference, how would this actually work, and quite appreciate your inviting discussion on that point, so let's indeed open this for discussion on our consideration of this data flow. John, any introductory comments you'd like to...?

John Halamka - Harvard Medical School - Chief Information Officer

Sure. We'll hear, during Jamie's discussion, some of the detailed standards around content vocabularies for some of these, but one of the things I think is a challenge is that the standards to do these various detailed and summary submissions are at various levels of maturity. And so I think you'll hear this afternoon, one challenge is it's clear that 2011 requires quality data submission as part of meaningful use, and depending on how you architect that, we may or may not have completely mature standards, so what do you? Do you, in the meantime, temporize? But if you do that, that may suggest that vendors and hospitals have to actually go one direction for one year and then change direction two years from now, and that's not desirable. So I think the committee and its workgroups, making sure that that path that gets us to nirvana is as smooth as possible, will require a lot of effort.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I just would reflect that in addition to thinking about the continuity of standards, both for a coherent data flow to answer particular quality metrics, as well as to project, as John suggested, a longitudinal progression that allows, as painless as possible, an evolution of architecture needs to be defined. The other is that at a very practical level, wondering, and I'd be interested in my colleagues thoughts on the actual ... standards then the technologies that would be used to do this.

I mean, for example, you made the point, Floyd, in that box where one or more EHRs, which may have the inherent capacity to perform the functions of the data collection assistant, or there might need to be another technology. Perhaps it's a registry. Maybe it's a data analytic warehouse or something of that sort. I know that the current state of play may require multiple approaches for a variety of metrics because, of course, registries are one sort of answer usually to a monolithic set of questions, and so it may actually require multiple pieces. I appreciate the elegance of the presentation. As we consider the messy bits of the implementation guidance, I think these are the sorts of questions that the broader environment, which we hope this to take traction, will be asking.

My question for consideration of the group is not just with respect to the standards, but did the standards that we're offering to this process bode for a process that allows not only the metrics to be answered, but a longitudinal progression, as John identified 2011, 2013 and forward. I see Jim Walker has his card up. We'll start there.

Jim Walker - Geisinger Health Systems - Chief Health Information Officer

Is this a measure reporting workflow? This really only addresses measure reporting.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

This does address measure reporting. The purpose though for drawing it as it is, is part of the measure enterprise, and I'll go back to the use case that drove the HITSP effort was that the EHR having implemented functions around the measure should have the ability to show some not necessarily real time, but near real time performance evaluation to improve performance as care is delivered rather than waiting until it was reported and, the end of the year, you know what to change. In order to do that, that's why it could be that the EHR and collection assistant – I purposely didn't call it registry or HIE. I just gave that as examples because that's more of the function – may be one thing to be able to do that feedback loop internally, and so that is why that's in the picture, although...

Jim Walker - Geisinger Health Systems - Chief Health Information Officer

So that's what I wanted to address then is that this could be read, if this were going to be published, this slide, this could be read as saying it's sort of optional whether measures are built into the EHR. And I just think we want to guard against that. We want to make sure that everybody understands that at some point down the road, for practically everybody, the efficient way to do this is going to be to have an EHR that prompts the appropriate actions and captures the appropriate data in that process of care and reports it automatically, and this could be read as saying it really doesn't matter if it's in there. You can have it anywhere you want.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

That's an excellent point, and I realize there are many colors in that slide, but the EHR and data collection assistant, I think, to manage just what you talked about, whether it's an interoperability with a third party that does it with EHR or the EHR alone, should be performing that capability is the way I would suggest....

Jim Walker - Geisinger Health Systems - Chief Health Information Officer

We might even try to draw this so that it's a clear trajectory, sort of the, you know, ICD-9 or SNOMED in 2011, ICD-10 or SNOMED in 2013, and 2015 it's SNOMED so that it's clear to people that the end game is to get in the EHR in almost all cases.

Jonathan Perlin - Hospital Corporation of America - CMO & President

(Inaudible)

Janet Corrigan - National Quality Forum - President & CEO

Yes. I think, I guess the one issue there is there are some instances where we have complex measure systems. Some of the registries, like STS registry, that has very elaborate risk adjustment mechanism, and they're proprietary, and it's not clear to me that those will ever be in the EHR. It may well be that you've got to move into that – move the data to the registry, get the measures calculated, and then the feedback of information, especially the comparative data that would do it. But I, in general, agree with your point. There's just probably going to be some exceptions to the rule, but the vast majority of time you'd sure like to see it pushed right down to the front line of the EHR.

John Halamka - Harvard Medical School - Chief Information Officer

As you can imagine that this is architecturally neutral, and I think of my own institutions. We have our registry functions both inside the institution and in the community. I mean, they're for different purposes, and so, for example, I have this challenge. Beth Israel Deacon is affiliated with the Joslin Clinic, but it's not an ownership relationship. We have to commingle data from two non-owned institutions to report on quality measures for diabetics, so I have a data warehouse for internal operations with direct feedback, real time decision support, and a community effort to unify such measures.

And I think an interesting question for the vendor community, and this is where I think we will have more work is does the EHR do a direct submission to CMS? Well, I suppose that's possible. Does it do a registry function to an internal or community registry or specialty society? Is there risk adjustment, and then that goes to CMS, or all of the above? Unfortunately, alas, our vendors may create a heterogeneous set of architectures, which requires a lot of product development.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks, John, for that comment. Let's go around the table. Let's start over with Jodi, and then we'll come back to Wes, Marc, David McCallie, Jamie Ferguson.

Jodi Daniel - ONC - Director Office of Policy & Research

Thank you, Jon. My question is actually tied to Jim's comment, which is, as the entity that's the recipient of advice from this committee, how that plays out when we're trying to find certified EHR technology, and which, you know, what is your view as to what is maybe not necessarily the EHR, but part of the certified EHR technology, and what do we need to actually make sure that we're developing the standards and certification for to build into the certified EHR technology, consistent with your vision of how this would work. If some of it, as John Halamka is saying, is community based, well that makes it a little bit more, you know, community based registry, that makes it a little more challenging for us, so just trying to get some clarity on what your thinking is on how this would fit in the construct that we're actually working under.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

It's actually a multi-faceted answer because I don't think there is one answer to that, and it's my own opinion. I can't say that our workgroup has provided this, so I'll take responsibility myself. But I know there has been talk about advanced quality certification. I don't know if that's where you're headed or not, but where I would see that is a set of criteria to manage quality reporting and interplay back to the

provider. I would see as required whether it is a certification of the EHR proper or certification that the EHR can and does communicate with that third party that's playing the role of the data collection assistant.

I think, because there are different architectures, as long as there's appropriate communication back and forth that could be acceptable. I'm not pronouncing. This is your decision. But I think it makes sense to say the requirements are that there is reporting or collection of information, ability to calculate performance, feed it back to the provider, and it's either certified within the system EHR product, or it's certified that it is the EHR and that data collection assistant together can do that function would help solve some of the architecture issues as long as it can happen.

The processing entity is there mostly because of certification that it can assess the data and verify the data are correct, and perhaps certification requires that such verification that the data are correct is also needed. Does that help?

Jodi Daniel - ONC - Director Office of Policy & Research

Yes. Thank you.

John Halamka - Harvard Medical School - Chief Information Officer

You'll hear a thought, and that is, this is the difference between product and project certification. Product certification could be an EHR uses the appropriate standards that have been specified to report data natively to the receiver. Whereas a project may be, ah, I have an EHR, and it emits data to a registry, which then goes to a quality reporting entity, and then submits data to CMS, and that in total is a suite, a project that is certified as accomplishing what needs to be done.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Right. If I can make an analogy to when I worked in the managed care field, we always – we were evaluated by NCQA as a health plan for credentialing, but we could also contract with a certified credential verification organization, and as long as we had an appropriate contract, and there was proof of activity with them, then that part of the certification or accreditation was not required, as long as the CVO, certification verification and credential verification organization was up to date. That kind of analogy might work here to allow if the EHR is working directly with and fits certain criteria with a certified collection assistant that could work. It seems like a good analogy.

Jodi Daniel - ONC - Director Office of Policy & Research

Thank you.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Let's to go Wes Rishel.

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

Thanks. I was going to try to lead the witness with questions, but I think I'll just make a statement. I'm probably not the first person who coined the distinction between meaningful use and useful use in an EHR. I think we always regard the meaningful use things that are certified as, at best, tokens or points holding down a broader spread of functional values of what could really happen. This is one of those areas that is particularly important that we keep that in mind.

One of the things that Floyd did a wonderful job of explaining on a call on Friday was the various methods of responding to requirements to submit quality data. I don't mean standards here. I mean IT architecture, depending on organization size, everything from a small practice in Wyoming to UPMC or something, and depending on what you were submitting it for. And I think it's important to recognize that these standards that are being identified in this workflow that's being identified will have this near term importance of letting people qualify for meaningful use. But the real importance is to support the broad community of different places that quality is being measured, that pay for performance is going on, and to have a uniform way to submit to all of those different places and so forth.

I think that this diagram is great if someone, A, is not color blind, so they can tell the difference between the green box with the green border and the green box with the brown border and so forth, but for a lot of people, I think it would be helpful to play it out into a sequence of diagrams, even if a bit tedious in terms of the thing. The comment that Jim made, I think it's important that we not lose something that he said, which is that he wants to see an expectation created through the work of meaningful use that EHRs are participating at the point of care in collecting quality data.

He wants to – he said it. Correct me if I misquoted him, but he said he had the expectation that EHRs would be smart enough to collect the right data during an encounter, including – and now I'm speaking for myself – including contraindications for following a pattern of care and things like that as opposed to just report out what was entered in the system. That's a functional standard. It should be addressed in functional criteria, or we need to make the statement that we aren't doing functional standards and we believe that our interoperability standards are sufficiently robust that it couldn't happen any other way and meet the needs of the community. But I think we should address that issue specifically.

Given the variety of ways that meaningful use data is collected, even for the measures we've picked out of 150 to push on, do we know that an entity seeking incentive money can qualify on its own for meaningful use? In other words, I buy the EHR. I buy seven components and assemble an EHR. I write my own code. I do everything right. Can I fail to qualify on submission of meaningful use data because someone else in the community didn't do everything right? I think that's an important issue for us to evaluate. I mean, I can argue it both ways. I can argue that what a great way to create pressure on a community to actually do some work, but I think we need to know the answer.

Finally, I love number one on the chart. I think it's a great idea. Some people may interpret it to mean that midyear or midweek or midday, we could change the criteria, send those out to all the EHRs in the country, and that afternoon we'd be collecting new data. I don't believe that's the intent. I just want to make sure that we're clear on what the intent is.

Jonathan Perlin - Hospital Corporation of America - CMO & President

First, just to recap ... number of questions on the table. I think if we come back before your comments, Wes, John offered the taxonomy of product versus project management. Is this a discrete function of the electronic health record, or is it a composite function of multiple technologies to address a particular project outcome? That's one question that's out there.

Two is the concept of architecture neutrality versus specificity. Wes, you introduced into that discussion should the specificity also include not just architectural standards, but also functional standards. That apropos of Jim Walker's comment is that this shouldn't report at the end of X period of time, but perhaps should be a substrate, if I quote you correctly, a substrate for real time decision support, which is the second component of the discussion.

And then the third is that, Wes, to perpetuated your comments, it ... again the taxonomy that John had introduced, product or project. If one goes to the latter and it's a composite, whether one builds or buys, and assuming one buys components, which are meant to interoperate together to create the composite project outcome and they fail, what then? How does one assure that if one picks a composite – you're shaking your head. You're not agreeing....

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

That wasn't my question. It's a good question.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I thought that was your question.

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

No. Let's suppose I do that right, that is, as an institution, as somebody who expects to get paid an incentive payment, I do everything right, but my path to calculate the quality data involves not that John's institution would fail, but there's this other group out there that may be dependent on John in order to

make meaningful use. Will they; are they are risk for John not doing his job in order to get their incentive money?

Jonathan Perlin - Hospital Corporation of America - CMO & President

Okay. Let's hold those as some of the questions for discussion. John, I know you wanted to weigh in and clarify on some of this because I think this flow is terrific, and I don't want to lose the sense that this is absolutely fabulous work, but I do think that there are some pieces that will require additional consideration, particularly as it relates to the functional specification, the concept of neutrality, the concept of singular EHR function versus composite function.

John Halamka - Harvard Medical School - Chief Information Officer

With regard to meaningful use, so much of what we're talking about is an ecosystem of many stakeholders, and the wording from the policy committee had been you must submit biosurveillance, immunization registry information if there is a receiver. And so there has been an out placed in the meaningful use criteria, so if in Massachusetts or if in Boston there's no one to receive immunization data, well, we'll do everything right. We're ready to submit, but there's no one ready to receive, and that's still okay. So I think that has not been stated to my knowledge explicitly on the quality side.

I think the assumption is, by 2011 that CMS will have an infrastructure for which quality measures can be sent to them, but ONC being a rational organization, I'm sure would say, oh, CMS wasn't ready by July of 2011. We can't hold you accountable for submitting information that wasn't ready to receive it. I think, to your point, the policy side of things will address some of those concerns.

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

It's not clear to me that an institution can compute these measures without the help of a third party, so I mean it's not just the case of having a receiver. It's the case of having a collaborator, and that's my concern.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Let's take that then and let's see if we can't work through some of the other questions on the table, and as we go through this thread of discussion, if we are introducing new concepts, if you could frame that as another clear bullet point to that. Marc Overhage, do you...?

Marc Overhage - Regenstrief - Director

Thank you. It's Mark Overhage. I'll try to be brief because it really builds on, I think we're hearing some of the same issues. One is this question that Wes raises, and Janet commented on, about how often. And certainly there are sophisticated organizations that are going to have both the data and the technologic sophistication to create appropriate measures.

What I worry about, and I think this is echoing some of Jim's and Wes'. If you can have an organization with perfect skill sets, software, and tools, but incomplete data, and the measures will be less helpful, so the example is, look at a real patient, and ask the question, how much of that patient lives in this particular EMR? If you're Kaiser, wonderful. If you're the VA, it's not quite ... you know, there's shared care, and there's a whole bunch of data about that patient that ... isn't in the system to use for reporting. So while they certainly have the skills, have the tools, have the capability, have the interest and motivation, the data has got to be there.

I think that's where Floyd ... this data collection system becomes so important. Whatever it is, where it becomes so important is what are the holes in the Swiss cheese of the data, and how big are they is very hard to know. And so assuming that you're going to have all the data in the EMR, I just want to underscore that because I think it's a critical point.

The other is, I want to go back to the question about building the measures into EMRs from the standpoint of, and this has been a very hard lesson for me. I started out four years ago with our quality improvement effort, out quality health first, thinking I could use the same measures for reminders to physicians and quality measures. Floyd is smiling because he's made the same error, I assume,

sometime in the past. They're not the same rule. They're not the same rule for a very important reason, and that is, it's a different level of specificity and sensitivity that you need.

If I'm going to remind a physician about a specific clinical condition and action to take, I darn well better be right. And I better be right at the 90%, 95%. I mean, the clinicians aren't idiots, you know, we take the input along with others. Well, sometimes we are, but we take the input along with other things, and we make a decision about the patient. We used to think we could get away with being right only two-thirds of the time or something like that. I think the bar continues to raise. We better be right over 90% of the time.

Quality measurement is a statistical process. It's not perfection, and so I found myself anyway arguing out of both sides of my mouth with clinicians sort of saying on the one hand, well, I've got this quality measure, and it's based on all this good, clinical stuff. You know, don't worry about whether a couple of these patients aren't yours or a couple, you know, it doesn't really matter at the end of the day because we're just taking 1,000 patients and figuring out whether you managed their depression or not. We're not nitpicking on an individual. But then I give them a reminder, and they want to – you know, then we start nitpicking, so I think those are two different tunings of the same knowledge base, and it's important to keep those distinct in our brain. I'd love to see them keep coming closer together, but I think it's really tough to shove them into the same logic today and be successful at both enterprises. But maybe I can get educated.

John Halamka - Harvard Medical School - Chief Information Officer

Yes. Can I make a comment on that?

Jonathan Perlin - Hospital Corporation of America - CMO & President

Great points. I know, Janet, I don't know if you want to weigh in because you've certainly done a lot of consideration to accountability and reporting measures versus real time decision support.

Janet Corrigan - National Quality Forum - President & CEO

Yes. I think the point that's been made is a very good one. We had seen in recent years those two worlds coming closer together, and I'm not sure whether it was a good thing or a bad thing, to be very honest, with some of the measures coming into NQF, at least, for consideration that have extraordinarily long lists of types of exclusions, and that is an attempt to make sure measure "perfect" and the same for every single patient to reflect it. It's very problematic because it makes the measurement reporting process very cumbersome. I agree, in theory, it should be a statistical process. It doesn't have to be 100% right for every single patient the way you want the kind of precision for decision support. But there is a blurring there that takes place.

John Halamka - Harvard Medical School - Chief Information Officer

Yes. If I can also make a comment on both of your comments, the reason that that EHR box is multiple and not one is because, in many situations, as you describe, there are many sources for data, and it might be a PHR and other systems than the EHR that are behind that, and it might be a nursing record that's not the EHR per se that provides that information for the system to get the data. I do think some of the data elements are identical in the measure and decision support, but decision support is a different process, so agreed.

Janet Corrigan - National Quality Forum - President & CEO

Can I also make one other comment? I think it seems to me that one of the things that could come out of our discussion today and over the coming year are perhaps a set of guidelines for the direction we want to go. I mean, for example, it may be that a reasonable guideline would be that an EHR should be able to provide the maximum amount of decision support possible to promote improvement on a measure, which would imply that you'd clearly want that EHR in any given setting to capture all of the relevant data that it can, that it has within its purview, and do as many calculations as possible to be able to provide real time feedback. But, at the same time, we'll need to make a distinction between the use of data collection assistance to bridge what is a highly fragmented delivery system in most communities where the data collection assistant is a mechanism because we don't have clinically integrated, well defined systems of

care that can assume responsibility for a chronic care episode. We just don't have that in many locations, so there you need that data collection assistant.

That's a different situation than when you have a data collection assistant that has value added because it's specialized expertise. So for example, the data collection assistant in the case of some of the registries, the specialty societies have, that's a little different situation where they have risk adjustment algorithms and specialized expertise for analysis of the data that you're probably going to have resident within the delivery system. And it seems to me, we're going to want to fashion guidelines that help to push the delivery system in the direction that we wanted to go in terms of reforming itself, which would lead us to encourage, through whatever policy decisions are made, that EHRs become and EHR systems become more all encompassing of that patient focused episode.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks. Let's go to Dave McCallie. Are you still in for comment?

David McCallie - Cerner Corporation - Vice President of Medical Informatics

Yes. I think this question has been asked. I'll just ask it a slightly different way. You made it clear that the data collection assistant might be rolled tightly up with the EHR, and clearly the receiver entity is a different entity. Is the quality report processing entity decoupled on purpose, or is that an optional decoupling? Does it have to be a separate entity for independents or is there any reason why that's called out as a separate color in your diagram?

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Actually, I didn't make a conscious effort on choice of colors. It was, to be perfectly honest, it was my first foray into Office 2007 PowerPoint, and I didn't have a lot of time to figure out all the colors while defining the boxes.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

In which case you did a good job.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

But no, there are some EHR vendors who are certified as processing entities, and they and their registries and the processing entity are one, which is why there's this green box, and I understand the color issues, that actually combine them all, so it's a different step in the workflow that is done, and it can be a third party that is different. It might be a QIO, for instance, quality improvement organization. So it's drawn to show it could be separate, but it also could be one in the same, and I know there are vendors that have that certification, and they do all of the above with a registry embedded into their own EHR.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Let's go to Chris Chute.

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

Thank you. I'm going to pursue the lump or splitter argument here, and I guess it's pointed to question that John had summarized as the project versus product. I really want to address Jodi's question in the sense of what should be looked at. My compliments, incidentally, on the diagram. I think it's a superb beginning, but I'd like to address the question of whether these EHRs are in fact monolithic and whether these EHRs are in fact the unit of consideration.

James made an excellent point that, gosh, you need real time reminder or interaction with a clinician if the information is incomplete or ambiguous or somehow fails to address these issues. But I submit that many organizations, if not most, are really in an information ... where you're dealing with multi-variate systems. For example, Floyd, you referenced, I think it was nursing systems and maybe other systems. That's accurate. I would submit that there are scores in most institutions of departmental systems, feeder systems of various stripes, laboratory systems, radiology systems, cardiovascular information systems, all of which feed into the EHR.

And if I were to make a recommendation on this diagram, while you do have the stacked little thing, compliments on the artistry there for stacking, I would make it more explicit. This is the lump or splitter issue saying that in front of the EHR are stacks of systems and environments, and it really begs what's being certified from a provider perspective, and this has been an explicit question.

I guess I'd want to register strong consideration that rather than call it a project, I'd really use the system word in a sense. We could quibble about vocabulary, which I'd love to do, but the issue of, for a particular provider, it's clearly an interconnected system that is going to fulfill this kind of functionality where the EHR may be a core or a hub, but only that. It could be that some providers choose to make an all in one EHR, and that's perfectly acceptable. But the disproportionate focus on that hub without taking into account the surrounding environment and contributing systems, I think is something we should avoid.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks, Chris, for that. Let's go to Doug Fridsma, and then Jamie Ferguson is the last comment on this particular discussion. Doug?

Doug Fridsma - Arizona State - Assoc. Prof. Dept. Biomedical Informatics

I just wanted to comment on the diagram, again, nice use of the colors and the like. I think that when I take a look at this diagram, I think about it in a slightly different way in the sense that you've identified the things that do these functions. But what you're really talking about is that you collect data on a patient. You aggregate data on a patient. You aggregate data across your organization, and then you may in fact aggregate data across an HIE or whatever in terms of trying to get to that.

It could be that that EHR in Chris' example works as the aggregator for that patient information. It could be the EHR is just sort of the data collection mechanism that then gets – kind of pulls things together and does it for quality reporting. But I think the thing that's important is you've identified sort of the entities that do those things, but there's another diagram that's sort of hidden within this, which is all of the things that you have to do.

You could have easily said, you know, you collect the data. You aggregate the data. You report the data, and then assign each of those functions to some sort of example entity, if you will. It could be the EHR, the data collection assistant or the like. But I think at that level of abstraction, if you talk about the things you have to do, it allows you to abstract out what the implementation details might be. It doesn't matter if it's an electronic medical record or a data collection assistant. The task that has to be done is defined in a way that people can then understand whether or not, from a certification perspective, whether that function has been met.

It also helps clarify the data that's needed to support that function, so I think this is really good, and I like that we're moving towards this notion of understanding not only the what of standards, but also the how of standards. And I think this is sort of the first foray into that, and I'd sort of encourage us to think about it, not in terms of the technology entity that's going to do it, but kind of what's the function that they're going to try to support.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks, Doug. I think that's a great segue to the next thread of discussion. Jamie, look forward to your comments, Jamie Ferguson.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Just a comment on this from the perspective of our discussions in the clinical operations workgroup and the standards that we're recommending for these flows. We started with the recommendations for the standards for submission of the calculated measures to CMS, which are flows four and five on this diagram. And our discussion really focused on the requirement for the meaningful user to perform that submission, and so we started out saying, well everything else is in the EHR, right? And so that comprises all the boxes at the top row: the EHR, the data collection, and the processing.

And as our discussions then evolved jointly with the quality workgroup, we understood that they were breaking out these functions that we had all lumped together. I would actually, for the purposes of that discussion, relabel some of these boxes. The data collection assistant is actually primarily a filtering function, and so you might relabel that box filtering because it's filtering from all the data about the patient to those data that relate to the particular measure. And then the processing, the quality report processing entity, we talked about as an aggregating and calculating function because that's taking from the patient level data, aggregating it together, and actually calculating the numerator and denominator for the reporting purposes. We had previously talked about all of those things as being functions that were required of the meaningful user.

Now to the extent that there's either incomplete integration of data about the patient or incomplete coordination of care or for other reasons where these other flows are necessary, flows two and three in particular, in terms of the standards that we're recommending, the standards that we're talking about for exchange of clinical data using the CCD or the CDA or HL-7 2.5.1 or whatever the other standards are, all of those, all the data required for all these measures can be expressed; can be exchanged between these other entities using those standards if indeed that's required. So I do think, in terms of the standards that we're recommending, we've covered the primary standards for the actual reporting of the measure, which is flows four and five, but all the other data exchange standards that we're recommending can be used in flows two and three when that's needed.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thank you for those comments. Between your comments and Doug Fridsma's, I think there's a theme that's emerging, which is that it's really the segue that we're somewhat naturally and organically taking and actually through this discussion between specification of certain standards implementation, the implementation guidance. I think there remains some questions about the architecture of how this is created, the specificity with which guidance might be given to functional requirements to support real time decision support.

Marc Overhage gave us great guidance that, look, if ... decision support, and you go that track, be sure that you're actually teeing up good recommendations, not redundant, etc. that flow out of that. But this very much is a segue of our conversation from the first tranche of activity in terms of definition of certain standards. There's terrific work that's been done to some of the real world, messy ambiguity around implementation. I think that's something that we are going to have to wrestle with, both in aggregate in the quality, clinical quality workgroup, and specifically in the ... developed implementation workgroup.

John, do you want to add any ... on this?

John Halamka - Harvard Medical School - Chief Information Officer

These are all great comments. When I think of my own meaningful use, I have a homebuilt EHR and a commercial EHR rolled out to my physicians, and we have a statewide entity, the New England Healthcare Exchange Networks, which is a filtering entity that gets data from the built and the bought, and then we have the Mass eHealth Collaborative, which is a registry entity, which is a calculator and aggregator, and the intent is we will go from EHRs, which will be meaningful used by physicians using the CCDU and HL-7 2.5.1 to send them through the filtering entity to the aggregator and the calculator, which will then report them to CMS. And we hope, whether you call that a system or a project, that that will meet the criteria for achieving stimulus fund payment to all the providers who do it this way.

Jonathan Perlin - Hospital Corporation of America - CMO & President

With that in mind, I'd like to propose that – I haven't heard – in fact, I've heard consensus around this general flow from a measure ultimately to the receiver. We've heard some need for detail surrounding implementation, intermediate point, and so let's take one last comment from Jim Walker, but then let's move to consideration of accepting this with an understanding, I believe, that we need further work in terms of that implementation specification or guidance that we would offer. Jim?

Jim Walker - Geisinger Health Systems - Chief Health Information Officer

I just want to emphasize what Wes said that there are a lot of organizations that are going to be resource constrained and aren't going to live in a wonderful, sophisticated environment like John's, and we need to do everything we can to simplify the minimum that an organization has to do in terms of project and products and systems to do good meaningful use and to report it.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Let me just put an exclamation point on that. I think that's absolutely right. It dovetails directly into the implementation guidance, but to John Halamka and John Glaser's metaphor of the escalator, that escalator is difficult with increasing complexity, and so we need to not only be able to bring along environments that may be less well resourced in terms of technologies, funding, or ... but in fact to move everyone forward. Wes ... say to this point of the implementation?

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

Joe Hyman isn't here, and I wanted to ask about the single neurology practice in Cody, Wyoming that – I mean, we're talking about quality in a major enterprise, and that's important, and it's very complex, but I just want to understand how a physician in an independent practice is going to qualify for meaningful use with these measures. And if we think that the low end of this is the EHR handling everything inside the green box with the green border, then I'm fine with it. I mean, if we think that there is always a more complex relationship, then I would like to understand it better.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Great point. Janet, did you want to offer a comment on that?

Janet Corrigan - National Quality Forum - President & CEO

Yes. Just a question: What do we need to specify in terms of standards for 2011; what do we need to recommend in terms of standards for 2011 and the overall direction for 2013 for this data submission to take place, whether it's to the filtering entity, the aggregating or calculating entity, or to CMS? I'm a little unclear. Are we going to be addressing that in Jamie's a little bit later, or do we need to discuss the issue of whether it's QRDA eventually or it's PQRI? What standards need to be specified?

John Halamka - Harvard Medical School - Chief Information Officer

I can address both Wes' comments and Janet's comment, and that is, what you'll see in Jamie's presentation is specifically four and five, as the data flows that though if you have the complex architecture like I may have, there is enough specificity in the implementation guidance to do it that way. That isn't specifically required. You could have the big green box as the EHR that Joe Hyman is using, and it's using data flows four and five with the standards that he'll discuss in a moment to get to CMS directly without any other intermediaries.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I think then we're in agreement on the directionality of this. I think the implementation work is required, and that's, as I say, a good segue to the continuing activity. Do we hear a motion for adoption of this flow and acceptance of the report from the clinical quality workgroup with the proviso that the implementation work apropos the questions raised in this discussion continue?

Male

So moved.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks. Any further discussion on this motion? Okay. Then let's accept that with the clear understanding that we have additional work to do, both in terms of the implementation and some of – we hope, John, that in your presentation and Jamie's, a greater clarification of the four and five that you identified in terms of the specific request for standards, more clarity around the standards that Janet identified will occur.

I'd like to acknowledge that we've been joined by Dr. Aneesh Chopra.

Aneesh Chopra - White House - CTO

I'm late. Sorry.

Jonathan Perlin - Hospital Corporation of America - CMO & President

No. Thank you very much for your continuing and ongoing participation in this process. Let us move now to in fact Jamie Ferguson and John Halamka. I'm sorry. I apologize. David McCallie will be playing the role of Dixie Baker today, and we greatly appreciate that. Dixie, as was mentioned earlier, joins the ranks of those stricken by flu, and so David, thank you so much for agreeing to step in and lead this discussion. As David McCallie is coming to the podium, let me thank Floyd Eisenberg and Janet Corrigan and the entire clinical quality workgroup. Very thoughtful work and....

David McCallie - Cerner Corporation - Vice President of Medical Informatics

Thank you, Jon and John. I may be a good bit taller than Dixie, but I don't think I can fill her shoes, so I will do my best to cover the number of discussions that we had in our off cycle phone conversations, and I'll depend on John Halamka, who joined us on most of those calls, to bail me out if I get stuck.

First to acknowledge the work of the members of the committee, in particular, well, actually the slide has been corrected. I was going to point out that John Moehrke is listed twice on this slide. In your hand out, he is, and John provided us a tremendous amount of input from the HITSP perspective, and we appreciate that input from him.

Our task after the last meeting was identified here on this slide in two points to reformat the recommendations that were accepted at that meeting, and then to identify specific recommendations on implementation guidance, as John Halamka introduced earlier this morning. On the task of reformatting, we'll go through it in a little bit more detail, but basically we split the – we actually focused particularly on two questions that were asked of us, one of which was to clarify the timing of some of the standards. The second was to clarify the and versus or optionality of some of the standards, and I'll point out in a few minutes, in a few slides, where we did that, and then to split out and focus in on the implementation guidance.

So to that end, there are two handouts further in your slide deck. Handout number one is the original standards proposal slightly reformatted. We added specific requirements or specific suggestions for certification. This is sort of an English language suggestion of how certification might proceed, and we made a few changes, which I'll call to your attention in a second. Then we created a new handout, which is the guidelines for implementation, which we were asked to specifically focus on. This is an attempt to move from our first output, which was really naming the lower level standards, to a higher, more constrained implementation approach, again as John pointed out.

Handout number one, I call out here a couple of things. The header for the standards column, as we had discussed in the past, includes information from a number of sources. First and foremost, regulatory standards such as HIPAA, standards that have been developed by specific certified standard development organizations such as HL-7, and standards developed by profile enforcement organizations such as IHE. Again, I believe we've covered this in the past.

In addition, we clarified in the columns that have the three date headers: 2011, 2013, and 2015. We clarified some of those columns. I'll call your attention to the specific ones, but we stumbled a couple of times on the question that it's okay. We want to make the point, I should say, that it's okay to implement a later standard in an earlier year, and the absence of listing a later standard in an earlier year doesn't mean that that standard is prohibited. It just means that it's optional in the earlier year. It would only be listed as a required standard in the year that it first shows up in the column. Again, no real changes there, but just a clarification that tripped up a few of us.

We've broken this up the best we could, a little bit along a fuzzy divide between those standards, which are really focused on the product itself and those standards, which are focused on the infrastructure necessary to support a product in a setting. Of course, one man's infrastructure is another man's

product. So this is an arbitrary distinction and shouldn't be taken to mean too much other than just a way to organize thinking and approach.

Let me focus now just on a few of the notable changes that we have either clarified or differed slightly from our previously accepted recommendations. First, we decided that due to the ARRA requirements for accounting of disclosures that it made sense to specify that the ATNA standard be required for 2011. That had been left off in previous versions. I know that many people are already using this standard, so we didn't think that this posed a particular barrier, and it is a requirement for the accounting of disclosures to be capturing this kind of information, so ATNA is the preferred way to do that.

Second, we had it pointed out to us that federal systems will cease to allow the use of Kerberos as an authentication infrastructure after, I believe, 2012, so we decided to change our diagram or our matrix to show Kerberos as an allowed choice only in the 2011 column, but after that, by 2013, XUA would be the preferred standard for cross enterprise user assertions.

Then the third line, this was an and/or question. The question arose for some need for some clarification among the choices for document exchanges, and we weren't specific about what happened in 2011, so we made slight clarification that 2011 should be governed by the advice and implementation guide of the service coordination, HITSP service coordination 112. Then in 2013 and onward, the choice for document exchange that respects appropriate security and such could be chosen from any of these listed profiles, which is essentially XESB, XDR, XCA, and XDM. We could go into detail during the questions if you want about what that means, but fundamentally it says depending upon the specific topology of the transfer of the document, one or other of these particular standards would be appropriate and acceptable. You aren't required to use them all. Only if the topologies of your transfers require the appropriate standard, so XDM would be for media based exchange of data. XDR would be for point-to-point based, and XDS would be for registry based or repository based transfers of documents.

Then, finally, the last line, we added just a small clarification that an architecture that uses a RESTFUL technology model instead of a SOAP model would need a profile to guide the implementation because, since RESTFUL approaches are less constraining than SOAP approaches, one can't use it without additional profile constraints to specify, for example, how one handles the transfer of a security assertion as to who the user is, a SAML assertion, because REST by itself doesn't specify that. One has to constrain REST to do that. It's somewhat of an irrelevant point because there aren't a lot of RESTFUL approaches available that have met that criteria. But if such should arise, they will need to address, through their constraints, the questions around security and privacy and integrity of data.

The implementation guidance selection, we spent a good deal of time with John Halamka and came up with this list to sort of prioritize our thinking about where to get implementation guidance from. It shouldn't be a surprising list to any of us because I think we're all drawing from a similar approach. We started with anything that is an output of the HITSP Tiger Teams, given the recency and the focus of their work, was sort of at the top of our list. HITSP use case base constructed developed a little bit earlier, but many of them covering low level components and transactions that are still completely appropriate was number two on our list. We looked to IHE profiles for number three, and then anything else that we found from an accredited standards development organization as number four.

The handout, we won't go through the details of it, but just to highlight the columns here. We've put the implementation guidance for 2011 in a separate called out column and then lumped 2013 and 2015 and anything that was optional for 2011 in a second column, so there's more specificity in the 2011 column obviously and a little bit more ambiguity perhaps in some of the 2013 and 2015. Then in the far right-hand column in a couple places, we called out specific notes where we felt attention needed to be drawn to particular gaps that existed, gaps that would be addressed after the 2011 timing.

Here are the specific guidelines that we ended up pulling in for implementation guidance. The headline on this slide is a little bit misleading. It says selected guidelines. This is selected as in these are the ones we selected rather than a selected list of guidelines, so these are the ones that actually made it onto that spreadsheet, so this slide pulls those out. And I won't read them all off to you. They're familiar to those

of you who worry about details. HITSP capabilities, HITSP service collaborations, as you see there, and then on the next slide, HITSP components and specific transactions. Then, finally, there were a number of IHE specific integration profiles that were called out and given a place on our spreadsheet.

That, I believe, covers the information that Dixie wanted me to present. John, do you have anything you want to add to that summary view before we take questions?

John Halamka - Harvard Medical School - Chief Information Officer

Sure. Dixie is extraordinarily passionate about insuring confidentiality of patient data is protected. The challenge, of course, is that security is always a balance between ease of use, cost, and bulletproof protection. What she's tried to do, what the workgroup has tried to do is give this rational timeframe, this glide path, 2011, 2013, and 2015, that gets us to increasingly constrained security that recognizes Joe Hyman and the fellow practitioner is going to actually need to comply to this. That there's cost to do this, and that there's going to be various demands at the policy level.

An example, the VA may have much stricter security with regard to authentication and data sharing than the fellow practitioner's office, but yet we're going to be as strong as our weakest link. And so you have to set these minimums at 2011, 2013, and 2015 that insure that the ecosystem is protected.

What we tried to do, as you see in that first spreadsheet, is give, here are the standards, and it's very clear what will be used, and what the ands and the ors can be, so you accept both SOAP and REST. You accept various mechanisms of authentication from the simple to the most secure that might be used in DoD or VA. And that the implementation guidance tries to incorporate as granular guidance as possible, which is, you see this hierarchy where we wanted to look to all the sources of implementation guidance, but start with the most specific that we could, and that is these service collaborations and these kinds of things that the HITSP Tiger Teams have done.

I hope, and I look forward to your discussion, that you feel like we've done a reasonable job at balancing the patient privacy rights to protect confidentiality, but also make it implementable over years, testable because we have enough specificity on the implementation side, and welcome any thoughts.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

I would add just an additional tag to what John just said. We had a number of discussions where we were on the cusp of trying to decide whether the debate was a policy question or a standards question, and obviously when it comes to privacy and security, many of the issues are in fact policy questions. So we identified a number of those policy questions, which will need to get flushed out, as we progress further, particularly around HIE and information sharing in the community. But the standards that we have chosen are architecturally neutral and flexible enough to support the policy issues that we envisioned might come up.

For example, one of the debates that we had and tabled as a policy question was what John just mentioned. If you have a network of systems that are connecting to each other, and they have differing levels of user authentication certainty, one might require two factor with a hardware ... such as some federal systems do. And those systems communicate with each other. Do all of the systems have to rise to the most stringent requirement of the most stringent member, or do the systems lower themselves to the lowest common denominator? The answer is not in this spreadsheet, but the technology tools that we do list would make it at least possible for a system to understand what the other system's level of authentication was, so they could make that decision based on their own policy. We tried to make sure these low levels technologies are capable of expressing sufficient information to make a rational decision once the policies have been clarified.

Then a second point, and this is maybe a personal interest of my own, so I'll take the prerogative of having been given the chance to sit up here to lobby for it. When we consider consumer consent after 2011, we get into some fairly murky territory in terms of the way the current standards are written. Again, the technology is all there. Tools like XACML and SAML, but the vocabularies and taxonomies necessary to express with sufficient granularity a consumer's wishes to control the spread of their identifiable health

information are not yet well developed, and that work needs to continue with the standards committee. John, would you agree with that?

John Halamka - Harvard Medical School - Chief Information Officer

Absolutely. In fact, when we talk about our next steps as a committee, I think that focusing on granular patient consent is very important to do because you'll see, on the consent management portion of the spreadsheet, we have suggested the use of an HIE profile called the basic patient privacy consent, which does allow the exchange of a consent document, but it doesn't get to the specificity of I want to share this data with this individual in this circumstance.

Really, although yes, as you point out, there's XACML and other profiles, other standards, there really isn't a widely deployed, mature set of constructs that get to that level of granular consent management, and so I think it will be both a policy question and a technology question for us all to work on for 2013 and 2015.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I just take this as an opportunity to note that I greatly appreciate, John Halamka, that clarification. David, you're lobbying for that, and do want to assure that the committee takes great note of all the input and coalition for patient privacy, patient privacy rights. Both emphasize that as a particular point, and want to acknowledge that.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

Yes. Should we do questions? I'm finished with the summary.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Sure. I think, Wes, you have a comment.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

Go easy on me, Wes.

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

No. Dixie gets away with go easy. You don't. I just have a question about ATNA. First of all, I want to say that I'm a big fan of audit. I think it's done more to create effective enforcement of privacy concerns than anything else so far in healthcare IT. The comment I have is I don't think ATNA is either necessary or sufficient to meet the HIPAA, the revised HIPAA disclosure requirements because they're about disclosure that can come out of so many systems. It's conditioned on whether the patient has paid or not for the service and so forth. But I do want to understand what we are committing the industry to with this standard. Are we committing them to using ATNA at the interface with another entity or internally in their systems?

David McCallie - Cerner Corporation - Vice President of Medical Informatics

It's my understanding, and I will preface by saying it's certainly not an area of deep expertise that we are focusing here on the certifiable EMR within itself, its own audit trail, that not the transfer of information.

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

So the requirement would be that an EHR be able to produce an ATNA log.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

Yes.

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

Of it's ... okay. That's fine.

John Halamka - Harvard Medical School - Chief Information Officer

But I could imagine it used in both contexts, so ATNA provides a couple of things. I mean, there's a secure transport aspect, X.509 certificates, MPLS with an AES cipher, and then there's a standard audit

format, so that you could imagine, although yes, absolutely. Auditing is – get the EHR to have a standard audit format that could be disclosed in the standards way or shared with the patient. I could imagine it as disclosures are made between organizations, that the same audit format is used. So, in sense, we come up with one standard for generic auditing internal and external to the organization.

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

And I think that's a great idea for both.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

Yes. I think that a unified standard makes the most sense. If you think of an internal disclosure to a practicing clinician in front of the EMR, and then he turns around and causes that same data to be published to an HIE, that's just another instance of disclosure, in this case to an HIE. You don't know who necessarily is going to see it in the HIE, so it's a level – the granularity is different. In the first case, you knew exactly who the provider was. In the second case, it's a system, but at least you know the EHR let that data flow out to a consumer.

John Halamka - Harvard Medical School - Chief Information Officer

Yes. I think, in the ideal world, every system would produce ATNA logs, and we'd have all kinds of great tools for analyzing them and, you know, finding out, but I am concerned that we not be driving healthcare institutions to adopt ATNA on every system they have internally, the EHR to quality. If we decide at the HIE level to do it there, that's fine, but I think it would be a step we'd have to consider carefully in terms of the economic impact on people's existing products.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Maybe, Jodi, you can help there. Some of that will depend on how the ARRA statutes are turned into regulations, will it not?

Jodi Daniel - ONC - Director Office of Policy & Research

Yes, and we're in ongoing conversations with OCR about this, so we're still working through the details, but the Office for Civil Rights is required to come up with regulations for the new accounting for disclosures requirement and ARRA, and they are looking to us, ONC, to provide standards to assist entities in meeting requirements that they would come out with under HIPAA. So we're trying to figure out how to line this up and make sure that there's enough built into the technology to support the regulatory requirements that OCR will adopt. And we're still talking that through. My understanding, and I'm not a standards expert, is that the ATNA standard is fairly flexible and has a lot of what may be necessary for the accounting for disclosures requirement, but we're still working through the details of that at this point.

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

Sure. I just think it's wonderful that two different agencies are trying to coordinate to use the same standard. I think that's great.

John Halamka - Harvard Medical School - Chief Information Officer

Just two other points, and that is the workgroup did debate, and I think we may have mentioned this in a previous meeting. Do you require encryption of all data flows inside the four walls of an organization? And to Wes' comments about burden, and the answer is no, unless you can imagine there's an open wireless network where the data is going to flow in the clear. Then, of course, that would be a breach, and that would be bad. And so we're not going to require double encryption. That is, encrypt everything that flows over your networks and then implement WPA enterprise and encrypt infrastructure. That is, if you encrypt infrastructure flows on wireless networks that that's completely sufficient.

The other debate we had is encrypting data at rest. Should we require every data center to have databases that are sitting at rest encrypted? Again, the economic burden of doing that would be very significant. However, if you're going to put patient identified data on a thumb drive or a mobile device that could be lost or stolen, should patient identified data be encrypted on a mobile device at rest? Our committee's recommendation is that yes, that should be, and it's consistent, actually, with the provisions of ARRA and some state laws that are looking at that level of data protection on just mobile devices.

Now Aneesh has just asked a question about standards for breach notification. Now, David, I don't recall that we had any discussions. Let's just imagine a horrible thing occurs. A rogue employee discloses 501 medical records from Beth Israel Deaconess Medical Center, and then I have to notify the *New York Times* or the *Boston Globe*, the prominent media of the area, as ARRA suggests. Is there a standard mechanism for me to do data breach notification? And I think the answer is maybe this is a policy as opposed to an electronic standard, but your comment.

Aneesh Chopra - White House - CTO

I'll further refine my question to John. There is a set of data breach activities taking place beyond healthcare around how the nation addresses issues of security and privacy. But from a technical standards perspective, the question that sparked in my mind, listening to the dialog, was – I wouldn't call it the RSS feed for data breach problems, but somehow if we had a common mechanism to harmonize such data, in theory it should give us a continuous feedback loop about the nature of the kinds of things that led to the breach in the first place.

Part of the anxiety about these standards discussions about all the things that we're doing, and that's why I wanted to serve on Dixie's committee, is that we're sort of chasing a future threat. We don't have a clear perspective who is the rogue actor in the stage. I don't have a good perspective of the market share of rogue actors. Was it foreign countries hacking into hospitals for data? Is it rogue employees? Is it mistaken code that opened up something that showed up? To the extent that we had a little bit more of a consistent method by which we could report out when things went wrong, we might be able to understand root cause and, therefore, as a committee, get at the issue of how we go after it.

I don't know if there is a role for us to standardize the basic elements of what you'd want to know for the purposes of feedback loop to us: the nature of the breach, the scope of the breach, the source of the thing that led to the breach. I just am brainstorming without solution, but I'm mindful, as we get into the mechanics of some of these pieces, that at least we raised the question. I guess I'll leave it there.

John Halamka - Harvard Medical School - Chief Information Officer

...because you can imagine developing a taxonomy that says, what was the nature of the breach: internal actor, external actor, etc.? But I'm unaware of either a standard today that does that, and has there been any discussion at ONC about the mechanism by which a breach would be – a notification would occur?

Jodi Daniel - ONC - Director Office of Policy & Research

A related topic, we've actually, we have been working closely with the Office of Civil Rights on their breach notification rules, and there is a requirement in certain cases of a breach that those breaches be reported to HHS. And so we are actually working with OCR right now to think through what are the things that they would want to have reported to them in those instances. If this committee had some input to that, that would be welcomed. But it is something we are looking at because we are hoping that we can get some intelligence from those reports that will help us to provide some guidance back to the field on how to either prevent the breaches, understand what the vulnerabilities and risks are, etc.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I think it's further work for the privacy and security workgroup because I think it's a very interesting idea.

Aneesh Chopra - White House - CTO

That's my job. I try to come up with interesting ideas.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Okay. Once again, I think it's an interesting part of a segue toward implementation, but since it also transcends a concept of breach notification as a responsibility to potentially agreed parties to the idea or notion of a learning system that helps to amplify the signal to harden more effectively, so I really think that's a very well taken point for further consideration. Any other discussion on this? Then ... that we're in consensus on the recommendations here, to hear a motion for such?

Janet Corrigan - National Quality Forum - President & CEO

I think I'll move.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Okay, a motion to accept the recommendations of the privacy and security workgroup, and second, and any objections? ...first question? Oh, I'm sorry. Thank you very much for that second, and then by consensus, we'll adopt these recommendations. Many thanks to David McCallie and also to Dixie Baker and Steven Findlay and all the members of the workgroup and some additional considerations for continuing work and as well as a segue to implementation guidance. Now, John, we will turn to you and Jamie, and move to the granularity of discussion in the clinical operations data standards.

John Halamka - Harvard Medical School - Chief Information Officer

Two presentations for the committee – we'll start with the presentation by Jamie looking at how we've refined the implementation guidance, changes that have been made from a clinical operations perspective, and then we'll have a presentation from Lee Jones about implementation guidance in general.

Now when you look at the standards harmonization activities of the last decade, ten years ago we had the CHI standards that were simply name-based standards. And if we were satisfied with name-based standards, we could have declared ourselves done a decade ago. The work that has really happened in the last ten years is getting to this granular level of guidance, so you'll hear from Jamie about that and from Lee about how the last four years of HITSP work has got us to these constructs that are much more specific such that vendors, as I mentioned, could actually follow the guidance and achieve interoperability.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Thanks, John. This will be truly a brief update, I think, because our revisions are truly minor. We have a detailed matrix in the handout, which was not distributed at the last meeting, but this is an update to the detailed matrix of our recommendations that was handed out the meeting before last. And, as you'll see, there are actually no changes to the recommended standards, although we have made one change to the recommended timing that I'll discuss, and we've clarified and changed our language describing our recommendations based on tons of input and discussion.

So just a couple of brief points on that: We've clarified that the use of a single standard for each purpose is our basic guideline with a couple of noted exceptions: one for lab results reporting, and one for quality measure reporting. And we've also clarified that the recommended use of local and proprietary codes has an exclusion where specific codes are required for purposes of the quality reports.

We've also clarified where we mentioned the use of legacy HL-7 version 2 implementations, that that's really intended to be only for preexisting implementations of lab results reporting or other exclusions that are going to be specified in guidance. And then we've also clarified in terms of the version, being version specific. We're saying that you should just use the most recent approved version of implementation guidance, and that is so that we're not tied to a specific version of implementation guidance, but that in fact when the rule or the guidance is issued by ONC, just use the then most current version of the implementation guidance that we're referring to.

John Halamka - Harvard Medical School - Chief Information Officer

To give an example of what Jamie was referring to, let's imagine RxNorm as a vocabulary for medications. Now many of our organizations use proprietary code sets, so we might buy products from First Databank or Multum, Micro Medics, Gold Standard, etc. So are we going to require specifically in 2011 that everyone gets rid of proprietary codes and moves to RxNorm? Well, to Wes' point on burden of implementation, that would probably not be achievable. It would be expensive and unrealistic.

But yet, are we going to submit to Floyd and Janet, here are the medications and the quality measures in First Databank coded format or Multum or Micro Medics or Gold Standard? Well, that would be unreasonable to have the standards metrics organizations provide vocabularies and code sets for every

proprietary code set that might indicate that a medication was administered appropriately. So for those limited measures, there's 17 measures that they've defined. RxNorm for just those 17 data submissions should a medication designation be required as part of a data type would be in an RxNorm vocabulary. This allows a relatively straightforward transition from – I'm proprietary today. In fact, I may stay proprietary for a long time in my organization. The burden on me in 2011 is very, very limited with regard to using some more advanced vocabulary and mapping.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Just to those particular codes that are required by each measure.

John Halamka - Harvard Medical School - Chief Information Officer

Right.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Okay. Just to summarize our recent workgroup discussions, and this goes back to the single change in timing that I referred to earlier. Previously we recommended the PQRI registry XML specification for quality measure reporting for 2011 with QRDA to be used as soon thereafter as possible. Now the change in timing is that we're now recommending either PQRI or QRDA for 2011 and for 2013 with a long-term direction to move to QRDA only by 2015 or when possible, so this is another example of saying that you can use either one, but there's a directional statement towards the QRDA standard.

And this is again one of the very few cases, one of, in fact, I think, two cases where we are recommending two different standards as an option for exactly the same purpose. In general, we're trying to avoid that, but this is one of those exceptions. And also, just to refer back to the previous discussion of the quality workgroup, in the diagram that was discussed. This is for steps or transactions four and five on that diagram is where this applies.

We've also discussed implementation guidance in general, and this is something that Lee will come up shortly and will discuss in much more detail, but I just wanted to note that all of our implementation guidance uses the HITSP specifications, except for the PQRI quality reporting option. Now in terms of some of our next steps, we have talked about establishing a series of meetings to talk about some of the vocabulary gaps that we've talked about. One of the top priorities there would be for a compendium of orderable labs, and we've also talked about the need to discuss the long-term standards recommendations for procedures, and SNOMED to ICD mapping, and a number of other issues, so we're looking forward to those meetings in the future.

We also want to discuss enhanced guidance and implementation specifications for quality reporting and for things like patient access to electronic records. We also, in the future, want to talk more about standards maintenance processes, and then look forward to moving on to the 2013 measures and starting to work on the next round of work.

John Halamka - Harvard Medical School - Chief Information Officer

And so to the comment Janet made at the end of her presentation about PQRI XML versus QRDA, here's our challenge. We don't want to confuse the marketplace by offering two approaches. As you've said, parsimony is getting to one standard for every purpose, but what do you do, based on the maturity guidance that we've talked about for several meetings of a – gee, is it widely implemented and understood? Is it kind of implemented? Is it not implemented? Is it a gleam in the eye?

And QRDA is basically a nascent standard, so requiring it as the single standard in 2011 is not realistic. But yet, for meaningful use, we need to get that four and five, that transaction reporting to CMS done. So interesting challenge, do you choose and force an immature standard because it's required for meaningful use, or do you allow a migration path that says we'll use something that is well understood, the PQRI XML, not perfect, but well understood, and then directionally move us to QRDA.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Right, and we also discussed the existing national infrastructure to support the use of these standards as a practical matter for the quality measure submission in this particular case where there are approximately 70 registries currently operating, so using the PQRI specification for measure submission to CMS, which is accepting them, so that's working, QRDA not so much.

John Halamka - Harvard Medical School - Chief Information Officer

Right. Also just as a comment on the vocabulary, you know this is part of meaningful use that exchanging lab results is required for 2011, but ordering is not required until 2013, so we'll have, from a HITSP perspective, the capability that specifies all the standards for lab ordering by January, and the orderable lab compendium vocabulary that accompanies that is work that's still in process. But we will be able to hit the 2013 standards. When you see all this, this falls into the category of important next steps to make all this work for 2013 and 2015.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Questions?

Jonathan Perlin - Hospital Corporation of America - CMO & President

Any comments or discussions are welcome. David McCallie?

David McCallie - Cerner Corporation - Vice President of Medical Informatics

One question, Jamie. We discussed this a little bit last time. I'm just curious to know what your reasoning was around the NCPDP Script 10 decision, which is not yet implemented anyway.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Right. We did come back and discuss that again in the workgroup, and I don't know, John, if you want to comment on some of the other discussions on that, but we did feel that it was feasible to move to Script 10 by 2011, recognizing that if there aren't changes in regulations for MMA and other things, that may not, you know, that may inhibit it, but we did feel it was feasible.

John Halamka - Harvard Medical School - Chief Information Officer

It's a technology question and a policy question. The technology question, Kevin Hutchinson from Prematics said, I just want to let you know that actually all the guidance, all the implementation that is necessary, all the testing for the NCPDP 10.x actually will be complete by end of 2009, so hitting 2011 technically with NCPDP 10.x shouldn't be a problem.

Now I know that NCPDP has been working with federal agencies to make sure that that 10.x policy is allowed because right now the Medicare Modernization Act specifies 8.x. And so, yes, we would run into the problem that if the policy weren't to change, and the technology were available, that's an issue. But let's hope that the policy changes and that, therefore, we'll converge on 10.x.

Jonathan Perlin - Hospital Corporation of America - CMO & President

We've got Karen Trudel and Gina Perez.

Karen Trudel - CMS - Deputy Director, Office E-Health Standards & Services

I'd just like to follow that up. CMS is putting into HHS clearance an interim final rule that would adopt 10.6 as a voluntary additional standard to 8.1 through our backwards compatibility process.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Great. Very helpful contribution. Gina Perez?

Gina Perez - Delaware Health Information Network - Executive Director

Can you talk a little bit about your thinking around an order compendium for 2013 and standardization in that direction?

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Well, again, that's the lab order compendium. We recognize that that's something that is likely to be needed for lab order standardization, but that's not a 2011 requirement, so we're just listing that on our, I guess, wish list of future topics.

Gina Perez - Delaware Health Information Network - Executive Director

Is that what the committee is going to be looking at soon?

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

Yes. As I said, we're anticipating setting up a series of meetings on a variety of vocabulary topics, and that will be one, and so we'll invite members of the other interested parties from the other workgroups to those as well.

Gina Perez - Delaware Health Information Network - Executive Director

Great. Thank you.

John Halamka - Harvard Medical School - Chief Information Officer

What Jamie has requested of ONC is the notion of getting world experts on vocabularies to focus on these issues of lab order compendium, the SNOMED, ICD crosswalks, the incorporation of LOINC and these sorts of things. It's a little bit different than the focus of clinical operations, and it would probably require some different external experts, and so we hope to move forward with that activity.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I think David had another comment.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

A technical detail question reflecting some confusion in our company in interpreting HITSP capability 120 for moving documents, so the question would be, in 2011, simplest possible scenario for interchange of a structured summary document from provider to patient. Would that require an XDM or an XDR formatted transfer of the document, or does capability 120 allow for just a secure channel and an unstructured, if you would, in terms of the directory formats and the like required by XDR and XDM? Sorry for the details, but it's actually a pretty big technical issue.

John Halamka - Harvard Medical School - Chief Information Officer

Absolutely, and so to explain these two capabilities, capability 119 is the unstructured document, and 120 is structured documents the CCD, CDA kind of construct, they both refer to service collaboration 112, which allows data transfers to take place using XDR, which is basically a push of information over an encrypted channel, XDM storage of data on mobile media that could be a thumb drive, XDS pushing it to a registry. And so, you know, in terms of the simplest, a push using XDR to a personal health record, or giving the patient their data in an XML form on a DVD, CD, or thumb drive using XDM is the current guidance.

David McCallie - Cerner Corporation - Vice President of Medical Informatics

That's how I read the capability. I just wanted to make sure that's what your intent was.

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

That is our intention. Just to clarify, 120 is the unstructured document, 119 is the structured document.

John Halamka - Harvard Medical School - Chief Information Officer

Right. It's backwards. Sorry about that.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Aneesh Chopra, you had a comment or question?

Aneesh Chopra - White House - CTO

Just a quick question, and forgive my ignorance. I'm not familiar with QRDA. Could you just give a little bit of flavor about what does that mean for average Joe on the street for the ability to report quality?

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

The quality reporting data architecture is a CDA-like construct. It's an HL-7 standard for quality measure exchange.

Aneesh Chopra - White House - CTO

But relative to where we are with PQR, is it easier, simpler, more widely adopted, just a little bit of flavor of what....

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

No, it's generally not used yet. It's a newer standard, so I don't know if, Floyd, you want to....

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Can I just make a comment? It actually has been tested. It's a ... standard for trial use. I believe Farzad Mostashari has done some testing in New York City. Some other areas have. It is not in wide use. Absolutely. It allows reporting of multiple patients' data or single ... XML, and it's also using CDA similar to CCD and other CDA constructs. It's consistent management of data, which is the reason for looking at that.

Aneesh Chopra - White House - CTO

Multiple patient, is that the new dimension? PQRI doesn't support the multiple...?

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Well, PQRI allows that too.

Aneesh Chopra - White House - CTO

Got it. Is there an innovation you could just take a minute to describe? What's the innovation of this over the PQRI if there's...?

Jamie Ferguson - Kaiser Permanente - Executive Director HIT Strategy & Policy

I would say it puts quality reporting on the same basic technical architecture as all of the other documentation exchanges that we're recommending.

Aneesh Chopra - White House - CTO

Thank you.

John Halamka - Harvard Medical School - Chief Information Officer

The idea is we can use across clinical care and clinical quality, individual patient and aggregate data, the same framework for data transmission based on a CDA document. It's going to be simpler for vendors to implement.

Aneesh Chopra - White House - CTO

That's the answer, simpler. Thank you.

John Halamka - Harvard Medical School - Chief Information Officer

Any questions? Okay. Well, you want to move on adopting this, and then we'll hear from Lee about the background?

Jonathan Perlin - Hospital Corporation of America - CMO & President

I think, since we've exhausted questions, and this is really refinement ... consensus? Do I hear that as a motion? To move?

Janet Corrigan - National Quality Forum - President & CEO

Second.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Second, great. Any objections? Terrific. Then we will take this forward and move on to the next section of the agenda, and I actually might ask John Halamka to introduce Lee Jones.

John Halamka - Harvard Medical School - Chief Information Officer

Sure. Great. Lee Jones serves as the program manager of HITSP, and this has been a four-year process of harmonizing standards, hearing from multiple stakeholders, 700+ organizations coming together to develop implementation guidance. And so Lee is going to give you a sense of how does one go from base standard to implementation guidance. Why does one want to do it? And this really because today's theme is specificity, implementation guidance, getting things that are testable. He'll give you a sense of the process, where it's gone, and where it's going.

Lee Jones - HITSP - Program Manager

Good morning. I appreciate the opportunity to speak with you today. I certainly want to applaud you for your great work, and I was very encouraged to see the recommendations as they came forward when HITSP was included in a number of them, so I'm particularly pleased.

I was asked to come here and to talk a little bit about implementation guidance in as much as you're now at the point where you have to wrestle with how to select appropriate implementation guidance, and so I wanted to just give you some additional bolstering of your mental framework for thinking about that, as well as try to give you some insight into what you actually already get when you selected and made recommendations around HITSP constructs. And so hopefully I'll be able to accomplish those two goals.

The first question really is what do we mean when we talk about implementation guidance. I don't think that there is a standard definition that one could find that says that this is implementation guidance and that is not. In fact, you will see a number of different organizations publishing things that they may call implementation guidance or serves as such, even though they may not call it that. So it may be as simple as a definition of a standard itself, which to some extent is instructive on how one would use the standard and gives you guidance on its implementation, or it could be as complex as a reference implementation where someone builds an actual system and says this is how something is done. In fact, you could take that to the extreme, and someone could say, it's not just a reference implementation. It is the implementation where everyone uses the same technology, as an extreme case of guidance on how you would implement a solution.

In addition to that, the implementation guidance can span different kinds of areas of implementation, so we can talk about standardizing around data, standardizing around technology platforms, architecture, the content of the data, how that content is encoded. And so when we talk about implementation guidance, we're really talking about a broad set of things that you have to consider in order to be able to instruct someone on how to accomplish an implementation. As a working definition, I'd like to put forward implementation guidance should really be linked closely to testing or how you're going to recognize that an implementation has been done successfully.

And so that's what we try to think about in HITSP as we move to produce implementation guidance and that's what I'm going to talk about a little today.

So as is often the case with many things upon subsequent thought, I've greatly improved this slide and it's on my computer, greatly improved, but it's not greatly improved on your piece of paper and on the screen here. So I'm going to try to take you through a little bit of a visualization. So I have somehere. One is the degree of implementation specificity versus the degree of automatic interoperability without solution. Meaning that people can implement something with a set of instructions and without collaborating with one another can arrive at a solution that's interoperable is what I mean by that.

So you could image that this could be a scatter plot of a number of different points that are unrelated, each on corresponding to a specific standard. It could be instructive to some particular degree and it could insure interoperability to some particular degree. But there are a few dimensions that aren't really,

aren't called out on this graph. One is how you define interoperability and what that really means and another is the context in which you would be measuring these things. And so our challenge in HITSP is if we have that scatter plot of different standards that have all kinds of implementation guidance and they have all different degrees and levels of specificity around that, how is it that we plot a course through all of those different points and arrive at some consistent way to describe how you implement something and to insure a particular level of interoperability.

So this blue line that you see here is really what I would call the implementation guidance function, if you will, or curve around harmonized standards, so not any one standard, but a set of standards that all have competing dimensions and requirements. And we try to take those and make ...way to implement interoperability with them. So with that kind of a curve, you could argue that we could, that the curve may not look like this in practice. That it could, the slope could be different, it could be tilted one way or another. It could be moved up and down depending on how you would define it. And really those things sort of get at what makes your choices around implementation guidance not arbitrary. I think in order for it not to be arbitrary, this is a little bit of an art versus a science, we have to have some sort of dampening function that controls us and puts a chip on how we select that guidance. So this red line is trying to depict plotting on the same set of axis, but introducing the degree of freedom that you have in implementation. The fact that more implementation specificity that you provide, the fewer degrees of freedom that an implementer has. So if you're very prescriptive about how something can be done, then an implementer doesn't have a lot of choice on how to do it. Conversely, if the implementers have lots of choices, then they may do it in different ways and you don't have a lot of specificity.

So I would call this red curve our proprietary innovation constraints on interoperability. I say proprietary innovation because there's often this argument that's made that the more prescriptive we are, we're limiting innovation. But really what we're limiting innovation around is the interoperable portions of an application. So we don't want those interoperable portions to be proprietary to the extent that we can avoid it, but we want them to be common and available to all.

And so when look at these two curves next to each other, the thing that keeps HITSP in check is that we invite implementers to the table and they naturally bring this perspective about the red curve. And so they keep us from going too far up the spectrum of specificity around interoperability and especially when you start to talk about constraining hardware architecture or software architecture or particular technologies or platforms. And so that is sort of a natural tension that we have and what we wind up really being specific or more prescriptive about are constraints around data and information, the flow of it, the representation of it, formats and the contents, even the rules around the information flow. However there are some boundaries that put a natural chip on what we would specify is an implementation guidance.

So with that in mind, the portion that really is important when we consider implementation guidance is how we're going to recognize that one has been compliant to that implementation guidance. And so testing is really a very important part of trying to select what implementation guidance you want to have. So you could imagine if we have this curve around implementation guidance for harmonized standards, that if you pick a particular goal for interoperability or level like you have done for multiple years, 2011, 13, 15, etc., then there is some particular level of implementation guidance you would want to select in order to insure that that goal can be recognized. And so you don't want to say that people have to do things by 2011, or you don't have way to tell if they've done it. And the only way to really tell or make sure that your test for how they've done is to consider the instructions that you've given them, or the implementation guidance that you've given them.

So when you do that, that test or that line that you draw around interoperability really creates sort of ..., so that no matter how more specific you are about your interoperability guidance, people don't tend to go beyond a particular level of interoperability because that's where the test is set. And so you have to recognize that there is this natural relationship between the guidance that you have and its utility and the testing or criteria that you use for testing to recognize it. So similarly if you try to move further along the dimension of interoperability, you can prescribe different levels of implementation guidance that implementers will have to follow.

This is for on the HITSP, just to come back to HITSP's viewpoint on this, we have continually to work very closely with NIST over the years and with IAG in order to make sure that we had a channel to actual implementation and feedback in testing and a body of work that is built up over the four years within NIST that allows us to couple our interoperability specifications with specific tests that can be used by implementers to verify their compliance. So that continues today and has been evolving over a number of years.

So HITSP really harmonizes standards by identifying the appropriate set of standards for a given context or problem that's trying to be solved and then producing guidance around how to implement those standards in concert. So there are implementation guides that may be offered by a given a standards development organization around their standard. But when we start to enjoin multiple standards from multiple standard development organizations, we really have to be prescriptive about how those things work together. Our goal is to produce a system of documentation that facilitate different implementers to come to the same conclusion. We try to make sure that our implementation guidance is testable and as I mentioned NIST has been working with us in that regard. So when you have selected these HITSP constructs and capabilities, etc., you really are selecting more than just an endorsed standard. You're selecting a set of guides about how those standards can be implemented in concert with one another.

As so this next slide just tries to enumerate some of the components of what HITSP specifies pictorially. So at the bottom we have the universe of all health care IT standards. So HITSP does not create standards, nor does it try to change standards. Rather it tries to reference that universe of standards across different standards development organizations. And so our documentation by design is indirect and referential and so some people levy that as a criticism. However, we don't want to supplant the SDOs. Rather we want to make use of the good work that they do. In our body of work, which is represented here by these encapsulated circles, we do pull forward excerpts from those standards, so that in the implementation guidance itself, we can give enough of a context on what standards are being used and how they should be used, so that it's understandable and it's not just a bunch of pointers. In addition to pulling forward those and having a balance between that and referencing external standards, we have constraints and value sets that we choose around the content of the standards and the use of the fields within the standards, primarily data standards.

We provide other implementation guidance around the flow of information and other aspects. And then we really have done a lot of work to implement a framework or semantic framework around what interoperability means. That's very important because we could use the same words and we can use the same phrases, but be talking about different things. So we try to be very explicit about what we mean when we talk about the exchange of information and who is participating and how those actors are described and what they actually are doing relative to one another. So that's part of the system of documentation we have. And then more recently as you all made use of in your work, we've specified capabilities and service collaborations, which really now have tried to provide the right level of extraction, so that you can tie all of these technical details to a real world problem that's not described in a technical way. So when you give a use case or you give us some other problem statement, we want to be able to select from a library of capabilities that are close to that level of abstraction. And yet, they carry with it all

of the technical details that you probably don't want to think about at this level, but are necessary for us to achieve real interoperability.

And so I provided on the next slide this chart, which just tries to give you some sense of what HIPBE does versus what you may get from a given choice of a base standard, like just selecting HL7 messaging, 2.X messaging, for example. With a based standard you certainly may get a data format. You may get some prescriptions around the transport, the basic transport of how you move data around and the definition of what you're talking about, which are all critical for implementation. If that FDO provides an implementation guide itself, you would get all of those things, as well as maybe some additional instructions around the data content and coding and how you might represent particular concepts within a particular format that's specified. You may also get some optionality around different contexts that they know that the standard is used. But what HITSP does is it tries to pull forward all of those things that are offered by the standards development organizations, so you get all of the guidance that they give themselves.

But when we enjoin all the other standards and we put together that system of documentation that I already described, you get a number of other things, such as specific value sets within a large vocabulary. These are the items that are a particular concern for a given context. You also get universally defined transactional actors. So we want to be able to say in EHR when I'm talking about it performing this kind of transaction, it's the actor as I'm talking about in this other kind of transaction. So that when an implementer who cares about a set of them, they can identify where they play across the spectrum.

We also bring along any required attendant standards that goes beyond any one SDO. We provide a contextual conformance requirement. So anything that the problem space dictates as a constraint on how things are implemented, like regulations, policies, laws and other things, we try to account for those. And then we orchestrate how those transactions actually will happen, so that the implementers know the rules of how to put these things together.

So in conclusion it's really important in our view that you tie the definition of how you will recognize compliance or testing and certification to the implementation guidance that you select. So we don't want to just grab things that have a particular label or...implemented guides. We want to be thoughtful about it connects to your testing. The HITSP implementation guidance as I said tries to unify multiple sources of implementation guidance, whether it's from the SDO or from organizations like IAG. We graph all those things in. We constrain them. We add those layers on that I've discussed. And so to the extent that HITSP work is referenced in your recommendations, you get the benefit of all of those different things and you have some attendant implementation guidance built.

And so that was really my presentation and hopefully I want to go to break too soon, so hopefully it's added a little clarity on your thing around implementation guidance and also what HITSP provides.

John Halamka - Harvard Medical School - Chief Information Officer

I want to thank Lee for just a spectacular presentation. I don't know if you're an economist, but if you're not, you have the heart of an economist. The adoption curve you showed I think is so instructive. ...it has sort of a parable of history. You can imagine shipbuilding before the 20th century. Every shipyard used to manufacture its own bolts independently. And then it was determined that you walked into a particular supplier who made bolts that were inoperable with their own bolts. You quickly see where the metaphor is going. That when the threads were standardized, all of a sudden it meant that people had multiple suppliers that improved the quality and the efficiency of shipbuilding and indeed created a platform for innovation.

On the other hand, it required a market to really accelerate shipbuilding any further and ...that market was created in part by the first world war where ships were necessary. So there are two pieces. One is without that degree of specificity, your grasp of tighter specificity and the ability to have interoperable pieces without collaboration was really what was achieved in that metaphor of shipbuilding.

On the other hand, to really pull forward and accelerate and amplify, it was the market that developed. Here we have both opportunities. There's the opportunity for us to converge as we're doing in terms of standardizing the threads, if you will. But what I think is so spectacular about the moment is, of course, that the market has been accelerated dramatically by the incentives that the White House has brought to bear and have been approved to support this process. So I think that is a terrific presentation in terms of context setting because it also addresses that the tension that we have been really grasping with each and every time between specificity and innovation. I think it helps us understand that the two are in effect very complementary.

Let take some comments and we'll start with ...and work our way around the table.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Lee, great work and I think you actually clarified HITSP in a way that was useful for me personally, but I'm hopeful for the crowd. Just a question, the last bullet on the slide about the values that we bring to the table, orchestrated participation in transactions, could you just give me a few more words about what that means from the provider standpoint?

Lee Jones, HITSP

Sure. So when we're talking about interoperability among different kinds of entities and they're using different kinds of enterprises and they're using different kinds of tools, etc., it's important not just to say what information is being exchanged, but what are the rules of the transaction. So I send something to you. You acknowledge that you've gotten it. You may have to log something about it. I may have to give you some other information and response. It may be a complicated transaction like e-prescribing word in joint eligibility checking, as well as the prescription itself. And so we want to say what are all the different components of a transaction at the level of granularity that people think about it.

Jonathan Perlin - Hospital Corporation of America - CMO & President

When we think of interoperability, there's technical interoperability. I send you fax, not a whole more we can do. Semantic interoperability, I send you a structured XML document, you can interpret that and that information can be used for decision support. And then there's processed interoperability. We agree that we're business trading partners. I'm going to send you a request. You're going to send me a response. I'm going to send you an acknowledgement and we have orchestrated a relationship that is a processed based transaction. That's really what you're referring to.

Lee Jones, HITSP

Thank you.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Let's go to Linda Fischetti next.

Linda Fischetti - Chief Health Informatics Officer - VHA

Thank you, I'm going to go ahead and use your metaphor. You're a customer of the SCOs for the base standards. And so using the supply chain management metaphor, it appears to me that what you've done at this point in time is that you've gone and taken the existing standards off the shelf. You're doing this at the exact same time that other national programs are doing this as well. All of the sudden, the SDOs have multiple national programs with new customers, such as yourself. Knowing that what we're taking off the shelf today will not sustain all of the vision that we have getting through the next six

years, what's your assessment of your supply chain of base standards? And what needs to be done to make sure that base standards are meeting HITSP's needs to meet the goals of this committee?

Lee Jones, HITSP

Were you asking me that or were asking John?

Linda Fischetti - Chief Health Informatics Officer, VHA

Anyone.

Lee Jones, HITSP.

Well, I think ever since HITSP has come into being, there have been parallel efforts where various people are doing various things that are either duplicative or overlapping or complementary. HITSP's approach has always been wherever we find out about such a thing, let's try to collaborate and bring people to the same table. So HITSP is a come one, come all, open consensus based organization and we proactively solicit people to participate. So while it doesn't totally solve the problems, we only know about what we know about. And some things happen in parallel.

We do have a philosophy of not invented here is exactly what we want. So we want to go and get what other people have done and take advantage of that. In terms of ongoing maintenance HITSP certainly has a process to—every year we sort of put a statement of work together, technical committees do, on what needs to be done looking retrospectively at the work we've already done and then try to balance that with the work that is coming. Sometimes as you can imagine being government contract, we're beholding to the newer things versus addressing the older things. But I think that's probably going to change as people actually start to implement things as a result of your work, where the focus on needing to keep that body of work up-to-date and appropriately evolving is going to be of greater import.

John Halamka - Harvard Medical School - Chief Information Officer

Linda, I just also wanted to reflect that for 2011, we're in pretty good shape. We were able to find HITSP implementation guidance and HITSP was able to find standards that really fulfill substantially all of the 2011 proposed meaningful use measures. For 2013, though, for the proposed measures for 2013, we're going to have some gaps and HITSP is going to find some gaps. So not only do we not have necessarily at this point in time, the implementation guidance that would be needed for the proposed 2013 measures, but there are, in fact, some gaps in the base standards and in the implementation guidance for those base standards that it's going to have to be addressed somehow for 2013 and beyond. But for 2011, we're in pretty good shape, but I see a lot of work ahead of us.

Jonathan Perlin - Hospital Corporation of America - CMO & President

We'll go to Peter

Peter ?

...responsibility that is has under the are and to help identify where the base standards need acceleration and figure out ways to accelerate. So we've been working closely with HITSP as...said and we will continue to use this new capability of funding to figure out what the priorities are and where we need to move the quickest to help this along.

John Halamka - Harvard Medical School - Chief Information Officer

The supply chain of standards has been adequate today as you've described. You might imagine there will be commissioning of standards where there are gaps that are identified and this will play an important role in that.

Peter ?

We encourage the voluntary consensus process, but we can encourage.

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

First of all, I want to say this was a tremendous presentation in the intersecting supply and demand alternative curves were wonderful. I hope you'll post a more advanced slide somehow, so we can all see

it. Just to show that there's no metaphor that can't be overused in series among multiple people, the supply chain metaphor here, I think of a grocery store or a bodega, if you will, where standards groups puts stuff on the shelf and HITSP comes through and takes several things off the shelf and say these things together will make up a meal. But I have to provide the recipe for how to mix them.

Like any supply chain, there are time lags in the process. So when standards groups set out to create a product, it's long time from where it starts to it gets on the shelf. If I'm going to make dinner tonight, I don't have any choice about going back to the farm and saying why didn't you grow the rice differently. I take whatever rice is on the shelf.

I am concerned that we have a way to identify two SCOs, what needs to be on the shelf in two years and that the SCOs pick that up. I think they're trying to do it. I think when you get to \$38 billion, you're talking about real money. But I want to see that process go forward and I want to ask you a question. What could SCOs do better in terms of how they package the stuff on the shelf? In other words, you have this diagram with a concentric circles that starts with a big arrow down to a circle that is the reservoir of all standards. That would look better as a camouflage colored thing because they're all different shapes and sizes. Is there anything that the standards organizations can do individually or together that would make the process more efficient and the work product more accessible to non-standards experts?

Male

So I'll start with that. So the standards charter organization has come together as a multiple SDO group to say things like if we're all going to reference gender in our various standards, clinical, administrative, quality or whatever, how about we all agree on what the value set is and we'll all use the same value set? So that in a sense pre-harmonizes the work of various SDOs, so that all the cans on the grocery shelf come in the same size. Certainly that kind of pre-harmonization is helpful.

John Halamka - Harvard Medical School - Chief Information Officer

I would add in talking to the SCO, they have had discussions about who is their customer, their collective customer and what does that customer want. I think that the beauty of what is happening with the Office of National Coordinator and groups like this is that it's making that clearer because they all serve multiple stakeholders and worldwide and all these other things. But with respect to health IT and health information exchange, it's clearer now who the customer is. So when you can identify or put a face on the customer, you can understand better what the customer wants. And so I think what's true of HITSP is going to be true of them.

As I know look at, for example, if I look at this group as HITSP's customers, I look and see what activities you're doing. And I notice now you are roadmapping these standards and you're trying to say that there's a progression of adoption that's important for you to capture. Well, for me that would mean maybe HITSP ought to do something to make that job for you easier. So we should start to think about that roadmapping activity that you're going to do in the production of our documents. Similarly for SCOs who participate in HITSP, we've been encouraging them to produce implementation guides. In fact, these are the kinds that we're advancing to the government and they're using. Maybe your implementation guidance can have similar hallmarks and take on some of the characteristics, so that as it progresses down the chain, people have less of a burden to try to reconcile their own mission with the work that's passed to them.

Male

That might be drilled down on that specific point you just made. Which is that you have to deal with a very mixed set of inputs. Is there work going on, so that your ability to meld the standards will be easier? And the second question is what about standards groups licensing requirements for their standards—I don't mean licensing, I mean intellectual property protection for their standards, are there things that should be done to—would it facilitate the work of HITSP a great deal if the SBOs were able to come to a common way of dealing with intellectual property issues?

John Halamka - Harvard Medical School - Chief Information Officer

Well, let me take that last one. I think that's very important. One challenge that I have in describing HITSP's work is what I would call indirection. And that we start off at the top level with the most granular guidance and that refers underneath it to, let's say, we go from a capability to a service collaboration, to a transaction package, to a base standard. And then when you go to click on the base standard, it says you are now on the HL7 Web site. Please deposit \$400 and you can get all this guidance. And wouldn't it be wonderful if you had a Web based, yes, fine, maybe at the top level there's some intellectual property protection, but you wouldn't have as much indirection. You could get directly to what you needed because the SDOs have a business model. They need to charge for the intellectual property to survive. And that means an implementer has sometimes a navigation challenge getting to all the necessary soup cans to make a dinner by going to multiple different stores to buy the ingredients.

So, yes, they come and approach the intellectual property or licensing SNOMED types of constructs where there's global licensing for certain users would be a great help.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Not only that, that one thing if we were able to really automate the presentation of our body of work because not only does it go to your ...Web site, \$400 and all of that, but then HITSP for a given context may be talking about this ...sliver of what HL7 is doing. And then you're going to get this huge tome of information and it's hard to weed through. So if we can make it easier for them to integrate their work with these downstream uses, I think that that would be good.

John Halamka - Harvard Medical School - Chief Information Officer

So what I hear is that one of the way that the SCOs are not standard is in the automated versions of the standards that they produced. They use very different formats and conceptual models for that.

Male

They also have different business models associated with—

John Halamka - Harvard Medical School - Chief Information Officer

Right and then the other area is any time we could avoid a licensing issue consistent with the FBO still being able to do its work that that would be a membership issue. That would be helpful. I think I heard John hinting a sort of a Web solution or a 2.0 solution or something that said a user authorized to access HL7 standards could start at the HITSP Web site and link down into very specific sliver of HL7 without ever knowing that there was a transition because they were already authorized. That's really interesting.

Male

That would be ideal.

Jonathan Perlin - Hospital Corporation of America - CMO & President

...on some initial ...and then Jim Walker, I want to make sure that before we go to break we have some opportunity to set up the discussion of some adoption and implementation. So it was a terrific discussion, an excellent presentation.

Nancy Orvis, DoD

Thank you for doing this presentation where you've shown the comparison of implementation guidance sources. I was looking through all the various attributes of that and I think John and lots of people know the various kinds of intellect needed to help produce information on folks who want to help determine the format or the content versus the sequencing and the processing is pretty varied across the health care organizations. I think what I was trying to go with Linda's question is, we've done a lot of the content of this work from 2003 through 2009. It seemed like a decade, but it was really only six year ago where a lot of this has been produced. I think there is a concern and I've told folks in my organization for health care trying to recruit people saying we need to be thinking, actually if we can get something out there within two to three years, it will be used, it will be a likely contender for national adoption because we need folks who can understand the clinical and health care processes and help create standards and content in that area.

It doesn't seem quite as sexy to them as saying I've just put in a new iPhone and put all my mobile devices together and had all this great information. But I think we're trying to figure out how we can stay ahead of this curve for '13 and '15 because there's more and more rapid consumption standards. But I don't think that we figured quite how to produce standards faster. Like you said, there's more grocery stores that want to open up and use what's on the shelf. But we have to figure out a way to keep that content going. I don't know if there were ways that we could help you and various others can figure out better ways to communicate where those needs are in terms of the right people to help within organizations and with you all. Do you guys have thoughts on that at this point?

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

Certainly I expect this committee to come up with a series of next steps, because we're going to focus now on adoption. And if today's meeting is implementation guidance, the next step is adoption and that's going to create feedback loops. I would have to imagine that this constellation of this committee for HITSP and ONC is going to be working with the SDOs to fill gaps to get commissioning of standards where necessary to accelerate adoption. So I think that this is absolutely the right next focus.

David McCallie - Vice President of Medical Informatics - Cerner Corporation

Yes, David McCallie, I want to leverage some of what Wes said. First before I make anything that might come across as a criticism or a complaint, let me congratulate you on an excellent presentation. I wish I had seen it earlier in the process. It would have helped explain some of the terminology and approaches. And John with the work that HITSP has done is remarkable and the output has been extremely useful. So take what I question or suggest as in the context of a deep appreciation.

But I would say as someone who in my career in HIT was involved with standards bodies fairly aggressively in the early part of my career, and then moved off and did some other work. And then by virtue of being on this committee coming back to the process, so coming at it with somewhat fresh eyes, I'm astonished at how complex we've made it not the least of which is that just the navigational complexity to figure out what the heck the standard is and then to run into these, I'll call them, picayune barriers, that even though we're spending \$30 billion on stimulus for HIT, we've run into license issues that we can't have a direct link into an HL7 Web site. It just is crazy and frustrating.

There's a competition out there where there's a group of people who believe that there's a simpler way to do this. Nothing will stop from going forward with that if this approach that we all invested so heavily in is going to turn out to be the right way to do it. We have to make it easier.

So I guess the broad question is, can we remove some of the levels of indirection? Can we solve this intellectual property issue, so that the linkages can be navigated quickly and easily by a startup garage company that wants to jump into this space and can figure out how to play by the rules? Do we need to consider things analogous to the connect-a-thon, like a air-a-thon maybe where people that are trying to do stimulus can get together and test their stuff out in a context outside of maybe a certification environment? Should there be open source reference implementations sponsored by HITSP or endorsed by HITSP that would speed the process of adoption of some of these more complex protocols? What's it going to take to make it, so we make the path easier to slide down?

John Halamka - Harvard Medical School - Chief Information Officer

So these are all excellent topics for the adoption work group that we're going to be talking about. One of the things that HITSP is trying to do and working with the HRQ is, HRQ has a tool called USHIK and this is the U.S. Health Information Knowledge Base where you might imagine you can go just type in problem list and then get the list of the constructs that are necessary to transmit a problem list.

Now this is still a work in process. We have to insure that to your point, that this tool as front end to all the work that the SDO and HITSP has done make this whole process much easier to navigate. I think we've heard from the committee and I think it's worth exploring, how might we remove some of these intellectual property barriers, so that what HSHIK could do as a front end is one click access directly to the SDO artifact and not having to go through multiple layers of indirection. That's not yet a body of work

that I am aware of, the intellectual property side that is being addressed. But at least a Web based navigatable framework for much easier access is in process.

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

I guess the one thing, I think it can't be, that point can't be overstated because I think a lot of what people perceive as the complexity and difficulty is in the presentation. We're bound right now to Word documents and before usability, they have to really be decomposed, so that you can string together in different ways. I liken it to an automobile. If automobiles didn't have the outside, you could just see the engine and all the mechanical parts and those sorts of things. It will be much more difficult to select one over the other without having to inspect those things. But when you put the cover on top of the automobile, it really helps you make a selection and implies things underneath.

So you can tell this is a sports car. It's probably faster than that sedan. You can tell that this is more powerful than that. And so I think that we're trying to get at that with capabilities and that sort of thing. But putting that cover of a Web based interface on top of things will dramatically improve its usability.

John Halamka - Harvard Medical School - Chief Information Officer

This is a fabulous analogy because a car can't run without a carburetor. A carburetor has 270 parts, each of which have their own standards for specification for every screw. But when you buy a car, you buy a car. You don't care about the carburetor. Alas as a standards organization, we have to specify how the carburetor is built. So these ideas of these capabilities and service collaborations are trying abstract us away from the carburetor and get us to a construct, as you just said, and a bill of materials, this is a done part. You don't worry about the complexity behind the scenes and making the products easier to navigate would certainly give the sense to implementers that that complexity is not something they have to deal with.

Jonathan Perlin - Hospital Corporation of America - CMO & President

The last comment on this, ...but let's give Jim Walker an opportunity for your question and then we'll come around one more time, but please limit it to very brief points following. So we'll start with Jim.

Jim Walker - Chief Health Information Officer - Geisinger Health Systems

Great presentation, thanks. I want to follow up on Linda's and other's comments and just maybe put a little more point on it. As we get through the first few years of this in which the work is pretty clear and there's a ton of it and it's critically important. And it's pretty obvious what the gaps are. We're going to get to a point where we need to really re-imagine health care if we're going to make fundamental improvements in quality and efficiency, things like interoperable care processes. It seems to me that this committee is probably one good group to really somewhere down the road, not too far, start trying to think about what would really breakthrough transformed health care look like and what kinds of standards that aren't even in view to be required to support that and start guiding that commissioning process early, so the pipeline stays full

Jonathan Perlin - Hospital Corporation of America - CMO & President

I think that's a terrific question. That in a sense is the essence of the kinds of adoption implementation and it's not just putting standards into use. It's used toward the end, where does that end. I certainly personally hope it's for the improved health care that is transformed.

...a quick response ...because I think this is really, there's obviously a lot of interest in this topic. What I recommend is that after we come back from the break, this is really the meat of that. I want to have some discussion actually setting up. Then this is actually a good segue to that, although it's time for that because of a couple of time schedules to honor.

Wes, a quick point on this?

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

Are you saying that the next agenda item will be about the implementation committee?

Jonathan Perlin - Hospital Corporation of America - CMO & President

Absolutely.

John Halamka - Harvard Medical School - Chief Information Officer

The thing that I think is really important that we keep in mind, we just spent several minutes talking about the problems of penetrating our standards implementation guides, etc. We've created that mess. We have added complexity and layers and made them impenetrable in a lot of cases. Now we have a complex enterprise that we're trying to engineer. Lee described how we try to reduce that by building implementation guidance and decreasing optionality and so on for specific use.... But the trade-off to that, I think, is that we end up with a lot of complexity and, frankly, differences in how implementations get done as a result of the complexity. HITSP, for example, I think has four different ways to send a radiology report because we've dealt with very specific use cases. And I know there's work to bring that together.

So I guess it's a plea for us to think about at least the UNIX tools approach, give me three simple ways to do things and let's reuse and reuse and reuse those...vocabulary standpoint. We talk about quality data sets, for example. What the heck is that? People get very confused and find it hard to work all the way through, including those of us who spend their lives trying to sort through this stuff. So I guess it's a plea for thinking about how we can accelerate adoption, not just by removing optionality and adding complexity, but by saying how do we take one or two approaches and reuse them again and again and again for every use case that we possibly can and only when we have to expanding them.

Jonathan Perlin - Hospital Corporation of America - CMO & President

The body language for those who are online, I think there's a lot of consensus in this notion of an economy of mechanisms to achieving implementation. Thank you for that.

John Halamka - Harvard Medical School - Chief Information Officer

And to that point, that's what these collaboration service collaboration thinking abilities is all about because he's absolutely right. When we receive these use cases, they were very constrained as to actors, actions and events. And therefore, here's a complex set of interoperability specifications for just this particular use case and across the 13 use cases, you might see different approaches because of the nature of the specificity.

What we did with these tiger teams over the last 120 days was say let's take what we learned and let's try to do it one way for every function, try to reuse components. What you see is, oh, secure transmission, here's a one way to do it. Oh, document exchange, and here's the way we're going to do structured, nonstructured documents and reuse that over and over and over. So getting to parsimony is always our goal.

Jamie Ferguson - Executive Director HIT Strategy & Policy - Kaiser Permanente

I want to compliment HITSP in terms of exactly what you just described, John, the appearance of components and service capabilities and the like has been a huge simplification. We could quibble that there's yet more parse money to be achieved, but I would be, if nothing, consistent in that one of the functionalities that I think it still grossly underspecified and starts to impact how do you use and engage and these kinds of standards is not surprisingly coming from me, the vocabulary space. There has been much ink spilled over the notion of a U.S realm and of having a consistent, simplified access method for value sets and terminologies. The U.S. health information knowledge base is clearly a step forward, but I think I and others would argue that there's yet more loops to be closed with respect to having a national terminology resource that would house, manage and maintain the value sets and terminology infrastructure, so that these capabilities and components could reference them transparently.

John Halamka - Harvard Medical School - Chief Information Officer

And I think you'll see in some of the work group activities that Jamie is talking about, organizing with NLM and other stakeholders that that's exactly a goal to achieve.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Well, I really appreciate the discussion. I think it just ratifies the importance of the adoption implementation discussions that we'll have, the chartering of the implementation work group. Toward that end, I know that Dr. Rene Shepard wanted to respond to some of these comments, but for those of you who may not know ...history, it's interesting. If I might share some of your personal story, a bit of an adoption implementation challenge in the commonwealth of Virginia, the chief technology officer there, there were all sorts of resources that were available. But many of the barriers that we just enumerated were barriers to the citizens of Virginia, the businesses of Virginia, the public servants of Virginia getting access. I think one of the reasons that the White House reached out to ask ...to be the chief technology officertechnology policy was because he's had some real world experience.

I also think it's instructive sometimes when we look outside of our box of health care to people who have overcome challenges in other areas. I know I'm embarrassing you because you're a very humble individual, but these are the achievements with that in mind would like to do two things. First, I'd like to share that Dr. David Blumenthal, health national coordinator, and John Lumpkin and I have asked if ...would consider chairing the implementation work group. And second if you would offer some framing comments for what translates from another sector that you think we should be thinking about in terms implementation and adoption. So with that, let me turn to Aneesh.

Aneesh Chopra – CTO - White House

I appreciate that very much and your kind remarks. I want to say this just at the outset. When the president was inaugurated he had a line a line in his speech that I think is the basis for this conversation, what motivates me in service to him. And that is he asked that we have a government that works. And as we think about a government that works, we think about a standards body that works. I kept thinking about the question. I have a lot of physicians in the family and friends. I asked them if I knocked on your door tomorrow and I said, hey, we'd love to have a copy of the patient's record. Take your pick. Here's the standards. How would you go about doing this? How easy would it be for you to actually do this?

All the way through the conversations with hospital CIOs, where we would say, hey, look, we have no money. We have no investment capabilities, but could you just give the veteran a copy of the record and could you make it available in a way that would be accessible because we're faxing things and doing silly things. And the answers were largely well, we have a roadmap. I haven't put the resources to do this in the current budget. Maybe when I do the upgrade in X months or a year or two, I'll get around to this. Though it's really important we do this, it's right for the country, but I just am swamped and I don't have the ability.

So my on the ground experience is such that, when you knock on the folks' doors and you say can we start playing in the sandbox today, it's not the easiest conversation to have. I'm assuming all of us share this challenge. As I think about the President's goal of a government that works and that we're successful in the work that's been done, I basically have three basic principles that come to mind and I would hope you all would engage in and debate on this as the afternoon proceeds. I unfortunately have to attend some STEM education work for the President later today.

But my three principles I would imagine or what I suggest are as follows. The first is, it would be nice to have a little bit of a measuring about where we are on the standards today. There's a lot that we've talked about that's novel. There's a lot we've talked about that's been around for a little while. It would be nice if we could find a way to get our arms around are one percent of the nation's providers today doing X, 20%, 15%, 3.01%. It would be nice to have a little bit of a where are we in this space and how do we get that information. If we can't get it through formal channels, is there way through collaborative technology where we can engage folks to give us some of that, some way of listening to where the baseline is terms of the use of some of these capabilities would be very much appreciated.

The second principle, by the way, you did a great job, John, just summarizing the three pieces as you set up this discussion. But I would say the second principle is can we start listening to those folks who have to make the tough calls. My presumption is the CEOs of the large hospitals and health systems are aware of this issue. They're going to defer the next steps discussion to folks on their team, likely a CIO of sorts. There may be group practice administrators who might engage on these discussions on the

physician side. There might be extension centers, who as you know, have a funding announcement on the street for extension centers. There may be a network of those that are growing up that might weigh in. But can we knock on their collective doors and ask when can you get us a copy of the patient's summary? Or when can you report the following quality measure or some subset, to just ask, how are you thinking about this and listen to what the barriers might be. So that feedback loop could come into our work.

I love's John's framing of commissioning new standards to close the gaps. I loved that we've, as Lee pointed out, harmonized the existing panoply. There may be a third component, which is what do we adjust back at the source the source that actually might be a modification, as opposed to a new. And I don't know what the answer to that is. It's kind of like this QRDA thing. I don't where that came up, who was the idea creator for that standard and who birthed it and launched and therefore, allowed us to harmonize. Following that story would be an interesting one since it's a new term for me.

Just being able to listen to folks, just to knock on folks' door metaphorically, if you will, through some capability to get that all in the spirit of pulling forward, we have this beautiful map that we've been talking about of '11, '13, '15. That doesn't mean that we don't want to get folks to start sharing now. And so while we want to have this broader framework, and you'll see regulations to get how to go about doing that, my presumption is, again, I lean on my friends at the DoD and the VA since I'm here on behalf of the administration, we have agencies here.

These folks are hungry now. They want that data now; 70% of the DoD care at this moment because of the capacity constraints we have in the system is external to the military health system. I kind of think we want that data now. I would imagine the same for the 30% over at the VA. So how do we pull forward the technical barriers, how do we take the lessons learned about those who want to start consuming? If the President's budget passes with the investments, the incentives around 30 day readmission rates, my guess is we're probably going to want to see some data flowing to encourage outpatient and inpatient communication as a way to go about response to that policy lever. So how do we get feedback from the folks who want to embrace those data needs now, so that we can listen to their feedback?

Those are just the general themes that are in my mind. I welcome your all collective input over the course of the next couple of hours. I just think that the success this group has had in delivering phenomenal work over the last 120 days would like give great confidence that we'll be similarly productive in the go forward. So that's my final word or two concerning my thoughts.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thank you very much for that introduction. I saw a lot of resonance in again in the body language around the table. Certainly I think any of us who subscribe to this theory if you can't measure it, you can't manage. So, in fact, I think we hear the charge to build on some of the terrific work that David Blumenthal andhave provided in terms of some basic measurements of the country. There's obviously the opportunity to have a level of granularity with respect to specific charge in terms of meaningful use and the standards to support it.

What I heard back just to reply is the input on what the barriers are from the real world. What are people saying? And I think did a terrific characterization you gave to product versus project in our very first discussion of the quality measures. I think the unanimity of agreement in terms of the end goal, but there is a fair amount of consideration in terms of how this realized effectively. And so getting that....

The flip side is the third, which I'm going to replay back a little bit differently. Not only the hunger from those entities that are ready to move right this minute, but also something I really take as a ...of your experience, which is, okay, what about input from those who achieved certain levels of activity or interoperability? I hate to reinvent the wheel and frankly, I don't think we have time to reinvent. So I would hope that a large part of the testimony includes not only identification of barriers, but really the identification of best practices that we could emulate.

So I hope that's a fair recapitulation of the take home

Before we break for lunch, with that as a marker and knowing that you have an event at the White House you have to attend to, are there any clarifying questions amongst members of the committee on this point?

Okay, I think you're in need for a bio-break and hunger, please join me in congratulatingour new chair of the implementation work group.

Thank you in advance for the long hours. We will reconvene in a half an hour, 12:30, half an hour.

(Break)

Jonathan Perlin - Hospital Corporation of America - CMO & President

Okay, many thanks for everybody to reconvening. I tried in advertently to give the group an hour for lunch, recognizing that a hal and hour is not possible to get lunch and return, but many thanks to everybody sticking pretty close to that half hour.

We will regroup, terrific, terrific discussion this morning. I hope that's really a prelude to a continuing discussion this afternoon after some further thoughts on adoption and implementation. Before I get to that, I just want to just remind people that as we discuss and deliberate the process both at the federal advisory committee and by virtue of the high tech statute itself is that we, of course, make recommendations to the Office of the National Coordinator. There is a process that described in high tech to consider this recommendation. So I just want for the record to state that as we discuss things if we have a degree of exuberance or a degree of definitiveness, that that really is the passion of the participants of the ...and our discussion, but the process remains the process. And that is that our work product is ultimately expressed as a series of recommendations to National Coordinator. So I just wanted to state that for the record as a reminder.

Okay, that said, let's move on into discussion of the upcoming standards committee agenda and the work around adoption and implementation. I think the thread of discussion that we had before really got to the salience of this committee. I'd also note that there have been a number of people that have expressed interest in participating on the implementation work group. So it would be just terrific if others have interest who express that interest to John, May or Judy. And we'll work with John Glasser and Dave Blumenthal to get that committee fleshed out to all of the processes that have to be honored in terms of federal advisory committees and their work groups.

So let me turn, John, if you the opening comments on this and I know we still have some footnotes. Wes, you have a footnote at the start of this discussion, but, John, any opening comments?

John Halamka - Harvard Medical School - Chief Information Officer

Sure. So as we think of our agenda going forward, we really need to be bold about it. That is, it isn't, here's a set of recommendations that we've made today and now let's just polish these and we're done. It's, it's 2013, 2015 criteria and we think of some of these bold challenges we're talking about this morning. How do we handle consent management at a very granular level? How do we think of segmenting the medical record aswould suggest, that mental health, HIV, or other aspects of the medical record get segmented? What are the standards to do that? How do we achieve adoption? How do we accelerate through either guidance and education of through refining standards?

I think it's very important when we want to have this discussion with the group not to limit your thinking to just, oh, I've read through all the materials for today and I see three or four gaps and let's work on those. It's not what other very broad activities should we engage in because we have the 2013 and 2015 mandates and many other aspects of just getting 2011 done and then fostering adoption.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Let me just build on a comment that John Glasser asked for some guidance on, which is something that really falls in that same continuum of a tight degree of specification to looser. And obviously in high tech, you recall, that obviously we have to recommend to the Office of National Coordinator the standards. And you may recall also that it requires that we recommend implementation guidance to the Office of National Coordinator and that....to the process of being ultimately considered Office of National Coordinator, the Secretary's office published final rule making process.

All that said, there's a degree of specificity that it can occur in the regulatory process, but it's unlikely to be productive to specify every last aspect of implementation in that process. And so some discussion of how we provide adequacy of support to the real world that we'll seek to make use of these standards to achieve meaningfulas effectively as possible with sufficient specificity that's appropriate to be suggestive as input into the regulatory process, but not so overly burdensome in that process or....to subsequent modification of over time. So that will be some of the guidance that we'll be seeking as well in terms both the discussion of adoption and implementation and insights into managing the process itself.

So let stop there in terms of initial comments and John and I wanted to really engage in a dialog with respect those thoughts, as well assuggestions that to give....baseline measurements of degrees of adoption to build on the work that Blumenthal and others' input in the real world in terms of barriers and ways in which we might learn in support of actually adopting these standards towards driving meaningful use.

Wes, you had a thought from the last session?

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

Thank you. First of all, it was inspiring to see Aneesh's energy, new thinking, just someone coming back to saying we ought to measure this. That was in itself very refreshing. I don't mean measured quality, I mean measured interoperability. As you talked through his experience and he talked through the user communities that he dealt with in Virginia, he, I think, was particularly focused on the government/nongovernment interface. That has been and continues to be a significant challenge for health care IT interoperability, everything from FISMA standards for security inside the federal government and what are acceptable standards outside and what is the interface like and so forth.

If at that high level, there is one thing I would like to have heard and mentioned that he didn't was the economic impact of cooperating of interoperating. We have done something, the ARA has done something to create a economic benefit for people in the civilian community investing in interoperability that is by government terms, a flash in the pan, \$38 billion over five years. There's at least one other significant economic opportunity that we should consider using to drive achieving interoperability. That is what was mentioned this morning in another context, which is doing business with VA and DoD by civilian health care organizations, there's work going on for Kaiser to begin to interoperate in a limited way through thebridge. If that works, if we solve the FISMA, it's not a technical problem, it's a policy problem, if we solve those that should create such pressure from Kaiser like organizations that stand to make more the better they work with the VA and DoD, that we should see a goal line run towards interoperability for those organizations. I'd like to see us able to support that rather than have it happen on another playing field while we're over here.

John Halamka - Harvard Medical School - Chief Information Officer

Sothe third concept that Aneesh offered, who's ready and what might they learn, I don't know if Linda or Nancy might want to offer any initial comments or certainly within the construct of the work group.

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

Well, I totally agree that working out issues like the federal information security law, FISMA, is very critical to what we do on this. I think because it's not only a Kaiser like, but it's the states working with federal agencies, too. That's always been an issue. FISMA applies to federal agency sharing only and that has been part of the problem, sharing between the federal and the state level. So I would say that I think one key thing on this as Aneesh said, it's very important that leaders in all of these areas know that how this

work is not whether the technology is advanced enough. It will have to be very clear policy and risk mitigation policy. I believe, and Linda may correct me, through the federal health architecture and with CMS, we've been working on a draft policy for release of information from the federal to other U.S. entities that are non-covered HIPAA entities, which is basically set a guideline for risk mitigation in case of breach or alternation of data. That, I think, is still being worked, I think, at this point, but that's one aspect of dealing with this, so that there's a risk mitigation policy. And that leaders and other health care organizations understand what risk mitigation would be in case of security. I think we need to keep working that.

Jonathan Perlin - Hospital Corporation of America - CMO & President

I agree with that. I though I even heard more beyond as an economic driver to facilitate the pull.

John Halamka - Harvard Medical School - Chief Information Officer

I didn't mean to highlight the problems of policy, which isn't our job anyways, but to recognize that—I had a conversation with somebody at lunch who said, hey, I talked to C suite and they say we have enough money to invest in adding more support for our nurses or in becoming inoperable with our competitors. Which shall we choose and somebody says, "Am I on *Candid Camera*?"

It has been my solution, not my view that when there's an economic driver, technology and policy things get solved. When there's not, if you're trying to push the string by solving the technology problems, it doesn't work. We don't always get a chance to see them, but when we see a big one, we ought to pursue it and I think this is a big one.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Linda, did you want to?

Linda Fischetti - Chief Health Informatics Officer - VHA

Sure, absolutely. ...Nancy said, I think we're in the actionable items that the subcommittee could take on focusing on adoption implementation. It has to do with listening sessions related to the nationwide health implementation network. This is critical to the federal pass for interoperability. It would be invaluable to hear what the community has to say about NHIN as the go forward pass, so that we can anticipate and fix anything well ahead of the glide path. Thank you.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks, good points. Jamie Ferguson.

Jamie Ferguson - Executive Director HIT Strategy & Policy - Kaiser Permanente

Thank you, Wes' comment on the federal interoperability with the private sector, it seems to me that there are some things that may be enabled by standards, but that should be out of scope for us and other things that, I think, should be in scope for us as a committee. Let me give an example of what's out of scope and that is there are a number of security standards that are required that we require here in our recommendations to date, but that are required by FISMA. But there's also a cultural aspect of implementing those where federal agencies to this date typically require separate agreements, security agreements with each entity that they deal with and are not willing to use a common agreement form like the ... I think that's more of a cultural issue that we can enable that to be bridged by having adequate security standards that we recommend. But we can't get over that cultural bridge that's out of scope for us.

But something that I would like to see in scope for us would be to form the basis for collaboration to enable bringing together the standards that are used in the NHIN with those of HITSP and meaningful use into one, great blob of standards, if you will. That's something that really should be in our scope very clearly in my view.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thanks, that's very helpful. This sort of conversation would be very helpful in terms of ...to the Office of the National Coordinator, what's in, what's out, what should be done, what may not be done. We'll go to Gina Perez first and then Janet Corrigan.

Gina Perez - Executive Director - Delaware Health Information Network

So one of the things that we spend a lot of time really focusing on is electronic health records and standards with regards to those. I would like to see as we move to implementation, that we really look at the role of various types of organizations, so it's the health information exchanges in collaboration with the electronic health records. In the new grant requirements, the cooperative agreements, there is the requirement that the HIE now provide quality reporting. So I think it's important that we consider the direction that ONC is taking with regard to all of those programs and the impact on implementation with regard to that.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Thank you very much. Janet

Janet Corrigan, NQF

Yes, following along those same lines, the other area that Aneesh mentioned was the hospital readmission 30 day readmission as one where we may want to provide some focus to how to get that information available sooner rather than later. We have laid out measures for 2011, 2013 and 2015. We have for 2011 readmissions to the same hospital. For 2013 it was readmissions to more than one hospital and for 2015 it was all hospitals in a community to be able to look at that.

I'm wondering if that wouldn't be an area where we should focus particular attention. I don't know offhand, which standards here out of all of Jamie's bundle or all those standards really relate to their particular area. But if one could at least get that kind of interconnectivity between all the hospitals in a community and I realize solving the readmission problem involves...hospitals involves the ambulatory area to monitor patients more carefully, so that they don't enter the hospital. But it would be a big step forward if we could accelerate that timeframe rather than having the ability to even calculate and report on 30 day admission across the hospital in 2015, if we could move that up a couple of years and really push that end of it, I think it would very strategically helpful.

It is a win/win economically. Hospitals should know we are going to get lower payments for those readmissions. I think it would free up, there's substantial evidence that there's a very sizable proportion of readmissions that are avoidable. So it would free up dollars.

Jonathan Perlin - Hospital Corporation of America - CMO & President

So if I heard you correctly, it's not only the issue of readmissions per se, but as an example of how to achieve use of interoperable information meaningfully, something this is self-reinforcing by virtue to its adherence to economical—

Janet Corrigan, NQF

Yes, exactly

Jonathan Perlin - Hospital Corporation of America - CMO & President

Dixie Baker, I know she couldn't be here, sent me an email last night about what she thought some next steps might involve. And it was exactly this issue, which is even though we're not a policy group per se, are there best practices, the cultural issue that involves security of data exchange that her committee could start noodling through because she views her work as the technology standards, the infrastructure on which they ride and in some of the best practices that actually enable secure exchange. It looks to NIFT, for example, for the guidance that you offer and we'll be working with you closely on some of the cultural aspects because you have some documents that are quite helpful. Because to me if we get this transmission piece taken care of, then the packaging is actually not so hard. There's the technology, the infrastructure and the policies and culture and best practices around transmission that seem to be the hardest nut to crack at times.

Male

Okay, anything that anyone wants to put on the table in terms if the implementation group doesn't do this, what we've missed or does something else with us, Linda Fischetti and Liz Johnson.

Linda Fischetti - Chief Health Informatics Officer - VHA

Thank you. Again to go back to a comment earlier today, I think that we do need to be excruciatingly evenly aware of our entire ecosystem by which we have our arm to function. We've consumed so much from HITSP and we always consume from HITSP, but worrying about the supply chain management back to the SBOs. So again, talking about the supply chain management back to the SBOs, and so I do think that it would be worth this implementation group having a listening session with SBOs to see if, in fact, NIST were to provide them funding, do they have the organizational maturity? Do they have the organizational constructs while also supporting and being true to their open consensus rules by which they are audited to actually be able to take in commissioned work and do this on behalf of the U.S. federal national initiatives at the same time that they have many other national programs that have just ramped up expectations, just as we have. So I would like to consider that within scope for our listening sessions.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Terrific, I appreciate those thoughts. I think they reinforce the ongoing dialog about that that the continuum of development from the SBOs to the technicalto introduce thethat's done at HITSP or elsewhere to actually adoption in other quarters, as well as the broader ecosystem in which that operates because it's not linear or is necessarily development or identification at a particular stage guaranteed. The broader adoption to the point of the broader ecosystem operates not only in terms of the development, but also the ultimate expression of these standard. Liz Johnson.

Liz Johnson – Tenet Healthcare – V.P. Applied Clinical Informatics

I was listening to Aneesh and I think Janet talked about JumpStart and Linda is beginning to talk about really looking at where we are. What I've not heard yet and what I think we ought to talk about is kind of current state baseline concept because in the past as we've had that discussion we've said we're going to set some standards, we're going to clearly illuminate what we want, but we've not talked about where people are and I would like to hear from others around the room what the impact of that is.

For example, if I said at a given set of 50 hospitals we are not using many of the standards that have been shown today as being appropriate. We are looking at Edge technology right now so that we will be able to transmit in those standards, agree with it completely. But what's the value as Aneesh was trying to get to a current state, what are we looking for? How do we define current state because as the Implementation Group goes forward we need some kind of criteria to say what do we actually survey for? Do you know what I'm saying? I see heads nodding.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I think this is a very important and, frankly, a somewhat difficult task. I know it took a great deal of research actually to characterize the state of adoption of technologies as... and Dave Blumenthal did. Ironically, the further down the road we get the more the use can be somewhat self-evident, as a sort of a trace of the use. But we're not at that point and I think that's why we have a definite challenge mechanistically.

So we're going to circle around the room and we'll go to Cita Furlani next.

Cita Furlani – National Institute Standards & Technology – Director

(Inaudible) what was said earlier about listening and trying to figure out where the standards need to be and which ones are the most important and I think that's something this group can help to identify the

priorities because it's which ones do you need most, that is the sticking point sometimes rather than do everything.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let's start with Chris Chute and then we'll go to David McCallie and Mark Overhage.

Chris Chute – Mayo Clinic – VC Data Government & Health IT Standards

I feel like we're going from the sublime to the ridiculous here and I'm repeating myself from this morning, but I'll give you a ridiculous technical issue. And that is shared vocabulary infrastructure. Right now value sets and terminologies are not – and I want to emphasize this point – they simply are not available in what I would characterize as common consumable access methods.

Obviously, I have my pet interests on what this might look like, but the requirement to formats and structures that are readily usable cannot be under-emphasized. And I think that's been a huge, practical sticking point for the implementation of many of these standards historically.

John Halamka – Harvard Medical School – Chief Information Officer

I think you know where... on this one, but it's not, I believe, insurmountable. There's been a lot of progress made in terms of SNOMED itself as an example of movement toward broader availability.

Chris Chute – Mayo Clinic – VC Data Government & Health IT Standards

Yes, politically and economically, but I submit once you get physical access to SNOMED it's still left as an exercise to the re-user what to do with it.

Jonathan Perlin - Hospital Corporation of America - CMO & President

Fair enough.

Mark Overhage – Regenstrief – Director

And it's up to the CDC through their SINBAD repository who has tried to make some of these value sets available. It's not complete at this point. Certainly between USHIK and SINBAD we have the seed of doing what you suggest.

John Halamka – Harvard Medical School – Chief Information Officer

Terrific, because without some constants in service value sets and terminology sets can be very difficult to have a degree of interoperability at a practical level that we would hope to envision.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Dave McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, maybe slightly off topic from the implementation topic, but I think in the broader question of what are challenge is that we can focus our energies on, I'm struck as a vendor looking at requests coming in from clients and from states that are trying to build channels for the state of the flow over that the unanswered architectural questions of organizing wide scale interchange have been somewhat sidestepped by the HIE Committee, the Subcommittee, Workgroup of the Policy Committee and are not well addressed in the existing standards. The standards just sort of run out of gas when you start talking about federation.

So I would put on the table that in line with solving some of the granular consent management questions to focus on the architecture that are available and, perhaps, recommended for wide scale data sharing is another unsolved problem.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Again, a lot of heads nodding on this and this may be in terms of feedback to, indeed, the Policy Committee and some question marks that we have to leave, perhaps identify some practices, but areas that we may have to filter over to our colleagues for some guidance on.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

For example, to that point, suppose that I want to send information from Massachusetts to Cerner Corporation and it turns out I need to have a routing director that tells me how to get from me to you. Well, at the moment there is not a standard for a participant directory in a healthcare information exchange that's completely standards-based. And so, there's been some talk of using LDAP or using DNS or some combination of those, but there hasn't been wrapping of that in Web services.

So, this is a very rich area. Think of the components that are necessary for various architectures, whether it's HIE, whether it's the NHIN and where are there gaps and what are the priorities and how do we solve them?

John Halamka – Harvard Medical School – Chief Information Officer

And I think even fundamental questions of what is the right kind of data to share at what levels of localities. So, it may make sense at a state level to share information around state mandated reporting requirements, but patient data may not make sense following state boundaries, speaking as someone who lives in Kansas City where everything is two states and thinking through some of the choices of how we might decouple HIE into the subsets that make sense at what level of granularity.

So, I don't see how my patient record has to be regionally based at all, because I'm not regionally based much of the year. I move around. But my local state reporting requirements, obviously, are highly regionally based. I don't think we've teased those apart yet and some of those are policy questions, some of them are standard that don't yet exist. Some of them are standards that haven't been applied.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Again, I think this point is extremely well taken because moving beyond the second level to that improved healthcare or transformed healthcare that one might imagine, here we are in the District of Columbia, 72 square miles of the state, with Maryland on one side and Virginia on the other and residents of this area typically get care in two if not three, so if we don't support those individuals, the continuity of information, we've failed. Your points about the regionalization of the reporting are well taken, but a great area to interface with our Policy colleagues on.

Mark, I believe; Nancy, were you up?

Nancy Orvis – U.S. Department of Defense Health Affairs – Chief

Time out; I'll come back later.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Mark Overhage.

Mark Overhage – Regenstrief – Director

I'm just trying to help you with the transition here, but I always get, the hair bristles on the back of my neck every time we get to talking about, well, we need more and better standards and to fix SDOs and stuff like that because at the end of the day, it isn't about mandating. You can't mandate a standard; they've got to be adopted. And so this implementation discussion we're going to have is incredibly critical

because we can do all the fine tuning that we want and Chris's point about they're not consumable and we talked before about complexity and all those things are absolutely true, but at the end of the day if we can just take some of what we have and get it into use we'll be a lot further down the road than if we continue to worry about how things are going to work 12 years from now.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you. Again, I think there's a resonance in parsimony and economy of standards, but also the reality that the standard ultimately has to be adopted by popular demand, not by anointment. On the other hand, I think the sort of economic graph that Lee Jones pointed to earlier is very instructive, absent certain degree of specificity.

You would run the risk of many parallel paths and the lack of interoperability. So, this is going to be, I think, one of the fundamental questions in the Implementation Workgroup as to how one fosters. I think the economic incentives create a bit of the market, to use that shipbuilding metaphor, and if, as you know, I didn't complete the story entirely even though the thread gauge got standardized as late as 2009 there is still the English thread system and the metric thread system. So, it may not be entirely perfectly parsimonious, but we got to a place where we build product.

Wes.

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

When it comes to metaphors, you can beat a dead horse, but you can't make it drink. Going back to the supply chain metaphor yet again what I hear Mark talking about is let's not put more products on the shelf, let's make use of the products that are on the shelf and what that means, in effect, is let's make those things work as opposed to wait for the perfect solution downstream and I would support him entirely in saying that has to be our number one goal.

I'm still worried, though, about the packaging of those things. Are there ways we can make it easier to take them off the shelf and the long-term supply? I mean, CDA seems to have been one family of standards that has come into being by being created de novo by a standards organization and over a mere 10 or 12 years have become actually pretty useful.

We somehow need to either decide that it's an entirely open market and we want every innovator to put together a little thing and put it on the shelf or we want some sort of systematic approach to what's on the shelf and I think that has to be part of the things we do this year to support the longer-term mission. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

I think that if I look at the work of the last, okay it's not 10 years, it's been six, seven, eight, there has been this convergence of figuring out how we go from a multitude of choices to fewer choices and now how do we get to specificity on how those choices should be used and now it's getting to take those products off the shelf and making them as useful as they can be. So I hope we hear from the Implementation Adoption Workgroup the, well, we went out to do what you suggested and it was hard for the following reasons, therefore go change CDA. The XML in CDA is overly complex in this regard, can you just take out this or that and make it easier for us all to use? And I think it's important feedback for the whole eco system, the SDOs and everybody else to hear and I really think that Aneesh's comment of asking the users for their experience and then feeding it back so that the products that we have become better and easier to use any implementation and educational materials become clearer.

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

Yes, you know, I helped write the grant application that started HITSP. I was involved in discussions before that framed that and to be honest, what I had in mind at the time was IHE with governance and authority. And the part that we have not achieved is the Connectathon in the feedback loop and I understand we're looking for the Implementation Committee at least to find some ways to grease the feedback loop.

I also think we need to seriously talk about the Connectathon. I was involved in a standard called CCOW, which started out as an individual group and we used trade shows as our Connectathons and it was just remarkable to see all these competitors sitting down and helping one another entirely because if any of them didn't work, none of them worked and because programmers like to help each other. I mean, at that level they're collegial.

Somehow in the quest for governance we seemed to have lost that and I hope we find a way to get back to it.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Well, I appreciate that discussion. I think there's a lot the national coordinator to consider and for us to digest in terms of effectively stating a charter for the Implementation Workgroup. I think this discussion strikes exactly how difficult this is. At every sort of element of the discussion there is a tension between over specification and inadequate specification in terms of to Mark's point, inadequate support for standards that are available versus going off and trying to fill all holes, a point of actually getting some use and experience before one seeks to modify and perfect a standard, the cultural issues, the connectivity issues in terms of the broader interoperability.

I think if I could sort of synthesize my hopes for this group is in part that there's a market that's been created. We described it as potentially somewhat ephemeral, but I think it's very difficult to go back. If we can obtain some degree of connectivity where the value of the health product has increased by virtue of that interoperability then the economic model has changed and I hope it's not reinforcing. At least that's my person bet. But how to tap into that so you get that CCOW experience and there's convergence of desire for interoperability requires the sort of incentives that have been put forward right now to jump start this.

Jim Walker, do you want to jump in on this?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Yes. We've talked about the need to prioritize and you just mentioned, you know, do we fix what we've got or do we create new things that fill important gaps? And I think one of the things we might do is put those two things into the same prioritization scheme. It may be more important to fix this than to fix that. It may be more important to fill this gap than to fix that thing, and if we put that all in one continuum I think we would provide a real service. It wouldn't be final, but at least it would be a discussion starter for us to start to organize how we do this.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Again, lots of agreement from the body language around the table and, in fact, I think there is a clue list for the prioritization and that is what's been put forth thus far in terms of meaningful use. It would seem to be a natural pathway.

Okay, well, this will be I'm sure an ongoing discussion. It's difficult; some of us are very practical and operational and sometimes it feels a little bit theoretical. On the other hand, absent the theory we're not apt to be good. I'm reminded of the famous philosopher, Yogi Berra, who talked about the difference

between theory and practice. He said, "In theory, theory and practice are the same. In practice, they're not."

So, that is our challenge essentially is we have to move from a theoretical and I'm excited about this Workgroup for the reasons that Aneesh, is that we will take the theory and the intellect around the table, but also couple it with the experience both, frankly, bad bearers as well good, those exemplars that can help to hopefully provide insight into where to set the balance on some of these things that do exist on the scale and, hopefully, be very pragmatic, practical and Jim, I think that was the perfect summary comment there, prioritize, again, given the guidance of meaningful use.

So, I believe that we have completed the planned agenda for today. Let me just ask around the table if there is anything anyone wants to offer for the good of the order more broadly? John, the comments you'd like to offer.

John Halamka – Harvard Medical School – Chief Information Officer

I think this discussion we've just had on next steps has been fantastic. So we know there's polish to be done in each of the Committees. On the quality side you've got the five different transactions that Floyd outlined in his diagram, making sure that we have articulated the standards approach for all five transactions. And in clinical operations there are the vocabulary issues that we have to work on and some of the quality standards that are going to support Janet's work. On the security side, Dixie has said she wants to work very much with NIST on some of the aspects of learning on best practices, but also then begin to work on some new issues around consent that might be necessary for 2013 and 2015 and this cultural aspect of the NIH eco system is also something quite interesting.

And then I think we've all talked about the need to work on implementation, simplification, communication, education, and prioritization so it's going to be a very rich agenda going forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Absolutely. With that in mind, let me just ask if there are any comment from our colleagues at the Office of the National Coordinator that anyone would want to offer? John Glaser.

John Glaser - Partners HealthCare System – VP & CIO

I'd like to, again, join the rest of you in commending the terrific work that has been done, certainly visible today and visible over the last multiple meetings. It's been extraordinarily important to us as we put together the regulations, which we're in the process of writing, so immeasurable and invaluable contributions on you all.

I think, Jon and John, what we will do is follow up with the two of you and Aneesh and take the discussion we just had along with some ideas that we have, frame a preliminary agenda for the Workgroup and be in enough condition to present it back to you in October. So we look forward to that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific. Thank you so much. Thanks, to all the ONC staff for all the hard work. Many thanks to members of the Committee for all that you have been doing. Again, I can't overstate to the public, really, the degree of dedication that every member of not only this Committee, but all of the Workgroups have contributed; hours and hours daily, literally, since the inception of the Committee.

And that, too, goes to the members of the public who have contributed with great insight, great references, resource material and we really appreciate that insight and comment. It helps us not only honor the intent of the FACA, the Federal Advisory Committee, process, but it sharpens our thinking, it

challenges us with questions and it contributes to our knowledge base. So, many thanks to all who have submitted information.

Toward that end, we will conclude this component of the meeting and move to our public comment session, that also being one of the components of the FACA process. As Judy mentioned, that's going to divide into two parts and I will actually Judy Sparrow to remind us of how we're going to divide this next session.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, I think we'll take 10 or 15 minutes for comments from the audience and on the phone for this particular meeting and we actually have had three people sign up for comments. I really can't read this too well; Allison Veda from HEMA and Beth Feldpush and Lawrence Hughes, both from the American Hospital Association.

And if the Operator could give instructions for dialing in on the phone, we'll do that for about 10 or 15 minutes. And then we will take comments on the recommendations from August Standards Committee Meeting and we'll do that for about 20 minutes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific.

Judy Sparrow – Office of the National Coordinator – Executive Director

So, the people who signed up, if you would please step forward and, Operator, if you would please tell us how dial in. Actually, you dial 1-877-705-6006 and if you're already connected you just push star one to speak. And would you introduce yourself, your name and your organization, please?

Allison Viola – American Health Information Management Association

Good afternoon. My name is Allison Viola from the American Health Information Management Association – HEMA – and I'm serving as a representative of 54,000 professionals who will be required to support and execute the decisions being made. Many of these same professionals have been working in the area of quality measurement and reporting, research terminologies and classifications. The issues being discussed at this meeting and the Policy meetings will have a lasting impact for providers, payers, vendors, patients and health information management professionals for years.

HEMA has been and is a proponent in the use of uniform data standards and we have been active in promoting the use of SNOMED CT as the basis for standard EHR systems and currently we are working with the healthcare industry to ensure an appropriate implementation and use of the ICD-10 classifications for 2013. SNOMED and ICD is just a sample of the classifications and terminologies that comprise healthcare data and we encourage you to consider the concerns AMIA has raised regarding the coordination and integration of all of the terminologies and classification.

We would like to work with you to take a pragmatic look at how these classifications and terminologies can be used appropriately and we stand ready and look forward to being called upon to support you in your efforts as you continue to tackle such challenging issues. Thank you.

Beth Feldpush – American Hospital Association

First, I'd like to state that hospitals' overall goal in implementing HIT is to improve patient care. Meaningful use should primarily be defined by the ability of the IT system to provide a path that moves hospitals and doctors forward in improving care. When assessing whether have fulfilled the meaningful

use objectives, we should focus on metrics that assess whether hospitals are using HIT to support activities that have a direct and meaningful impact on patient care.

Activities that fulfill these goals would include items like checking to ensure that summary care records are transmitted to the next provider of service in a timely fashion or testing to ensure that the IT systems can help prevent unintended harm, such as wrong dosage or wrong medication errors.

Unfortunately, many of the metrics identified in the meaningful use definition, such as the percentage encounters with insurance eligibility checks, do not meeting this criterion. Using criteria unrelated to core patient care functions will be distracting and is likely impede hospitals' ability to ensure that their investment in IT results in better care and better patient outcomes.

On the measures themselves, AHA strongly believes that all measures assessing hospital performance should be endorsed by the NQF and adopted by the hospital quality alliance. Although the Committee is supportive of the use of NQF endorsed measures we know that the Quality Workgroup has identified many physician level NQF endorsed measures, but has largely ignored the fact that concurrent hospital measures do not exist. It would be nearly impossible for these measures to be developed, tested, specified and implemented and endorsed by the beginning of FY2011.

AHA is most concerned about the listed readmission measures, which would require hospitals to be measured on whether they decreased their readmission rate by 10%. This is an unrealistic expectation in the absence of any scientific research or testing to show that such a large reduction in the readmission rates can be achieved within one year. Most importantly, this is wholly unrelated to HIT adoption and is inappropriate for inclusion in the meaningful use definition.

Currently hospitals report 30-day heart attack heart failure and pneumonia readmission rates on Hospital Compare, yet we're confused as to why the Quality Workgroup has listed a different measure not currently in use in its meaningful use measure grid. We question the wisdom of asking hospitals to report on two similar, but different measures on the same topic. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much.

Lawrence Hughes – Assistant General Counsel American Hospital Association

I'm Lawrence Hughes. I'm the Assistant General Counsel at the American Hospital Association. I'll confine my remarks specifically to the privacy and security standards that the Committee has developed and keep my remarks at a very high level so we can follow up with additional details if necessary.

We certainly support, as the statute indicates, the requirements that the meaningful use definition take into account privacy and security under HIPAA. But the statute also has a particular warning that suggests that the work of this Committee should not change or alter the authority of the secretary under the privacy and security standards.

We're afraid that some of the standards, in fact, don't adhere to this warning and, in fact, will change the nature of what it means to comply with privacy and security standards and if I might take just a moment to use the example of security in the security rule requirements to illustrate my point.

Under the security rule there are both required specifications and addressable specifications. Some of the standards that I think the group has developed sort of change the addressable specifications into

something that is mandatory and uniform in terms of what it means to comply with the security rule. I think that should be avoided.

HHS certainly has avoided that sort of dilemma in dealing with the regeneration requirements and the guidance on security PHI, making it quite clear that while the guidance remains voluntary to use if you voluntarily use them you would be exempt from the regeneration requirements. But it is quite clear under that interim final rule that HHS is clear that nothing about those guidance standards changes your obligations under the security rule.

So we believe that it's important for the group to be very careful about going beyond the requirements of both the privacy and security rule in making up standards and thereby introducing particular modes of compliance and changing the nature of what it means to comply with a security and privacy rule.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much for your comments.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you and we have one caller on the phone. Let's see if that person would like to come on.

Operator

The caller on the phone will be Charles Parisot from EHRA. Please proceed with your question.

Charles Parisot – EHRA

Hello, can you hear me?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Yes, we can.

Charles Parisot – EHRA

Okay. Thank you. My name is Charles Parisot. I am the Chair of the Standards and Interoperability Workgroup of the Electronic Record Association. We would like to commend the great work and the consensus developed by this Committee in recommending its... standards to be supported by certified VHR under EHRA. We welcome the establishment of a clear consensus on such standards so that the nation may proceed with its deployment of 55VHR. The Association, EHRA, has been actively supporting this effort for several years and the two comments that we make now only have one objective, ensuring that the selected standards as specified can be implemented and will then work the intended interoperability.

The documents circulated for this meeting are a major improvement over the output of the August 20th meeting. They're not quite sufficient yet, as John Halamka stated. They still need a little bit of polishing. And I would like to make two recommendations, a recommendation for this polishing so that it expectedly supports implementation and testing in an effective way.

In particular, we believe that the exceptions that are listed throughout the document needs to have a better linkage to the specific HITSP Capability. Today we have a list of HITSP Capabilities, a list of exceptions, and no direct linkage and in many cases there are many, many relationships, but not all relationships make sense. So we are providing a sense of complexity and a sense of risk of confusion that really can be quite simply corrected, clarified, and we think that this position can happen within a few days and we will provide written input in making a couple of examples where there is ambiguity that we believe that would lead to misinterpretation.

We would like also to comment on quality reporting and welcome the significant progress and clarity that has been brought there. However, we are not yet there. There is still work ongoing by HITSP who have to charter new territory, new waters. The standards selected are not complete. They are missing certain elements in terms of transport, in terms of security and we see the need for a slightly longer timeline to make the interoperability recommendations for quality reporting of the same effectiveness as the ones for security, privacy and clinical operations.

We would trust the Committee to make those minor improvements and to vote the planning and the implementation of this to start even before the regulation is issued.

For the third comment we believe that the ongoing work in HITSP in this area is making tremendous progress and that the HIT Standards Committee should continue to support, follow this work and further refine its selection of standards in order to make quality reporting for ARS effectively implementable. Thank you very much for your attention.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much for your comments. We'll go to the next question here in the room.

David Tao – Siemens – Interoperability Champion

Thank you. I, too, want to commend the Committee for the additional level of specificity provided this month and, in particular, the reference to all that hard work done by those hundreds of volunteers at HITSP in producing the capability. So, it's great to have the mapping to those capabilities.

I've learned from my 30 plus years in the industry that no matter how good a job you do writing down things and specifying them and developing a work product, there are always questions of interpretation that follow up when people actually use them.

And so I would strongly urge that either the Committee or perhaps ONC establish a help desk, help line Web-based FAQ or something where the hundreds or thousands of people that will have questions of all sorts can get them answered, perhaps, in a consistent way where you don't have a thousand people asking the same question because they will see it's already been answered. I think that would be a great efficiency that could be provided in clarifying the meaning of the various standards.

Two very specific brief points. I believe that in the glide path to SNOMED there is ICD-9 alternative allowed and then ICD-10, but there is a current out of sync by about a year condition in ICD-10 since the ARA year 2013 really starts in fiscal year, and therefore October 2012 really starts that whereas the CMS rule doesn't have ICD-10 until October of 2013 so it seems more logical to allow the ICD-9 option, if you call it that, to extend until ICD-10 actually kicks in in October rather than nine to 12 months earlier. So I would suggest looking at that and perhaps clarifying the wording around that particular glide path item.

And, finally, I really appreciate the fact that HITSP has limited its focus to the boundaries between organizations because that's where the standardization really pays off where you don't have lots of proprietary custom interfaces. And so, for instance, in the security area, as was mentioned earlier, ATNA for audit, XUA for authentication were mentioned.

I do think there is one exception where I would question the selection of a particular standard, which is the Enterprise User Authentication, EUA from IT, which is selected for 2011 and then disallowed in 2013. It's in terms of an organization. I don't see how it really is a glide path to XUA, since that's cross enterprise and it seems like there could be a lot of expense put into organizations who aren't already

there migrating to this only to see that it's a short-term investment and then in two years, it's not even what they're supposed to be using anymore. So, that one seems to stick out to me like a sore thumb, like why is that one there? What's the economic impact of this? Is this really worth it? Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much.

Tim McNamara – Technology Vendor

I just want to talk about four new technologies that people may not be too interested with. I want to reinforce what he said about setting up some sort of a collaborative Web site that people can participate in. We're involved in an effort to take the existing financial systems in each agency and department in the federal government and to link them together so you can track an appropriation up to a signature and then to OMB for apportionment and then back to department and then partitioning and so on, right through the outlay and so on.

And the key to us is we're going to have a very, very large collaborative Web site so we can get all the people under 30, because they're the only ones that count, to collaborate and tell us their best experiences of how to implement this so we can take the experiences we have in this demonstration at the Department of Defense and roll it out to education and HHS and whoever else. So, I want to reinforce that.

Secondly, maybe I'll just mention this one. I was surprised. I got a call this last week from my partner in a very large state who talked to the governor and the attorney general and they were upset about their Medicaid reimbursements. And apparently they paid for a wheelchair of a certain model, manufacture and model, and paid \$600 and you can buy it on the Internet for \$150. And they said is this fraud? Or, what's going on? We have some skills in terms of banking and some of the techniques you use there and the answer is we can set up a system in about a week for this government to be able to go in and have rules that if it's within 10% or 20% of the reimbursement rate, fine, prove it. If it's not kick it out so somebody can look at it.

And you'll always be able to test the market that way and they simply didn't know that that kind of technology to be do what are called mash-ups on the Internet and then be able to data mine them and then apply them against pre-specified criteria where possible; cheap, easy, fast technology. There is lots of stuff out there that's going to help people implement this. Thank you.

Clint Laird – Unisversata – CEO

I came down here because I was curious. I had no intention of getting up and saying anything, but I'm actually quite encouraged and I'd like to share with you in about two or three minutes why I'm encourage. First of all, any Committee at this level of technology that can actually quote Yogi Berra and get away with it, that's a sign of great encouragement.

In the post-mortem of the Santa Barbara/Rio failure David Brailer said this thing failed basically for two reasons. It was too high tech and there was no recurring revenue model; there was no revenue model. I'm here to give you some encouragement. There is a revenue model out there for interoperability in the National Health Information Exchange. It's called the release of information industry and you just heard from one of the industry people here at AHIMA. So, it's about a \$1.5 billion, very reliable recurring revenue model and these are people are in hospitals and in physician offices making, on balance, paper records, copying them and mailing them to the requestor.

Now, that's not what you would call very sophisticated technology, but it is a technology and working on what Mark Overhage said, we take what we have and move forward on that. Well, this is what you have. It exists today. It's a network that exists today. These people are teching up.

I'll give you the current element of that tech up, we happen represent, our company, someone who is South Carolina, the Medical University of South Carolina, Anne Castro's world, and we have a deal with them. All of their stuff is electronic and we deal with it all electronically. If the big one hits Charleston and they go out, our people from Minnesota can go in and get medical records out of there via API and move them where they need to be.

We also are customers, paid by a company called EMSI. EMSI is hired by insurance companies to get your medical records with your permission and they then underwrite applications for health and life insurance with it. Up until about six months ago we had 70 or 80 MSI locations asking us for stuff and we would try to send it to them electronically; we'd have to mail it to them. Now, EMSI electronically requests these records and we get them to them within one day and I'm happy to tell you they pay us the next day. Now, that's a PDF, but that PDF can be used creatively by the insurance underwriters to, since they have to deal with that data anyway, to put in various models or algorithms and create and hand to the customer something like a PHR that Judy is interested in in Aurora.

You're now engaging the patient, the consumer, in terms of managing their own medical records, their own medical information. And it's a start; it's a really good start. So, I'm very encouraged by what I've heard today when it comes down to a practical level where I operate and we operate, we're fairly broad for a small company, but at any rate my hat is off to you in that regard and I look forward to attending more of these.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much for your comments.

Lindsey Hoggle – American Dietetic Association – Dietician

The ADA is the largest organization of food and nutrition professionals in the world with over 70,000 members. ADA has been working diligently for the past eight years to provide and develop both evidence-based nutrition practice guidelines through our evidence analysis library and a standardized terminology to reflect nutrition care. The terminology is called International Dietetics and Nutrition Terminology or IDNT. ADA has been working with other organizations to ensure that a nutrition data set is included in research databases, electronic health records, quality measures and languages such as SNOMED CT.

This reflects an approach agreed upon both by ADA along with leading experts, such as Dr. George Blackburn at Harvard and Dr. Arlo Kahn at the University of Arkansas. ADA has been supporting implementation of the IDNT terminology and practice in the U.S. for the past five years. Several EHR vendors have licensed the terminology and are building it into their systems. We have published updates to our terminology and are in the process of conducting research to verify its use and validity in practice.

We have been identified as a standards development organization for nutrition and dietetic terminology. The IDN terminology has been adopted in Japan, Korea, the Netherlands and is under review in Canada, Australia and Israel. In the past the ADA has submitted to HITSP and to this Committee on how to include key nutrition terminology and concepts in meaningful use and certification standards.

Our comments have consistently addressed the need for an electronic health record system to have the capability to 1) provide key nutrition related data to registered dietitians, and 2) ensure that care provided

by registered dieticians be captured in a meaningful way to communicate with the health care team what the nutrition care plan is, to enable outcome data collection and analysis leading to continuous improvement in care, and to incorporate data into larger system-wide quality measures that portray the presence and impact of nutrition care as part of an overall treatment and prevention regimen.

ADA believes that we are a key stakeholder for the standard certification process and the initiative to create and use an electronic health record and health information exchange. Nutrition is known to be associated with seven of the 10 leading causes of death in America. We thank you for this opportunity to comment and look forward to working with you to support the use of nutrition related care and data for the support of individual and population health. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much for your comments.

Karin Rubin – American Academy of Ophthalmology

On behalf of the Academy we'd like to thank you for the ongoing dialogue we have had with ONC and the opportunity to provide comments. The Academy is the world's largest association of eye physicians and surgeons with more than 18,000 in the U.S., over 93% of all ophthalmologists in the country. The Academy still has concerns with the revised meaningful use matrix and standards, which if not addressed may hinder electronic EHR adoption among ophthalmologists.

For CPOE our physicians are in an ambulatory setting and may not order traditional laboratory tests and radiology procedures as other physicians would in a hospital setting. However, the Academy has created an IHE eye care technical framework, which provides technical specifications for computerized physician ordering procedures within the office; for example, visual fields, fundus photos biometry. These are all key point of order entries used for eye care and should satisfy the CPOE criteria. If not, eye care would have an issue with the proposed CPOE measure.

With regard to specialty relevant measures we found that for two priorities in improved care coordination and improved population in public health four of the 2011 measures are not germane to many specialties: 1) Report 30-day readmission rate; 2) Percent of encounters where medication reconciliation was performed; 3) Report up-to-date status for childhood immunizations; and 4) Percent reportable lab results submitted electronically.

If these are considered mandatory measures for achieving meaningful use ophthalmologists and many other specialists in ambulatory care settings would have difficulty qualifying because they do not apply to their practice patterns. Currently, we are unaware of laboratories providing electronic interface with eye care only EHR vendor, rather only for large enterprise vendors because ophthalmologists don't order enough lab tests for the laboratories to find it cost beneficial to create interfaces for data exchange.

In addition there are 2011 objectives that are not specialty germane: 1) Calculate and display BMI, and 2) The capability to provide electronic syndrome surveillance data to public health agencies in actual transmission according to applicable law and practice. In regard to the HIT Standards Committee Quality Workgroup we are concerned with their presentation on incorporation quality measures into the EHR. The list of measures presented to the Committee for 2011 did not have any eye care measures or any relevant measures ophthalmologists could use for qualifying for meaningful use.

If it is not possible to make quality measures electronically compatible for all specialties in 2011 then the requirement needs to be pushed further in the timeline until all measures can be electronically collected and physicians should still be able to qualify for the full EHR incentive of \$44,000.

The Academy appreciates the opportunity to comment to ONC and looks forward to providing ongoing input to ensure that the EHR meaningful use objectives measures are able to be achieved by practicing specialists. We also would be happy to provide real world feedback on implementation from an ophthalmology practice perspective. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much for your comments. Judy, are there any more on the phone, either for today's meeting or anything in follow-up to August 20th?

Judy Sparrow – Office of the National Coordinator – Executive Director

Nobody is on the phone so if nobody in the audience wishes to make a comment, I think we are complete.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, well let me thank all those who made comments. As I mentioned earlier, it really does add to our deliberative process and I very much appreciate the thoughtfulness of each and every commentator today. It is most helpful.

Thanks to all of my fellow Committee members for all of your work, ONC staff. And I believe with that we stand adjourned until our next meeting. Thank you.

Public Comments

Received Through the Webmeeting Interface:

1. This body can define the parameters to be collected in the standard, to do this all experts can suggest parameters to be used in the future to build expert systems for clinical decisions
2. We would like to know if NCPDP 8.1 will be acceptable as a standard for e-prescribing in 2011 meaningful use? This is the current Medicare Part D referenced version of standard, and is what has been the basis for certification for SureScripts and CCHIT to date. No certification program for NCPDP 10.x is yet available from SureScripts and the availability of such a program is not yet known. We suggest that the committee at least consider allowing for both versions to be acceptable basis of standard in 2011.
3. Interoperability can 100% achieved if one start building from scratch and implementing good stuff selectively from different vendors into that system => to do this requirements are needed regardless ones technical ability. the requirements will have everything
4. If you try to define the small and trivial, then one may discourage creativity which ultimately becomes a standard, as some participants said lets identify what to implement and what not
5. The standard body can come up with application like ITU does and vendors implement that
6. The EHR must be universal and applicable to all health providers including hospitals, the parameters in the system that define a patient is universal; I mean the same EHR applicable to all.
7. Can standard body consolidate all the privacy and security standards into one standard, have for each standard item identifying where , it is coming from, e.g., HIPAA, or any one of the standard so far specified. This will help to have concise document from which to work on and eliminated duplicate items. ONC has to set timelines for implementing, patient records and expert capability of the EHR system. Consider first record keeping, then expert function later
8. For Security Group: Request Clarification of storage on portable media requiring encryption and its effect on Matrix items for Engaging Patients and Families (ie: printing a CCD to a thumb drive should be encrypted? How would they utilize? If they can unencrypt with I assume a public key, then why encrypt if key is public? Thank you
9. With CCHIT publishing two certification paths next week, what is the opinion of the HIT Policy Committee as to the Preliminary ARRA 2011 Certification Criteria and Test Scripts? Thank you
10. The parameters defined will also be used by the system to guide the provider what do next (test and medication), if the decision made by the system is wrong and questionable, the provider can suggest in formal way using a method in place to do such thing
11. Do we have a standard for Universal ID, this is important to index a patient record, need a standard

12. Is HIPAA part of the standard, if so, what is its new name?
13. Are you talking about system quality or service provided by the provider? If you are talking about quality provided by the service provider, then you can do it by defining attributes in the standard for that purpose for the raw measurement, e.g., star time and end time of a patient on the exam table of the provider