

HIT Standards Committee Transcript July 21, 2009/9:00 a.m. EDT

Participants

Dixie Baker, CTO of Health & Life Sciences, Science Applications International Corporation
Jim Bialick, Health Systems Coordinator, Genetic Alliance
David Blumenthal, National Coordinator for Health Information Technology (HIT)
Anne Castro, Chief Design Architect, BlueCross BlueShield of South Carolina
Aneesh Chopra, CTO, White House
Chris Chute, VC for Data Governments & HIT Standards, Mayo Clinic
Jodi Daniel, Director, Office of the National Coordinator for HIT (ONC) Office of Policy & Research
John Derr, CIO, Golden Living
Linda Dillman, VP of Benefits & Risk Management, Wal-Mart
Floyd Eisenberg, Physician Consultant, Siemens Medical Solutions; Senior VP of HIT, National Quality Forum (NQF)
Jamie Ferguson, Executive Director of HIT Strategy & Policy, Kaiser Permanente
Steve Findlay, Senior Healthcare Policy Analyst, Consumers Union
Linda Fischetti, Chief Health Informatics Officer, Veterans Health Administration (VHA)
Doug Fridsma, Associate Professor, Arizona State University
Cita Furlani, Laboratory Director, National Institute of Standards and Technology (NIST)
John Glaser, VP & CIO, Partners HealthCare
John Halamka, CIO, Harvard Medical School; CIO, Beth Israel Deaconess Medical Center
Stan Huff, Chief Medical Informatics Officer, Intermountain Healthcare
Kevin Hutchinson, CEO, Prematics, Inc.
Elizabeth Johnson, VP of Applied Clinical Informatics, Tenet Healthcare Corporation
John Klimek, Senior VP, National Council for Prescription Drug Programs, Inc. (NCPDP)
David McCallie, VP of Medical Informatics, Cerner Corporation
Judy Murphy, VP of Information Services, Aurora Health Care
Nancy Orvis, Chief of Health Affairs, U.S. Department of Defense (DoD)
Marc Overhage, Director, Regenstrief Institute
Gina Perez, Executive Director, Delaware Health Information Network (DHIN)
Jonathan Perlin, CMO & President, Hospital Corporation of America (HCA)
Wes Rishel, VP & Distinguished Analyst, Gartner
Judy Sparrow, Executive Director, ONC
Anita Williams, Director of Benefits & IT, Wal-Mart

Presentation

Judy Sparrow – ONC – Executive Director

Good morning, everybody. Good morning, and welcome to the third meeting of the Health Information Technology Standards Committee. This is a Federal Advisory Committee, which means it's being held in public. We have members of the audience as well as people on the phone and listening over the Internet. And there will be an opportunity at the end of the meeting to make public comment. Please, committee members, remember to identify yourselves when speaking. The meeting is being transcribed, and we want to have proper attribution. Let me just go around the room now, if you could introduce yourselves briefly, and I'll begin with Doug Fridsma.

Doug Fridsma – Arizona State University – Associate Professor

This is Doug Fridsma from Arizona State University.

John Derr – Golden Living – CIO

John Derr from Golden Living.

Gina Perez – DHIN – Executive Director

Gina Perez, Delaware Health Information Network.

Jim Bialick – Genetic Alliance – Health Systems Coordinator

Jim Bialick from Genetic Alliance.

Judy Murphy – Aurora Health Care – VP of Information Services

Judy Murphy from Aurora Health Care.

John Klimek – NCPDP – Senior VP

John Klimek from NCPDP.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Anne Castro, BlueCross and BlueShield of South Carolina.

Wes Rishel – Gartner – VP & Distinguished Analyst

Wes Rishel, Gartner.

Floyd Eisenberg – NQF – Senior VP of HIT

Floyd Eisenberg, National Quality Forum, sitting in for Janet Corrigan.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

Steve Findlay, Consumers Union.

David Blumenthal – National Coordinator for HIT

David Blumenthal, National Coordinator.

Jon Perlin – HCA – CMO & President

Jon Perlin, HCA, Nashville, TN.

John Halamka – Harvard Medical School – CIO

John Halamka, Harvard Medical School and Beth Israel Deaconess Medical Center.

Cita Furlani – NIST – Director

Cita Furlani, National Institute of Standards and Technology.

Chris Chute – Mayo Clinic – VC for Data Governments & HIT

Chris Chute, Mayo Clinic.

Linda Fischetti – VHA – Chief Health Informatics Officer

Linda Fischetti, Veterans Health Administration.

Kevin Hutchinson – Prematics, Inc. – CEO

Kevin Hutchinson, Prematics.

Elizabeth Johnson – Tenet Healthcare – VP of Applied Clinical Informatics

Liz Johnson, Tenet Healthcare.

David McCallie – Cerner Corporation – VP of Medical Informatics

David McCallie, Cerner Corporation.

Stan Huff – Intermountain Healthcare & University of Utah

Stan Huff, Intermountain Healthcare and the University of Utah.

Jamie Ferguson – Kaiser Permanente – Executive Director

Jamie Ferguson, Kaiser Permanente.

Jodi Daniel – Office of Policy & Research – Director

Jodi Daniel, Office of the National Coordinator.

Judy Sparrow – ONC – Executive Director

We should have a number of members on the telephone. Martin Harris, are you on? [Pause] Linda Dillman?

Anita Williams – Wal-Mart – Director of Benefits & IT

Anita Williams for Linda Dillman.

Judy Sparrow – ONC – Executive Director

Janet Corrigan? [Pause] And Marc Overhage.

Marc Overhage – Regenstrief Institute – Director

Hi, this is Marc Overhage.

Judy Sparrow – ONC – Executive Director

Thank you. And I'll turn it over to Dr. Blumenthal for some comments.

Dr. David Blumenthal – National Coordinator for HIT

Good morning, everyone. I want to welcome you all to the Holiday Inn in our neighborhood. We are having, as you all know better than I, our third meeting of the Standards Committee. We had our third meeting of the Policy Committee, where—this pace of monthly meetings, I know, is probably not what many of you are used to if you have served on government—comparable government committees in the past. But I want to assure you that you're providing an invaluable service to us at the Office of the National Coordinator, Department of Health and Human Services, the Federal Government—I think, to the American people. I—to say that I'm in awe of the quality and amount of work that our Standard—our FACA committees are doing is probably not to overstate it. You all have done just an extraordinary amount of very high-quality thinking and formulating and writing, and I know it continues.

I'm sure many of you are thinking that you're being asked to do too much too fast and that you'd like to do it—if you had more time, you could do it better; you could be more thorough; you could design better plans, find more of the gaps, lay a better foundation. I know you all are thinking that, but I assure you that you're advancing our work enormously through the advice that you're providing. And we all are living with the deadlines that the Congress created for us. And against those deadlines, which are tough but also provide a kind of discipline that perhaps is beneficial in the end, we are working toward an initial—an interim final rule that will include standards and certification criteria for the—to underlie the implementation—undergird the implementation of meaningful use in the 2011 time frame. And our goal is to make sure that we give physicians and hospitals and patients every chance to have the benefit of and

the use of electronic health records and other health information technology that permits improvement in their care by 2011 to the maximum extent possible, and knowing that this is not—this is just the beginning of that process and not the end of that process and that we will be continuing to refine what we are doing, continuing to fill gaps, continuing to make things better over the next several years.

So we appreciate your willingness to stay with this, to continue working at the pace you're working. We want to assure you that we're listening carefully and that your work is helping us to do our work in very material ways. So I'm not going to take more time. I'm going to—I want to apologize in advance that I'm going to have to step out of the meeting at about 10 o'clock for a couple meetings that I can't avoid, but I will be back later in the morning.

Jonathan Perlin – HCA – CMO & President

Thank you very much, David. And good morning, everybody, on behalf of John Halamka and myself. I just want to thank this group for the extraordinary work. I, too, share Dr. Blumenthal's awe at the amount of—amount that's been accomplished. And when we sat together at our first meeting, I think all of us looked at the aspiration and wondered if it was doable. And to those individuals who haven't necessarily been party to all of the subcommittee work, let me just assure you that, daily, there have been conference calls.

One of the questions that arose at the last meeting was the need for the subgroups to coordinate with each other. Indeed, we were triangulating; the triangulation has gone on very effectively with much due to the Office of the National Coordinator—the ONC staff who helped to facilitate all the cross-thread of some very complex concepts.

Since we have a tremendous amount less to do and to review in today's discussion, I wanted to, in addition to expressing appreciation, just go through our usual process. We have adopted the process of asking if anyone has anything that they know to be in conflict, in terms of personal interests, with any of the items on the agenda. So let me just stop here and pause and ask, if we go around the room, if there are any members of the committee who have any conflicts of interest with any of the agenda topics that they would wish to disclose to the group. Doug, we'll start there and just...

Doug Fridsma – Arizona State University – Associate Professor

[Inaudible].

Jonathan Perlin – HCA – CMO & President

Thanks. John?

John Glaser – Partners HealthCare – VP & CIO

No conflict.

Jonathan Perlin – HCA – CMO & President

Gina Perez?

Gina Perez – DHIN – Executive Director

No conflict.

Jonathan Perlin – HCA – CMO & President

Jim Bialick.

Jim Bialick – Genetic Alliance – Health Systems Coordinator

No conflict.

Jonathan Perlin – HCA – CMO & President

Judy.

Judy Sparrow – ONC – Executive Director

No conflicts.

Jonathan Perlin – HCA – CMO & President

John?

John Derr – Golden Living – CIO

No conflicts.

Jonathan Perlin – HCA – CMO & President

Anne Castro?

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

No conflicts.

Jonathan Perlin – HCA – CMO & President

Wes Rishel?

Wes Rishel – Gartner – VP & Distinguished Analyst

No conflicts.

Jonathan Perlin – HCA – CMO & President

Floyd?

Floyd Eisenberg – NQF – Senior VP of HIT

No conflicts.

Jonathan Perlin – HCA – CMO & President

Steve?

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

No.

Jonathan Perlin – HCA – CMO & President

Dixie?

Dixie Baker – Science Applications International Corporation – CTO

No conflicts.

Jonathan Perlin – HCA – CMO & President

And Jon Perlin, no conflicts to disclose. John Halamka?

John Halamka – Harvard Medical School – CIO

I'm on the board of Envida Health, which is a decision support service. It has no particular relevance to today's work. And I belong to a provider organization, so sometimes I'm biased towards doctors and nurses.

Jonathan Perlin – HCA – CMO & President

Thank you. [Inaudible]?

Unidentified Woman

No conflicts.

Jonathan Perlin – HCA – CMO & President

Thank you. Chris?

Chris Chute – Mayo Clinic – VC for Data Governments & HIT Standards

No conflicts.

Linda Fischetti – VHA – Chief Health Informatics Officer

Linda Fischetti, member of provider organization, Federal representative on the board of HITSP as well as a peer-elected board on HL7.

Unidentified Man

No conflicts.

Unidentified Woman

No conflicts.

Unidentified Man

No conflicts.

Unidentified Man

I'm a member of the board of HL7 and also a Co-chair of the LOINC Committee, and so if those things come up, I have no financial interest or—in those organizations, but I do have a bias towards those organizations.

Jonathan Perlin – HCA – CMO & President

Thank you very much.

Unidentified Man

I'm also from a provider organization and on the board of HITSP but have no conflicts.

Judy Sparrow – ONC – Executive Director

Let me just say that Jim Walker has joined by telephone.

Jonathan Perlin – HCA – CMO & President

Okay, and let's pick up; we have Jim Walker online. Jim, good morning. Any conflict to disclose? [Pause] And we have Janet Corrigan online, I believe.

Judy Sparrow – ONC – Executive Director

Marc Overhage.

Jonathan Perlin – HCA – CMO & President

And Marc Overhage. [Pause] Okay, we will continue on.

As the second order of business, I trust that people have had a moment to review the minutes—and again, appreciation to ONC staff for the great work in putting those together. Let me just ask if there are any corrections, modifications, amendments that anyone would wish to offer. [Pause] Okay, it's clear that we have agreement on those and move forward to the meeting.

Let me introduce the first part of the agenda for today. We obviously are going to come together with a completion of our insights on standards to support meaningful use as it's been provided to us through the Meaningful Use Workgroup and the Office of the National Coordinator and a tremendous amount of work. Our focus immediately is, and not surprisingly, on the 2011 activities—the objectives and—that we would want to support—and appreciate what this group has offered in terms of fully identifying standards but really accessing the readiness of those standards for adoption. And a great deal of thought has gone into that, and I think, together today, we'll see a great convergence of the ability of those standards to support what's been teed up for meaningful use in 2011. Of course, there's—there are gaps, and there's work that will need to be charged. But between that that needs to be charged and that that's ready for adoption are two other levels of readiness: those activities that are essentially in progress and nearing completion and those that are, in fact, chartered and in line. And you can see a logic between what is really available in the near term and what requires more work further down the road.

Have some reports from our three workgroups today. And—the Clinical Quality—looking at the criteria for quality, how do we represent the data that would then provide insight into performance? And they've done just tremendous work on criteria for quality. The Clinical Operations Workgroup has just done extraordinary work and—in terms of providing specification of the really molecular granular data elements that are necessary for the exchange of information that underlies not only meaningful use but a real-life use of information for the care of patients and the care of population.

The Privacy and Security Workgroup has also started, I think, with a philosophy that's been just tremendously helpful. It has been trained from the outset into how to make meaningful use possible—how to achieve the aspirations of use of health information for improved health care. Beyond responding to the specific elements in meaningful use, they were charged by statute in the HITPC legislation of the economic stimulus or recovery package to attend to what we've been working closely at, as ARRA 8, four of which specifically refer to privacy and security standards. They also have been working with great sensitivity towards consumer perspective and trying to understand how assurances are created that allow people to have faith, no matter the relationship to the health system and the use of information—the information really are appropriately protected, usable, and accurate. And I am purposefully trying to avoid technical terms, because this is—really needs to, at this juncture, segue from those individuals who really think and speak in terms of standards and very molecular data elements to a broader understanding of how this information is actually used to improve health care.

Let me turn to my Co-chair, John Halamka, for introductory comments. And John has also served with Jamie Ferguson as the Co-chair of the Clinical Operations Workgroup. And I'll also want to thank you for work that I know you've been somewhat distant from, but your organization HITSP has provided an extraordinary service in terms of mapping the standards in a very functionally defined manner to the concepts around the nucleus. Good morning, John.

John Halamka – Harvard Medical School – CIO

Well, good morning, and thanks. Just to emphasize a point that you've made—and that is, we really took Marc Overhage's comments at the last meeting quite seriously and asked ourselves, "What is the

implementability—the deployability of the standards work we’re doing in all of the elements: quality, clinical operations, and security?” And so, you’ll see that we have—for example, in Dixie’s matrix, there’s a specific grade, one through four—the level of maturity—deployability of a particular security standard for a particular purpose. And we actually got quite granular in the committee, thinking through “Well, in what way is the standard used today? Is it used within an organization? Is it used between organizations?” And now you’ll see some detail saying, “Well, yes, within an organization, it’s probably ready for prime time. Between organizations, not quite ready, so maybe think of that as a little bit later.” So that is just a good way of taking the work that’s been done by HITSP, standards development organizations, and the industry and now putting it into a framework of how you can put into an [inaudible] rule that people are actually going to say, “Oh, we can do that on the time frame that you have outlined.”

Jamie has done similar things in his group. You’ll see, where we want semantic interoperability (one of Chris’s favorite causes), we say, “Of course we want semantic interoperability, the ability of computers to exchange information, have decision support, have data that goes between organizations that’s interpretable. Can we have it tomorrow?” Well, it may be slightly aggressive to have meaningful use for 2011 include every aspect of semantic interoperability. But we should not lose sight of a need to do it and say, “2011.” You should, but there’s an out. 2013, the out goes away. You have to use those vocabularies, like LOINC and RxNorm. And there’s this wonderful ramping up—I think, David, you used the term—an escalator where we had to set the speed of the escalator so that folks could get on and wouldn’t fall off because it was moving too fast. Think you’ll see that thread throughout Jamie’s work, and similarly in the work that Janice and Floyd have done. They’ve created this framework—this architecture for how one describes quality.

Now, I think we will all admit that when you look at the 27 measures that Floyd and Janet have created, there are some gaps, and there are some gaps specifically around how to measure meaningful use. How do I electronically measure the e-prescriptions I didn’t write? Or how do I measure paper-based educational materials being handed to a patient? And so, I think what you’ll see is, they have thought very clearly about “What do you want in 2011 and 2013? What can be electronically reported? What has to be just attestation?” And their work, which will continue on over the next several months, is to actually put some scores on each of these measures, just as Dixie and Jamie have done about deployability. And so, I think the sum total of the work you’ll see today, as you folks have said, is really remarkable. I mean, the coming together of these groups in the last month and sitting on these subcommittee calls—there has been very little dissention. There’s been great discussion, but I think it was rather amazing that so many stakeholders came together and had such unanimity about the path forward in all three of these areas. So look forward to the day.

Jonathan Perlin – HCA – CMO & President

Thank you, John. Thank you for your terrific leadership. I suspect, as with many members of the committee, you were asked, you know, about meaningful use. And next, John Glaser will update on the exactly the status of the recommendation from the Health IT Policy Committee through the Meaningful Use Workgroup to the Office of National Coordinator that we at the Standards Committee have been responding to. And I just want to amplify on one of John’s points: Many of us are often asked about this paternal—this is—this does change things. But then, I think my sense of the direction of activity is that the Office of National Coordinator and all the people involved from each perspective they bring—academia, industry, providers, etc.—are joined together to want to make this work. And that really, I think, has been what has been so encouraging to me to see from each of the workgroups—respond—bring together from consumer perspective, as patient, user, and advocate, from the technical perspective, what are the necessary prerequisites to actually put this in place and help to serve health care more effectively. So with that, let me just ask David if there are any other comments you’d wish to offer before we get into

meaningful use. And Dr. John Glaser from the Office of National Coordinator will review the meaningful use [inaudible].

John Glaser – Partners HealthCare – VP & CIO

Thank you, John. And as you all know and as this industry knows, meaningful use sits at the center of the huge range of activities that are being undertaken here. In the June Policy Committee meeting, Paul Tang and Farzad Mostashari presented the preliminary recommendations coming out of the Meaningful Use Workgroup, and I had the opportunity to give you an overview of that presentation at our meeting here that followed.

Subsequent to the presentation at the Policy Committee, there was a public comment period. Approximately 800 comments were received and fed into the workgroup deliberations in addition to comments that were received at the Policy Committee discussion itself. Last week, Paul and George Hripcsak, the new Co-chair of the Meaningful Use Workgroup—because Farzad, if you don't know, has joined ONC—presented the revised definition of meaningful use, which factored in the wide range of thoughtful and terrific comments that were received here.

I'm going to give you an overview of what Paul presented at the Policy Committee meeting last week. I'm going to move relatively quickly, largely because I want to make sure we have enough time for the report out of the workgroups of this committee, which is the sort of core regional here. Also, I doubt I can do the presentation the same justice that Paul did, and so we'll try to hide that fact by moving rapidly. And also to facilitate moving rapidly, I'm not going to be using any verbs for the next 20 minutes, and so we'll challenge you to [laugh] go along with this.

The core thing—and we'll look at Slide 4—is to remind us of the framework that's just behind the meaningful use recommendations that the workgroup came up with. And that is the evolution, using the escalator analogy again, moving industry from an emphasis on data capturing and sharing in 2009 into advanced clinical processes and then fundamentally outcomes in 2015—not quite serial, but there's a shift in emphasis as the years go by.

If you flip this over onto Slide 5 and be mindful that our—as the term used internally is “the North Star,” the truly transformed health care system that is remarkably more efficient, safer, and of higher quality than the one that we have today, and realizing that there are multiple threads that play in that, one of which is the work that we are collectively doing in the HITPC, but also health care reform agenda that is unfolding in Congress and the Nation today. And so, this captures, on Slide 5, the centrality of the meaningful use comments by year—'11, '13, and '15, again reflecting the escalator before.

Now, as the workgroup deliberated, as we go to Slide 6, its conclusions and recommendations, it had to consider a variety of things. One is obviously the reform agenda that's under way. The other is to remind us that we're here for outcomes, not necessarily for the software installation, etc. And in the course of trying to move an industry well and aggressively—also being quite considerate of the fact that the adoption rates are not what they ought to be in a lot of ways, and there are a wide variety of communities that would like to move but do not have the resources to go off and to move. And so there's a balance, a juggling act between aggressive movement and the practical realities of how long these things take and the state of the industry today. And factoring, last but not least on the last board on this slide, is the fact that the legislation has particular time frames that one has to keep in mind to love and conform to. So all of those had to factor in and be considered in the course of their discussion.

If you flip over on Slide 7, where they—just a screenshot of the—one of the pages from the meaningful use definition that was presented in the June Policy Committee meeting. And given the feedback—or

when the workgroup framed their responses according to the categories that you see on Slide 8, and so they already sort of categorized the comments. And obviously, one particular comment letter might have multiple points across several of these categories, and we'll walk through those categories in the next couple of minutes.

The first, on Slide 9, on the meaningful use framework—it was widely acknowledged that the framework was terrific, the right orientation to health care outcomes and efficiencies that we all aspire to achieve in this, and that the measures provided a good way of stressing. In other words, if you were able to report a wide variety of the measures that we've talked about, then clearly you had to be using the EHR and able to be doing them. You would have had electronic laboratory results. You would have had the problem list. You would have had and prescribed medications, etc. And so, there was a realization that measures did a nice job of moving us towards those expressed as outcomes, although, in some cases, there are process measures and would have exercised the broad range of EHR capabilities. And as the—we will go as evolved per these—framework represents—#4 from initially reporting of measures, as reporting to the movement of actual targets within the measures over the course of the years, and those targets would be expected to grow as the standards raised on our collective delivery of care will increase.

On Slide 10, with specific feedback regarding timing—and that is the, in a number of cases, concern about the aggressiveness of the schedule. In other words, can we really do all of this or can a large portion of the industry do all of this in a time frame when 2011, if you use the first of the year, is only 18 months away? And that was obviously of concern, a lot of it actually centering on CPOE, but there were some concerns elsewhere. And as the workgroup pointed out—that if you look at the payment schedule, that's your goal—is to receive the maximum amount of financial incentives possible—that the start date was not purely 1/1/2011 or even the Fiscal Year 2011; there is movement in '12—and that as the workgroup mentioned—recommended what the—as you see on the last board on Slide 10, an adoption year notion. And that is that, in fact—well, actually, the best way to illustrate that is on the subsequent slide on page 11 here. And as you see in that schedule—and this is the schedule that is part of the legislation, which points out that if meaningful use begins in 2011, there's a stream of payments that go from '11, '12, all the way out to '15, and then at some point, obviously, the penalties kick in. But you could start at 2012 and receive, you know, fundamentally the same payment stream. You could start at 2013 and receive slightly less payment. And so, the suggestion was—is that meaningful use start on one of these calendar years—in other words, if 2011 is a meaningful use year, as distinct from a calendar year. So you could actually start using the 2011 definition in your 2013, and that would be Year 1 for you rather than Year 3 at that point in time, so giving providers some time to move out on the schedule, realizing that if you move out too far, you begin to surrender some incentive—but nonetheless is giving the industry more time and more flexibility to pursue all of this. Since we don't have people who say, "I'm not getting on the escalator; it's moving too darn fast"—or, in fact, move too quickly and forget some of the fundamentals of engaging clinicians in doing thoughtful process design and things like that. So that was one of their recommendations—was this notion of meaningful use year to fundamentally give the industry more time to respond.

You'll also see, continuing on that thread in Slide 12—is rather than the initial definition, which had all orders by 2011—is to say 10 percent of orders. So you begin to move your way through the house or the inpatient units—there might be some pilots; that might be a couple of units—but not expect that it all be done at that period of time.

Regarding decision support, there were some suggestions that it be moved earlier, because that's a lot of the payoff—is through the guiding of—whether it's drug/drug interactions or health maintenance reminders—other—through decision support here. But also balancing that is the need to actually have the EHR in place, a lot of the data in place, and a lot of the implementation done before we can essentially

deliver these in the right moment at the right place in the workflow. And so, their recommendation was to start to—one rule, fairly wide open about what that rule might be, but make sure that it is important and relevant to a clinical priority of that organization or those groups of providers.

Flipping over to Slide 13, the feedback on patient and family engagement was to provide access to electronic health record. Now, whether it's sort of in a PHR-type approach, as distinct from simply an electronic copy, which one could envision as being a thumb drive with a set of the contents here—and so, they actually moved up the PHR recommendation from 2015 to 2013 in response to that particular feedback.

On Slide 14, there was comment. As in all appropriate comments—these all have been—is that there were dearth of measures on efficiency. Obviously, while our core emphasis is quality and safety, we are mindful of the health care costs and the affordability, both for governments, businesses, and individuals, and hence the need to be more focused on that. And it was pointed out the National Priorities Partnership—the framework that was adopted broadly for the meaningful use also has an emphasis on efficiency and a reduction of rates. And hence the group proposed some additional metrics and associated set of objectives to go with that. You can see them listed here as a percent of all medications, entered in as generic when generic options exist for that drug class; also efforts to reduce the inappropriate use of expensive radiology procedures; and then some two areas which are not per se dead-centered EHR but do have enormous efficiency goals and should be factored into this. It [inaudible] more of the administrative and financial transactions, both the determination of eligibility but also the electronic submission of claims. And so, they've brought in those two particular criteria, which I think are appropriate, although perhaps not dead-centered EHR. Nonetheless, it's a good recommendation coming out of the group.

Flipping over to Slide 15, some concern about—from the specialist communities when they looked at the measures—and saying, “These are largely primary care measures. They—some are relevant to us in our specialty practice, but most are not. And by the way, the specialty measures that we might, in our society—in our profession, might use—we don't see those here,” and so the cap line of “What about me?” And so, that's really the tagline for that. And so, the sort of recommendation here is that they focus on a couple of exemplar measures, which would be broadly applicable across a range of providers—maybe not all, but broadly applicable across a range of providers. And the other is that for the specialist, and particularly in the efforts to create registries, which CMS has been working on and will continue to work on—is—essentially suggest that specialists contribute to their specialty registry contr—you know, contributing the data that those registries contain. And that kind of contribution and that kind of activity would be more relevant to their particular measures of quality and also live out to the spirit and the specifics of having quality reporting as part of the meaningful use recommendations.

On Slide 16, some feedback that we need better measures for care coordination—and so they point out that NQF is working on measures in that regard and—both new measures, but also refinement of existing. And they—actually, the workgroup proposed a 2013 measure of the 30-day readmission that often happens because of—or inappropriate readmissions because of a poor coordination of care.

And then the second bullet, as you can see on Slide 16, is the concern—and on one hand, we obviously want to encourage and incent and motivate the use of health information exchange but recognize, in 2011, we may not have broad HIE capabilities across the country. And so, their recommendation is that in 2015—that we might require the exchange, giving the exchanges time to come to be and to grow, etc.—but also is to require the ability to exchange in 2011. And then they deferred some additional recommendations to the HIE Workgroup, which also had some material that was presented on the Policy Committee, and I suspect we'll hear more from them.

Moving in on this, on the privacy and security, the major comment was under investigation, and we'll hear more from Dixie and folks along these lines here. I mean, you can be paralyzed for reasons that were—had nothing to do with you or might be a spurious complaint or things along those lines. And so, there, as you can see, the revised wording that they recommend is that, to the degree there is a complaint—that there is effectively an option for the entity to put in a plan saying, “Here’s how we’re going to resolve”—or that they, in fact, have resolved a particular issue, so as to, you know, both ensure that people conform to the privacy and security regulations, but also not to inappropriately keep them hamstrung during the course of a pursuit of a malady or a need to redress something.

You can see, on Slide 18, their future work. We're going to give them a break because of some extraordinary work in the last couple months. So I think at some point, we may give you a break. But nonetheless, we'll give them a couple-week break, and then you can see their future work, which is to review and revisit the 2015 vision and to refine the 2013/2015 measures and criteria. The other is the process use, which—I think all the work is extraordinary to arrive at this definition. We ought to make sure that in the years out, we have a process this is more deliberative and more inclusive, etc., and not as subject to the legislative constraints that confronted this one. So they will be coming back with some recommendations in the go-forward annual—biannual suggestions about to do the meaningful use definition calibration process. And then, obviously, like all of this stuff, we put out what I think—or they put out what I think are terrific ideas. But we need to monitor and observe the industry to say how terrific are they when they confront the reality of implementation and have some feedback mechanism from the field into the meaningful use objectives and measures and to refine them as appropriate here.

I think the summary you can read—I won't read this for you—is a good encapsulation of all the work that they do. So I just wanted to give you a brief update on both their work and also the revisions that they propose to the Policy Committee. The Policy Committee approved these recommendations and has forwarded them to David and to ONC. And so, again, we're at the point of looking at those internally, but again, I want to thank the workgroup. And there may be a question or a comment on what I've just said, and we'll take it from there.

Jonathan Perlin – HCA – CMO & President

Thank you, John, and thank you for all the work you've done in shepherding this work forward, and—along with the ONC staff, who have been terrific as well. I want to just put in perspective, this is something that Jodi Daniels usually does, but I'm going to see if she's going to grade me on how well I do on this. And that is to lay out the—to put in context the recommendations of the Health Information Technology Policy Committee and the work that you all do. You are providing us invaluable recommendations under the law that created this body and the Health IT Policy Committee. Those are recommendations to the Office of the National Coordinator. And that—they will be transmitted to the Secretary, and they will inform a rulemaking process that will establish the definition of meaningful use. That rulemaking process will result in a notice of proposed rulemaking that, under current schedule, will be issued late this year, probably around December—sometime in December, but that is not a certainty. The Center for Medicare & Medicaid Services will actually be the part of the department that issues that rule, because it'll be governing compensation of providers under Medicare and Medicaid.

Similar—so while the recommendations are taken extremely seriously, they are not policy; they're not set in stone as policy. And the same is true for your work. You—what you recommend to us will be taken extremely seriously but will not—do not govern policy by themselves. Your work will inform an interim final rule that will be issued in—by statute, has to be issued by the end of this calendar year. And that will contain certification criteria and standards necessary to undergird meaningful use.

I just wanted—as you listen to John talk and listen to his comment on how we will modify these meaningful use criteria and objectives as we go forward, I don't want you to misunderstand that those are policy of the Department of Health and Human Services; they're recommendations. And we cannot say for sure whether they will or won't be, in all of their aspects, adopted. Anything you'd like to add to that, Jodi?

Jodi Daniel – Office of Policy & Research – Director

No, I think you did great. I think I can go home now [laugh].

Jonathan Perlin – HCA – CMO & President

Thank you, David. And thank you, John, very much. I appreciate your relenting and using verbs. It made the semantic interoperability all that much better. That's appreciated [laugh].

I know there's likely some questions or comments. So we'll adopt the rule of putting your name card on its side. And so, let me just skim around and see if there are anybody who has any—John Halamka, we'll start with you, and then we'll go to Kevin Hutchinson.

John Halamka – Harvard Medical School – CIO

So just one point for the committee. Because, as John has described, this has been a very aggressive process and a lot of work going on in parallel. One concern we had was that, as multiple iterations of meaningful use were issued, that somehow might not align with the work that we were doing. Well, the good news is, you'll see, across the multiple iterations we've all been working on, the themes are very, very similar. And there may be slight adjustments—10 percent for this and 30 percent for that, 2011 for this or 2013 for that—but there was not substantial change of direction. So there's very good alignment in a parallel process.

Jonathan Perlin – HCA – CMO & President

Thanks, John. Kevin Hutchinson.

Kevin Hutchinson – Prematics, Inc. – CEO

Okay, Jon. The question on Slide 16—it refers to “where possible”—you know, the information exchange, which is, I think, very applicable given that we know that not all lab results can be delivered electronically today, as an example, or other types of health information exchange. I assume that's what that is referring to—where there might be pockets of transmissions that you're simply not able to have on the receiving end—send information back electronically. Is that right?

John Glaser – Partners HealthCare – VP & CIO

Yes, I think, Kevin, there's a—listening to the workgroup conversation, you can have a sort of limitation on either end. Either the sender is not able to send it, or you might—for example, a provider—want to send an electronic discharge summary to a recipient, but they're not capable—or whatever set of reasons. So there can be, in a dyad, a failure on one of the parties.

Kevin Hutchinson – Prematics, Inc. – CEO

I think the one thing that we should be careful of—and maybe we already are, and I think you know that—is that if we require certain function, but the capability is not on the other end, it's going to make workflow, as you well know, very, very difficult if it's—if I'm still required to enter it in, but I'm going to have to print it and then fax it or print and then send it. But I'm still required to enter it, even though the exchange is not available on the other end. We may end up incurring some real workflow challenges. We're trying to make that functionality still a requirement, even though the exchange of it is not a requirement.

John Glaser – Partners HealthCare – VP & CIO

No, I think that's fair, Kevin. And I think, as to David's point, if—you know, to the degree these sail through—and in December, you see similar or exact type of wording here—there's a fair amount of work in the industry collectively about how in the world do we ease this transition, because we won't have broad interoperability by 2011; we won't have full EHR adoption by 2011. And so, I think it'll take our collective—not only people on this committee but also the Policy Committee—but the industry writ large to help sort of sort through a lot of approaches to minimize the workflow hassles and all of that. So I think we have some—our work cut out on the—you know, the multiyear transition and to minimize the pain.

Kevin Hutchinson – Prematics, Inc. – CEO

Okay.

Jonathan Perlin – HCA – CMO & President

Let's go over to Steve Findlay and then Wes Rishel.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

John, the 800 comments you guys have gotten—have you categorized them in any way? Are they posted on the Web? Is there any categorization that's been done that's also posted on the Web? Or is there—if not, is there any intention to do that?

John Glaser – Partners HealthCare – VP & CIO

There's been categorization, Steve, by type of sender, you know, whether it's a consumer group or whether it's the IT industry or hospitals, etc. And then there's been categorization internally by sort of concern or recommendation. And so, for example, you know, we're clear on the categorization—there were a lot directed at CPOE, and hence why—you see why the workgroup came up with the recommendation that we did. I don't know—and Jodi—what the plans are at this point for the posting of those for public review, etc. Let me ask Jodi.

Jodi Daniel – Office of Policy & Research – Director

They are available for public inspection. Currently, we have hardcopies of all of them for folks who want to review them. We're still, I believe, going through and just redacting any proprietary information and personal e-mails—things like. Our intent is to make them electronically available as well. But I don't believe we have that up on the Web site yet, but it should be forthcoming.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

Thanks.

Jonathan Perlin – HCA – CMO & President

Wes?

Wes Rishel – Gartner – VP & Distinguished Analyst

Thanks. I have a question for Jon, but first I want to pick up on something that Kevin said, because I think it represents a general issue we have to keep in mind. Kevin posited that requiring the physician to enter an order wasn't worth the trouble if it wasn't being transmitted electronically to the drug store. My own analysis of who—what stakeholder gets what value for what part of the e-prescribing process—the prescriptions get the very minimum amount of the value. There's good argument for the efficiency of the overall system. They get the value by seeing the medication information. They get the value by having the opportunity for clinical decision support engagement, as opposed to however much money they saved in callbacks from the drugstore. The reason I mention it is not to pick on Kevin—he's such a nice guy—but that I think we continually battle with this distinction between the good society, the good efficiency, and

the good to the physician. And a lot of us have concerns, and there's an article in one of the major media yesterday about physician resistance to EHRs. I think keeping that balance in mind will be critical as we go forward.

Jon, in the meeting, there were other—that you reported on, there were other topics that were discussed that weren't discussed here. I just want to know what is the status on certification—if there'll be a comment period associated with that. I know there was a report from the workgroup; I'm not sure whether that became a recommendation of the committee or not and whether there's a comment period coming.

John Glaser – Partners HealthCare – VP & CIO

Wes, a—the certification group did rep—have some recommendations. The high-level recommendations were approved by a committee, but there was a request that they come back in August for a more detailed discussion and some recommendations regarding some of the specifics, you know. So, you know, there's a high-level recommendation of focusing on meaningful use, but, you know, that—it sort of stopped there at that meeting. And so, we're planning to bring them back on August 21, I believe, which is the next to present some further recommendations regarding the—you know, how they would see it as, both in the near term and the long term, carrying out the certification process.

There was a public set of hearings that they held on the 14th and the 15th of July and had a wide variety of testimony from vendors and purchasers on this and other organizations. That was open to the public. Related to that, there were some written comments received here. We've had some discussion internally of whether we open up a public comment period similar to what we've done for meaningful use. I actually think, Wes—I doubt that we will do that at this point here, given—it doesn't preclude any of you or anybody listening to this to submit comment, but we may not have a fully public comment period. So I think that's—and given the nature, there's been some public discussion on the 14th and the 15th. There was a public presentation at the Policy Committee meeting that we may not supplement with an initial comment period. But anyway, that's sort of the thinking at this point.

Unidentified Man

Obviously, you waived the fact that public testimony before the recommendation was proposed doesn't constitute comments on the recommendation.

Unidentified Man

Correct.

John Glaser – Partners HealthCare – VP & CIO

Correct. I mean, again, so there was a—you know, a—both hearing of these issues and the concerns, etc., but you're right; that was—you know, there were not recommendations put on the table on the 14th and the 15th. There were at the Policy Committee, but not on the 14th and the 15th.

Unidentified Man

Thank you.

Unidentified Woman

[Inaudible] say one thing. The—with respect to certification process, any certification process that we develop will go through rulemaking, so there will be an opportunity for public comment through that process as well. So there's obviously opportunity for the public to make comments at these meetings—at the public FACA meetings, at the workgroup meeting, when we had a public meeting—and there will be a formal comment period at the point in time when we go through rulemaking as well.

Unidentified Man

So whatever approaches adapted for certification will go through the rulemaking process.

Unidentified Woman

That is our plan, yes.

Unidentified Man

Okay. I know that it's awful when people as you when, but you have a sense of when?

Unidentified Woman

That is a good question. We are trying to shore it up with the other regulations that we've been talking about. I don't have a specific timetable right now.

Unidentified Man

That's fine.

Jonathan Perlin – HCA – CMO & President

Thanks much. And I think this exchange is indeed part of the continuing opportunity for comments. And having lived much of my life in Washington, that rulemaking process, as you know, introduces many opportunities for commentary, which—certainly, I think the volume of responses to the meaningful use attest that people are aware of and encouraged that—take advantage of those opportunities.

Any additional comments or questions for John Glaser before we move to the substance of the workgroup activities? Anne?

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Quick one: Is this final rule—final version open for comment publicly?

John Glaser – Partner HealthCare – VP & CIO

The public comment period on this has closed at this point. We now have a recommendation that has gone in the hands of HHS. The—as David Blumenthal mentioned, this will be part of the CMS portion of the rule. And so, when they come out, with their notice—NPRM in December, there will be a subsequent comment period on meaningful use which will be part of that rule. So for right now, it is closed, although once the NPRM comes out in December, there will be a public comment period on the CMS regulation writ large, including the meaningful use criteria, which will be part of that regulation definition.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

You reported that you would go back and look at 2013 and maybe allow 2015 some more?

John Glaser – Partners HealthCare – VP & CIO

Yeah, I think the workgroup has been very focused on 2011 because of the reg writing and felt that they did not have as much time as they would've liked to sort of look more closely at '13 and '15. So we have to—after their break, we will revisit with them and talk about their thoughts about how to do that and what they'd like to do, etc. But I think they will go back and want to take another scan. Whether that will change anything, I don't know. I mean, I don't know whether that will result in them making some modifications to that.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

My only concern is, this is the last chance—is that the disclosure is in 2015, but the access is in 2013 to consumers. So I wonder if that would make consumers be concerned about knowing who's accessing their information. That just looked a little...

John Glaser – Partners HealthCare – VP & CIO

Yeah, I think a couple of things. One is, as—when it comes out in NPRM, we can—you all collectively can revisit and express concerns and suggestions along those lines. And let's find out from the workgroup what they really think they'd like to do regarding '13 and '15. And so, to the degree they want to take a refinement shot at that, obviously there'll be opportunities for people to come at either and—when they present some initial thinking at subsequent Policy Committee meetings. So I think there will be opportunities for people to come back and say, you know, "I have an issue with this or that or something else."

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Thank you.

Jonathan Perlin – HCA – CMO & President

Thanks. Steve Findlay, and last comment.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

Yeah, to—just to be clear, what—and explicit about—what is the time frame of the CMS proposals, and then what's the length of the comment period that will be?

John Glaser – Partners HealthCare – VP & CIO

Yes, the CMS—there are two sets of regulation. The CMS regulation focusing on payment and meaningful use is due out mid-December as an NPRM. And so, there will be a 60—90-day—I don't know that we decided on the comment period—

Unidentified Woman

I think CMS rules are required to have at least a 60-day comment period if—and I'm not a CMS expert [laugh]—regulations expert. That's my understanding. Our interim final rule—the administrative procedures [inaudible] requires at least 30 days, and we haven't made a decision about whether it's 30 or 60 or 90. So CMS should be at least 60, and ours would be at a minimum—the interim final rule on standards and certification—be a minimum of 30, but it could be longer.

John Glaser – Partners HealthCare – VP & CIO

So anyway, does that cover it, Steve?

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

Yes.

John Glaser – Partners HealthCare – VP & CIO

So after December, 2–3 months, depending on whatever their call is [inaudible].

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

Got it, thanks.

Jonathan Perlin – HCA – CMO & President

Okay. Who will—[inaudible].

Unidentified Man

Just one last question for you, John, on the timing. The HIE debate on—in the Policy Committee was not finished.

John Glaser – Partners HealthCare – VP & CIO

Right.

Unidentified Man

Will there be additional debate around some of the HIE recommendations before rulemaking starts?

John Glaser – Partners HealthCare – VP & CIO

I presume they're going to be back in August, with refinement of that kind of stuff. And you know—and obviously, if there's a recommendation there, we'll have to factor that into the rulemaking process.

Jonathan Perlin – HCA – CMO & President

Okay. Well, I appreciate that. And I should also qualify that despite a decade in Washington, these processes are very arcane. But again, the balance of opportunities really poised to allow and even encourage commentary, and indeed, that's part of this discussion. Jodi, you want to close up—?

Jodi Daniel – Office of Policy & Research – Director

Yes, I just wanted to make one point. There—in the Policy Committee meeting as well as this meeting, there's been a lot of question about the process and when there are comment periods and when there won't be comment periods and what's going through rulemaking and what's not. We've heard that loud and clear—that there's confusion. So what we're actually trying to do is just put together a very high-level outline of what our process is that we would post on our Web site. I don't have it yet, but anybody who's on our listserv will let folks know when it's up, so feel free to join our listserv—and will just—it'll just be something very high level so folks can see what's going on. And if we make any changes or decide to have any more input, we'll make sure that it's being updated.

Jonathan Perlin – HCA – CMO & President

Terrific. And, you know, just to show that there is a response to this, Anne Castro charged at the very first meeting, I believe, the idea of timelines, and this is part of that. And they didn't—even your question about the things that are teed up for 2011—those are the markers that—really helping orient the field in terms of how to—what to be prepared to give a comment on initially or ultimate to work towards.

John, thank you so much for—and to the entire staff for just incredible work, and our appreciation as well to Paul Tang, George Hripcsak, and the Meaningful Use Workgroup and their work as well. Now to our work, and we'll get into, really, the bulk of the efforts of this group. These are decisional areas, in terms of going forth with recommendations—what may require further work that Dr. Blumenthal has charged us or outlined to us—what the time frame is, certainly for 2011 and understanding and appreciating fully, again to Anne's point, that there's work that's deferred to 2013 and beyond. That said, let's switch to the first of the workgroup presentations, and I'm going to invite Dr. John Halamka as Co-chair to moderate this section. And so, John, thanks.

John Halamka – Harvard Medical School – CIO

Great, thanks. So you'll see now a series of three presentations that build on each other. We'll start with quality, which gives us the framework for how we would actually measure performance. Then you'll see, from Jamie, the atomic standards that would be used to encode those quality measures and then, from Dixie and from Steve, how you would secure those and insure privacy and their transmission disclosure auditing and the other aspects of security. You'll see that each of these presentations include two types of

presentation materials: the report of the committee, which is in a PowerPoint format; and then a matrix that gives you incredible detail on the exact nature of the standards selected. And as I mentioned, you will see, in both Jamie's and Dixie's, a measure of maturity or deploy ability. In the case of Jamie, he's actually showed you 2011, '13, and '15. In the case of Dixie, she's giving you a 1-through-4 score. But they're both using the same sort of notion that Jonathan introduced us to—that, one, clearly ready to implement now for a glimmer in our eye; and two and three are gradations in between. So, Floyd and, I believe—is Janet still on the phone, or will you be doing the presentation by yourself?

Floyd Eisenberg – NQF – Senior VP of HIT

I'll be doing the presentation, and Janet will add comments if needed.

Jonathan Perlin – HCA – CMO & President

Great. Well, thank you.

Floyd Eisenberg – NQF – Senior VP of HIT

Okay, thank you. Let me start with—thank you for the opportunity to present. If we go to the first slide, just as a process to show our meetings—oh, I can do that. I'm sorry. Thank you—that we have had a two conference calls with the workgroup, on June 22 and July 15, as well as the consultation with the Policy Committee, where we met with the Meaningful Use Workgroup and presented our findings to the Operations Group and received feedback from them and also presented to the Policy Committee on the 16th. So we do have a lot of interaction back and forth. We identified a potential set of existing standardized performance measures corresponding to the quality measures that currently have been approved by the Policy Committee. And from that set, there are some gaps that—where there were no measures. We have selected endorsed quality measures, because endorsed measures have gone through the process of consensus and assurity of the evidence behind them and the value of the measures.

We also identified specific data types. I apologize for a new acronym: the quality dataset—you'll see "QDS," and if you look at our grid, that's the quality dataset. These are the quality data elements used to calculate the measures. And we've identified those in the 29-page grid that you'll receive—that you've received. And we've handed that off to the Clinical Operations Workgroup to identify standards for use.

National Quality Forum database has approximately 512 endorsed measures at this time. Others are going through endorsement in the pipeline, some by the end of next week and others through 2009. It includes—we include measures used by CMS for hospital and ambulatory reporting, Hospital Quality Alliance measures, accrediting agencies, and the Physician Consortium for Performance Improvement.

We have also, under AHRQ funding, convened a Health Information Technology Expert Panel to create a framework for identifying the types of elements required to measure quality. This includes a—the quality dataset, which identifies codes and their related context of use that creates a quality data element to identify its use within electronic health records. The HITEP draft report was out for public comment. The final comment resolution is in progress and went out last night to the full HITEP panel for review on Friday. We expect publication to AHRQ by the 31st. Except for some minor editing that will occur after that, it will out on our Web site for full reading.

Types of data necessary to calculate and report on performance are present in the dataset. We also identify data flow attributes so that quality measure developers can identify from whom the—or what device or from whom one individual identif—originated the data, records it, what setting it occurs in, and what health record field or location it would be expected from. There are currently over 56 data types identified, and that will help us with a future framework. We've also indentified, for the measures that map

to the Policy Committee, the specific data types to hand over to operations. In our handout of the grid, there are 27 performance measures. Part of our additional work, which we will do after this meeting, will be to add scoring and thresholds to the measures that currently exist—will be some additional work that we'll work on as well.

The recommendations are provisional until we go through the thresholds. You will see—and I'll give some explanations of some of the reasons why some earlier version of the measure or some version will—can be used in 2011 and more robust in 2013. Some of the retooling—when we talk about these measures, they are geared for, in many cases, claims submission or manual chart abstraction. So there needs to be some retooling rather than looking for creation of a new code that says, "The hemoglobin A1c is less than 8 or greater than 9." It's looking for "There was a hemoglobin A1c in the diabetic; the value was" whatever it is, and determining then if it was within the right threshold. So that implies some retooling. Some of them take a significant amount. I'm going to show four slides that are not in your slide set but will be on the screen to explain a little what that means. And we are seeking Standards Committee approval, understanding there may be some changes.

So just to look at a single measure, this is a measure actually published as a description by HITSP, out for public comment now if you go to HITSP site. This is for stroke, for inpatient care, anticoagulation therapy prescribed at discharge, and it's focused on abstraction. So all patients with ischemic stroke who have atrial defibrillation or flutter need to be prescribed anticoagulation therapy at discharge. It describes the numerator, those who received anticoagulation therapy—denominator, those with ischemic stroke. The measure currently is identified using an algorithm. I don't expect you to actually read that algorithm on the slide. And it also has data definitions in a data dictionary and, in about three or four appendices, all of the data elements.

So what—in order to describe this more clearly, what we have done in a process—I'll put on my HITSP Data—sorry—my HITSP Quality Tiger Team hat for just a moment—what we've done in that team is identify the data elements, the definitions, the logic. And what's new for retooling would be the derivation—where do I find it in the record?—and the code set or value set that represents each of these elements. The measures already identify the elements, definition, and logic—that's based on evidence—but it's the derivation and code set that's new. So in the grid in the report that you can find on the HITSP site, it talks about the elements, definitions, and logic that exist, but then where would we expect to find that in an EHR or an interoperable format? What—where is—some comments about that, and where would we find the code sets or value sets? And in that process for the specific measure, it has modified what might be an ICD-9 code set to a SNOMED code set. So there are now both for these specific measures.

Then the next step with retooling is to put it in some computer-readable format. We wouldn't expect the average reader to read an XML document, but a computer could. So that is actually a process that's in development now. The e-measure is a ballot coming forward in HL7 to be published for public comment on August 10 and go to ballot on September—the week of September 20. That will incorporate the components of this.

So to look at some of the challenges our group looked at, if we look at gaps, there are some measures requested: percent of reportable lab results, percent of patients with access to extralocal resource, percent using CPOE. For the current—2011, attestation is a like method for collection. There are actually some structural measures that we have endorsed that request, at the time each patient is discharged from the—or sent home from the office, if electronic prescribing was performed, to add an additional code. The folks on our subgroup felt that this was adding extra workflow for the clinician, and they

preferred more attestation that we do e-prescribing in our office rather than adding a code at every visit, although those measures do exist.

Available measures developed assuming more limited availability of data—we do have some clinically enriched measures, but measures don't always take advantage of the clinical data. And one example would be patients at high risk for cardiac events on aspirin prophylaxis. In order to do some retooling, we would need to identify aspirin—is on the medication list rather than an attestation.

Some measures require data types that will be challenging to capture. Even though we have endorsed measures, as we look at BMI, we have a pediatric measure that goes from H2 to 18, and we have an adult measure that is greater than 18. And it just so happens that the two measures have slightly different criteria. So there is some challenge in trying to align those two and not just accept them as is for selecting one measure. We also would expect some measure specification differences, and you'll hear that more from Operations Group, where everyone may not be able to use the SNOMED value sets for 2011. We would expect them more in 2013, but I'll leave that to Jamie.

Some measures also require data where there is no standardized means of collecting. The venous thromboembolism asks for the use of an antithrombotic device or anticoagulation. Anticoagulation medication administered, we can identify. An antithrombotic device—there is no standard to identify devices; they're all local codes. And to know that they're actually placed on the leg is another issue. So there are some challenges in some measures from that standpoint.

Some may require data that may be costly to collect. And this does—the example of lipid profile is not that the profile is costly, but the measure actually asks for a series of profiles. And in our workgroup, we identified that it's only the LDL that's needed on follow-up. If we ask for the lipid profile every time, we may be encouraging overuse. So in looking at some of these measures, those issues came up.

Significant harmonization measures should be patient centered. And current measures do vary somewhat across settings, whether in the hospital, ambulatory, long-term care, or other areas. I use the example of BMI being slightly different for children as opposed to adults.

So these are some of the challenges that we can address, but these—this was part of the challenge in selecting the measures that are on your grid. We are currently in a detailed review process of the individual measures. And a subgroup of the workgroup will be reviewing all the details of them to provide guidance for retooling and identify any needed changes, also to identify thresholds for performance, and also some scoring guidelines. So we will be classifying them for a degree of readiness by scoring and also the thresholds. So that's our next step, and that's the full report.

Jonathan Perlin – HCA – CMO & President

Great. Well, thanks very much. And just a couple of comments: So Floyd highlighted how HITEP actually looked at the workflow, and that is really quite important. Where in the process do you capture these measures? Because if something is an observation with the time-date stamp at the moment the nurse pushes the fluid versus a discharge diagnosis created 3 weeks later, that's clearly an important distinction. So they've got that level of granularity: who is the actor, what is the event, and when do you capture it in a workflow?

And to understand data types—you've heard this term. There are both nouns and verbs. A noun may mean "medication." A verb may mean "ordered" or "administered." And each of those noun-verb combinations might have an attribute, like date-time. So we will declare a measure based on the fact that the medication was administered and it happened within 30 minutes of the patient arrival. That would

require a date-time registration, date-time administration. So they've got to that level of granularity. But then, as Floyd has said, he then had passed off. There's been great coordination between clinical quality, clinical operations for Jamie's group to say, "Well, how would you actually represent that particular event in a standard that would then be transmitted to a registry or other quality metric-gathering organization?"

This is a quick comment about some of the gaps. So we chatted in one of our meetings about—it is challenging to measure some of these manual methods, like CPOE percentage—how do you figure what you didn't via CPOE or e-prescribing what you didn't e-prescribe? Now, there—conceivably, attestation may very well be for 2011 what's best, or there could be some proxies. Now, this would be slightly controversial and not securely accurate, but if you imagine I got the number of e-prescriptions that I wrote and the number of encounters with patients that I had, it is certainly not perfect; it is certainly not normalized across specialists and PCPs—those that are young and those that are old, sick and well; but if you wrote 100 e-prescriptions on 100 patients with 100 encounters versus 4,000 patients in 100,000 encounters, it gives you at least a qualitative sense that e-prescription's being used or not used in a practice, because the alternative, as we described in this call, was, every time an encounter is closed, have the physician check a box—you know, "wrote a prescription" or "didn't." That would clearly be both a burden to the workflow, and it would require modification of existing EHR systems. So it didn't seem like a very rational approach.

Lastly, one of the things you saw in Floyd's presentation is the terms "ICD-9," "ICD-10," "SNOMED"—those vocabularies—again, clear coordination between quality and operations has occurred, because we know this is a big moving target. ICD-9, very commonly used today; ICD-10, coming in 2013; SNOMED, being introduced into some clinical operations today, maybe not ubiquitous by '11, maybe ubiquitous by '13. So there has been, in their quality data type work, a recognition that multiple vocabularies might be used and there may be a path over time to use these various vocabularies.

So let me open it up to questions based on the presentation and on the matrix of the 27 items you've seen. Wes.

Wes Rishel – Gartner – VP & Distinguished Analyst

Always the same hands. First of all, I want to say that this is wonderful piece of work. The business of going from the high-level concepts, to the thing that looks wonderful when you first talk about it, to what really makes it work is such a, you know, slogging-through-the-mud job. And the work that's been done seems to be very, very positive and potentially doable.

I have a couple of big questions that may have been answered in other contexts. I'll be happy to take a reference instead of an answer. But the first question is, in determining the denominator—I mean, these measures look like queries from a database: "All patients who this were over all patients through that." But there seems to be some conditions missing in the queries, for those environments where patients are not arbitrary—administratively assigned to whoever you are measuring, where there are patients who come in and come out—you know, community health centers—things like that. It seems like determining what are the patients that have to have a measurement in order to do the denominator is this diff—is a difficult problem.

And the bigger question and the confusion I've had in this process is, what do we believe is the scope of the EHR? In most organizations that I'm familiar with, if you want to answer these questions, you don't go to the computerized patient record system; you go to a data warehouse. And there are lot of reasons for that, some good, some not good, but all real. And if, in fact, we are, in a meaningful use measure, determining the eligibility of a hospital or a practice to receive incentive payments for its EHR, can we ask

it to do more than the EHR does or not? And I hope we do, because this is what it's all about. I just want to understand how we do it. Thanks.

Jonathan Perlin – HCA – CMO & President

Great. Well, I'll start, just very briefly, then turn it over to Floyd. Denominators are challenging. And so, you can imagine—Floyd's said this in his slides before—diabetes can be defined as an ICD-9 code, 250.X. It could be defined as "You are on insulin." And in fact, it may be people on insulin have never had a diagnosis of "250.X." So you would have to actually try to look at multiple possibilities for defining that denominator. I'm sure, Floyd, you can describe some of the thinking behind that.

Regarding the data warehouse question, many EHRs that I work with have a query capability built in. Now, they may query the native clinical database or an abstraction; that is on a nightly basis, the EHR vendor itself provides a duplicate copy of the clinical data that can be queryable. But it is becoming more and more commonplace for these products to allow identification of, say, who in your panel has a particular condition or issue. In fact, that's part of meaningful use. So I think what we're stating is, you have the capacity, be it the EHR with integrated function or your environment that has an EHR plus a warehouse, of generating some of these numbers. But Floyd, please comment on those.

Floyd Eisenberg – NQF – Senior VP of HIT

Sure. Actually, for the two questions you answered, the first was pretty much attribution. How do I know who is in my denominator? And most measured developers have determined that by—perhaps in the ambulatory area, asking, "Have you had two visits within the year?" Now it's very likely that if you're looking at a specialist and you're looking at a primary care physician, each of whom had two visits with the same patient, you could say that the same—they each had attribution. But that's a measure developer decision of how that attribution is determined. The data element then becomes an encounter—the date and time—and that you need two of them, so each element is a unique two of those data elements or representations of it. And in a hospital, of course, it's admitted, so that's a little bit easier.

On the question about use of EHR, when I mentioned the data flow attributes that HITEP looked at—the Health IT Expert Panel—they identified health record field. And it wasn't down to the exact field, but it was suggesting that I find your conditions on a problem list, and so—that if a problem list is used in the EHR, that makes it more meaningful, because a problem list gives you all the conditions that are going on with the patient at any one time, and it adds value. The fact that your meds come from the med list—so the fact that you're on over-the-counter aspirin for prophylaxis because you're over 50 and you're preventing coronary artery disease, or you had an MI and you're preventing a recurrence—since it's over the counter, there's no prescription for it. But the fact that it's in your med list allows you to see all meds together and potentially do med interaction checking. So the purpose would be to say that it's on your med list. To find the allergy, it's not just in a note, but we would expect to find it on the allergy list. So that's how we would suggest that it's applied to EHR. What that means is, if it's in a data warehouse, the data warehouse has to identify where it came from, not just the element. So the allergy would have come from an allergy list to make it meaningful, or an intolerance can come from allergy lists or intolerance list. So that's really where we see the connection.

Unidentified Man

Jon, can I follow up?

Jonathan Perlin – HCA – CMO & President

Sure.

Unidentified Man

So usually, there's two reasons to have a data warehouse. One is for additional functionality in determining things, and the other—because my enterprise is badly fractured in terms of how it serves individual clinicians throughout the enterprise. You're—if I understand what your sense—and I think it's good—it's a good challenge—you're expecting the enterprise to solve that problem in order to get payment for an EHR, even though many of the visits for a patient may not be in that EHR that the enterprise serves.

Floyd Eisenberg – NQF – Senior VP of HIT

Well, I think what we're expecting is that the EHR is certified for use of and containing a problem list, an allergy list, a med list, and that—and have the functions to manage that. And if that function is obtained more as a service from a warehouse in that organization, I think that's potentially acceptable as long as it's in use.

Unidentified Man

Okay. So let's, for example—that if we use your attribution, as two encounters occur with the doctor and medication reconciliation is required at each encounter, that would imply a meaningful use for EHR would have a medication list. And whether you access it by querying EHR directly or querying a data warehouse to report it to the quality measurement organization would be fine. I think your question would be, "What if they visited somebody and didn't have a medication list or didn't have an allergy list or problem list?"

Floyd Eisenberg – NQF – Senior VP of HIT

No. You know, I can't count on the fingers or the hands in this room the number of medical centers that have a different computerized patient record for inpatient and outpatient—any of these in the middle or a third record. If they're reporting for quality measures, they're somehow assembling that data. That doesn't imply that any one of the users of those three systems have a consolidated problem list or medical list and so forth.

Unidentified Man

I am happy for us to just do anything that actually measures quality, and that's fine. I'm just having a hard time connecting it to paying for one of those three EHRs in that setting.

Floyd Eisenberg – NQF – Senior VP of HIT

Right. And so I guess the challenge—and it's an interesting question for the group—is—well, let's imagine a hospital has a hospital information system with CPOE. They have an EHR. They have some e-prescribing software, and they have a warehouse. And it turned out that you did get a medication list, but it actually came not from the EHR but from one of the other data sources, and it was used for reporting of the quality measure. Do they still get credit for having an EHR that's meaningfully useful, because a quality measure came from the organization? That's an interesting question.

Unidentified Man

And the only thing I would say differently about the question is, they have EHRs. This—our assumption that they have *an* EHR for the entire organization—that's how we're organizing ourselves conceptually, so that the different products they're putting together have to be as good as a single system. I think we have to be real clear on that, because certainly it's not the state of mind that people have when they buy Brand X for ambulatory even though they have Brand Y for inpatient.

Unidentified Man

So his comment is quite relevant. So take my own organization. I have a single EHR across all of my own physicians except the transplant team, because they have a very peculiar need for doing specific reporting, so they use a different EHR. And then I have a different EHR for my non-owned physicians out

in the community. And so, for me to declare meaningful use, I would actually have to report on three different systems' capability of reporting these measures.

Unidentified Man

For you to report quality, you would have to do that.

Unidentified Man

Right.

Unidentified Man

For you—that—yeah, okay, I think we're [laugh] clear on the confusion.

Unidentified Man

So yeah, I think that, you know, the take-home point in all of this is, if, as that interim final rule comes out, there is the notion of linking the EHR to the capacities report quality, we really have to make sure that it's data that came from the EHR and it ended up in a warehouse versus came from some other system and the organization reported it.

Unidentified Man

Or we have to knowingly accept that we made a compromise that would move the ball forward.

Unidentified Man

Right.

Jonathan Perlin – HCA – CMO & President

Dixie, I think you were next, and then Ann.

Dixie Baker – Science Applications International Corporation – CTO

Yeah. It occurred to me that the vetting of any of these measures seems to be a function of both how easy it is to capture the numerator and the denominator as well as the maturity of the vocabulary that's used to code it. And I was curious to know how you plan to assign a readiness value to these measures.

Floyd Eisenberg – NQF – Senior VP of HIT

Yeah, and actually the—part of the readiness—I think you'll hear more from Jamie on the operations side, but the readiness is the maturity of capture and the maturity and availability in use of the terminologies. So SNOMED is there, but how often is it used? —which is why—I don't want to get into your presentation, but you'll see that it can be used in 2011 but would be expected to be used in '13 and '15. So hopefully, that helps to answer the question, but that's what we would look at—is the ease of capture and the maturity of the terminologies.

Dixie Baker – Science Applications International Corporation – CTO

So you would take whatever Jamie comes up with...

Floyd Eisenberg – NQF – Senior VP of HIT

Correct.

Dixie Baker – Science Applications International Corporation – CTO

...and factor that into your assessment of how easy it is to capture the value and then assign the intersection to...

Floyd Eisenberg – NQF – Senior VP of HIT

That's right. In some cases, like the example of—every time I send a patient home from the office, I have to enter another code. Yes, there is a measure. Technically, you could say it's mature—there's a G code or CPP2 code that would do that—but that was considered by our Team to be contrary to workflow and add an extra step, so that was not felt to be what the Team wanted to use.

Unidentified Man

Correct.

Unidentified Man

And this is work that will go on over the next month, because we know the folks writing the interim final rule really want to have this information available, so—our next workgroup call.

Floyd Eisenberg – NQF – Senior VP of HIT

That's correct.

Jonathan Perlin – HCA – CMO & President

Anne.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Regarding Wes's comments earlier, we haven't said the word "certification" in terms of getting these source data consistently to any kind of reporting mechanism. So is that another group of people working on certification, besides us, of the EHR?

Unidentified Man

Right, well, in meaningful use, the certif—the criteria that are listed for meaningful use is the ability to exchange quality measures should there be an entity that can receive them. So it was just the capability to do this. So, you know, comments that you would make on—

Floyd Eisenberg – NQF – Senior VP of HIT

Well, actually, I do know that CCHIT has an Advanced Quality Certification Workgroup that is working in the very near term to have advanced quality certification criteria for EHRs. But I believe that's for 2013. There are currently certification criteria for EHRs to use a problem list, to use a med list, to do med reconciliation. And so, I believe, in fact, one of my additional responses to Wes's comment was, in order to achieve—if I remember the ARRA wording correctly, to achieve meaningful use, you have to use a certified EHR, and you have to use it meaningfully. So the assumption was, you're using—when we looked at these measures, you're using the certified EHR and using the certified components; you are meaningfully obtaining the data needed for the measures. That was really the direction we took. Does that help?

Unidentified Man

[Inaudible] 2011, just looking through all of the meaningful use matrix, does report the—require the reporting of these quality measures to CMS. Now, the one thing that is not specifically discussed is CMS's capacity to receive them at this point.

Unidentified Man

That is correct. Good point.

Floyd Eisenberg – NQF – Senior VP of HIT

Yeah, I agree.

Jonathan Perlin – HCA – CMO & President

Okay, I think next we had Chris and then Kevin and then Doug and then.

Chris Chute – Mayo Clinic – VC for Data Governments & HIT Standards

It's not clear to me that this is a Floyd question, but I'll ask it to the room, and we'll see what happens. And it's really thinking up on what Wes had said. You started something, Wes. In the context of the earlier presentation, John, when—with you, he was presenting what happened at policy, particularly with HIE. It begs within-enterprise communication. And if our goal is the whole notion of patient safety, if our goal is the whole notion of meaningful use within the context of an enterprise, then multivendor environments effectively might require, if we think this through, the moral equivalent of an HIE within enterprise, be that manifest as a warehouse, be that manifest as some other kind of communication between systems, because in our own environment, Mayo Clinic, we have three campuses, and we struggle fiercely to make sure that what happens in Arizona is known to Minnesota for those patients who move back and forth. In a smaller scale, what happens to the transplant surgery might be useful to other care providers and vice versa. And it really gets at the scope of—you can have meaningful use of an instituted—or an instance of an EMR, but it's not really, from the perspective of patient safety and from the perspective of meaningful use across an enterprise, where we want to be. But how we reconcile that doesn't seem to have been addressed.

Unidentified Man

Right, because the HIE Workgroup is looking at enterprise-to-enterprise communications. And we recognize, in the interest of coordinating care, just making our own organizations talk to themselves can be a challenge. So it's—although we have not, in our particular deliberations, talked about architectural issues inside an organization, mandating specific code sets within an organization, we've always said, "Border of an organization out. You may use closed and proprietary codes, but if you ever transmit to the outside world, they must be translated into these industry standard nomenclatures." So your issue of encouraging people to get their own houses in order if they're going to appropriately communicate to the outside world [inaudible].

Jonathan Perlin – HCA – CMO & President

Kevin.

Kevin Hutchinson – Prematics, Inc. – CEO

I have two comments, one just to follow on what Wes is saying, as—since you have started something, Wes—that I think we have to accept the fact that we're going to have multivendor environments. And by "multivendor"—not necessarily just multi-EMR vendor environments; you'll have some environments that have build their portals and have lab capabilities and e-prescribing capabilities, and then they have a database where they've stored a longitudinal medical record for patients. So there's going to be—the classification of meaningful use of EHRs should be down to the level of "Are they providing an ability to pull this reporting and this capability of storage of this information?" versus "Am I using System A, System B, or System C?" because there is the best-of-breed approach in the technology world, and then there is the single-vendor approach. And I don't think it's—behooves this committee to decide which of those paths is probably the better path to take—single-vendor- or multivendor-type approach—and especially large enterprises; you're just going to have multivendor environments that exist. And you're going to have partnerships that are created between technology companies to fill gaps where they don't have functionality to help meet this meaningful use criteria.

My real question is—and maybe this is really to Jodi—a lot of this measurement—because the funding and the incentives are Medicare based, are the percentages that we're talking about in here just around

Medicare patients, since it's tied to Medicare incentives? Or is it—are the incentives percentages tied to all patients that a physician sees? Because I'm not sure that they can legally—incentive payments are to—from Medicare, since I've heard it's going to be a CMS regulation. Is it specifically around a percentage of population for Medicare or all patients?

Unidentified Man

I mean, certainly Medicare and Medicaid, but I would think all patients is the goal.

Dixie Baker – Science Applications International Corporation – CTO

I would say that we would be looking for your advice on that, and then we'll figure out legally what we can and can't do.

Unidentified Man

I think we might want to defer to David and John Glaser. I know they'll be part of the discussion, and I'm sure that we'll go on within HHS. And I think your point, Kevin, is important. It's not without precedent that CMS has taken the perspective that it has a relationship with all patients through the quality improvement organization. That, of course, is the relationship that was—that the precedent was established with the HCAHPS Patient Experience Survey. So—but I think your point is very well-taken, because—and if you use the metaphor that John Halamka was sharing of the architecture in his environment, different systems actually related to different sets of patients. And I think the—there is a broader intent here to incentivize and propel meaningful use.

Let me just take a moment and recognize that we've been joined by Dr. Aneesh Chopra, the Chief Technology Officer for the White House. And thank you very much for joining.

Aneesh Chopra – White House – CTO

Sorry I'm late.

Unidentified Man

No, no, no. Great to—

Aneesh Chopra – White House – CTO

I wanted to be here for John's presentation.

Unidentified Man

[Laugh] You're in time.

Unidentified Man

So Kevin's point is actually a very good one. And let's reflect for a moment on the three possibilities for certification that Mark Leavitt recently outlined: that there is the comprehensive EHR, there is the EHR composed of modules, and then there's the self-built EHR. So if you had an iPhone app for laboratory ordering and resulting and another app for e-prescribing, and even though they were completely different vendors and completely different systems and they were capable of submitting measures from a clinician's office, should that be sufficient to constitute a meaningful, useful set of activities rather than a single, comprehensive EHR? And you'd think, "Yes, that would make complete sense."

Unidentified Man

So I think we had Doug next.

Doug Fridsma – Arizona State University – Associate Professor

So one of the things that sort of strikes me as we think about all these quality measures is that what we're really trying to do is measure things like evidence-based practice, what's the best care that's out there, and ways of both quantifying where we are and—you know, if you take a look at the goal that, by 2015, we really want to be driving towards continuous improvement. One of the things that strikes me is, do we need to consider, as we think about these quality measures, to build into the process the ability to support clinical research or to be able to do comparative effectiveness as part of gathering this particular information? Because if we think about it now, it may be much easier for us when we get to 2015 to continue this process so that it's not just that we have, you know, 90 percent of the diabetes that are under good control, but in fact we start driving even further, because we've instrumented our system in a way that would support ongoing clinical research and clinical quality improvement.

Unidentified Man

So HITSP has been working with HHS and ONC—a working group on the clinical research and clinical trials data standards. And your point's a good one, in that many of the data elements we're seeing aren't gathered as a byproduct of the process of care. And they actually require this putting a form to gather specific new data elements that are related to a clinical trial that would then go into a repository. So it would be very reasonable, I think, to have that body of work reported to this committee at some future date. And I know, Floyd, you had a comment.

Floyd Eisenberg – NQF – Senior VP for HIT

Yeah, an additional comment. As I look at many of the measures in our database, many require additional data elements, which we would still call quality dataset elements, to look at risk adjustment and to identify other issues around the population that's being measured to add to research. So, many of them already do that; the measure itself may include 5 or 6 elements or 15 elements, but then there's another set that gets reported with that for the purpose of risk adjustment and analysis. So I would see that as additional quality data set elements to do the same.

As John was saying, for a clinical trial, there are elements that would not normally be in the record and, for many reasons, shouldn't be in the record, because they're not part of routine care. But many of the elements can be. And I know one of the efforts of that clinical research group is to take whatever can be from the record and have that mapped into—to prefill this form and then allow manual entry of everything else. But I do know that a number of our measures already have risk adjustment algorithms to do that, and I think they will add to research.

Unidentified Man

So HITSP continues to work on extensions, gaps, and some of the aspects of use cases like clinical research and clinical trials, and so we'll make sure this is coordinated with ONC and brought back to this committee.

Jonathan Perlin – HCA – CMO & President

Wes.

Wes Rishel – Gartner – VP & Distinguished Analyst

I just want to comment that there was a breakthrough here. I'm not sure whether it was a breakthrough for the group or I finally caught up with the group, but either way, it was a breakthrough. And that is that meaningful use—the stimulus money—incentive money goes to either a hospital or a physician and is not directly tied to whether they have one product or many, but that—the breakthrough is that our criteria have to be specific enough for meaningful use that, if they have many, they are using them over their population, as opposed to only some subset of the panels of patients or something like that. So if we think

about—it's the responsibility of the organization to do meaningful things, where the organization might be a practice or it might be a hospital, then I think that helps clarify a lot of my questions.

Unidentified Man

And based on all these comments that were made, I'd want to clarify with the Policy Committee that they feel that that interpretation—that is, the physician that needs to demonstrate that quality measures of reporting—that these things are being done, regardless of the infrastructure. You know, it could be a self-built system in MS-DOS. As long as it can do this stuff, it's not the system; it is the practice, the doctor, or the hospital.

Unidentified Man

Now, I think, Jonathan, you had some comments or thoughts on that?

Jonathan Perlin – HCA – CMO & President

Yeah. Well, I think there's been a terrific discussion, because I'm trying to envision, in the real-life setting of a practice or a hospital environment—there are obviously a number of systems that come together, and to suggest—to thank Floyd for the terrific word—that monolithically, all of the answers to all these queries will come out of one, ideally certified system is probably wrong. It's probably the juxtaposition of multiple systems: front-end capture systems, data repositories, perhaps logic engines that query, and—you know, etc.

So I think that you're right, Wes. I think that really is a breakthrough, because it's not a monolithic or, you know, sort of one-to-one relationship with one of the systems. I think that implies a recommendation. I don't think it implies necessarily that we can set policy, but I think it strikes us, if I'm hearing the consensus, that there is an interpretation that it is likely that the data elements that are sought have to relate to the system that's meaningfully used and certified, but the elements are probably captured by some relationship of multiple settings in many, if not most, settings. I think we need to feed that back to the Office of National Coordinator to work with and, as John suggests also, to juxtapose with the Policy Group. But I think that really is a clarification that's important to point out. I think the [inaudible] attribution that were also raised are also useful in terms of their relationship to the five elements that you described. Is that helpful to the group in terms of setting that? Good, thanks.

Unidentified Man

Nancy?

Nancy Orvis – DoD – Chief of Health Affairs

To follow on that very theme, I think it would be—as we work on that recommendation to ONC, I think we need to also clarify that that particular issue—that the provider or the provider organization will need to be able to pull this data across several either platforms—you know, system platforms or whatever so that he can—they can report on their population or panel—that that very strongly talks about—the vendors need to be able to have standards between themselves too—that there should not—that there is absolutely going to be a need to have commonality in that information exchanges. And particularly, what I hear coming out of this is that clinicians are going to need to see how their clinical decision support is coming into play so they can answer these questions. And it's not strictly an EHR that's going to capture this data for them, because they're going to have to answer this question on “How many of my patients are on as—I'm going to need to find out if the patient's on aspirin or the patient's on insulin or my immunization profile for my kids, you know, my—in my family practice very quickly. And I'm going to need to have good querying capability within my EHR.”

Or—and in my organization, I absolutely—I have different packages in the inpatient environment for critical care versus what I am using in part of the ambulatory, and also in our theater, where our point of injury or point of illness occurs. For us, that's very critical across a continuum of care—that we can never—we never want to rely on one single product, but we want to be able to create a single view for that patient or that population. So I guess that's—this—I think in 2011 or 2013—I think we should be able to say that, as we talk to those who put this out in the vendor criteria population—that they more than anybody will need to see the need for standardizing their information interchanges to support this.

Unidentified Man

Right, and a very good point. I mean, certainly in the ideal world, the vendor systems themselves would embrace all these controlled vocabularies. We know that, in the interim, there may need to be proprietary codes that are mapped between systems, and some vendors may even refuse to change. So it will be an interesting challenge for some enterprises internally. Aneesh.

Aneesh Chopra – White House – CTO

Well, I just wanted to—I love reading the materials, and I'm very excited about the progress that's been made. And I just had a quality question, if I could. South of clinical trial but north of just everyday running of the practice and reporting measures, are we starting to see some consistency in, maybe for lack of a better term, the business analytics set of activities that people are running? So my presumption at Kaiser is that there's a team of really smart people that are querying the data to decide whether or not A or B intervention makes sense. It may not be internally treating it like a traditional clinical trial, but they're looking at mechanisms for quality improvement. Are we starting to see some consistency in how people are running those kinds of analytics? And if so, are we—what can we do to help make sure that that's incorporated in our work?

Unidentified Man

Okay. Good question. I think it varies with institution from place-to-place. I think in small ambulatory practices—I don't know that we're seeing consistency. There are products that are geared to collecting data for the purpose of specific measures; pre-identified; and when something changes or a new one comes out, they update the system. But I think, in most large organizations, there is starting to be some consistency. I know there's talk at standards organizations like HL7 about how to combine the terminologies and the data from using for research and clinical care, but I know some of that work's still in progress. It's not done. But I think, somewhat, it varies by institution. And how do we encourage that? I think through... well, the easy answer is semantic interoperability tomorrow [laugh].

Aneesh Chopra – White House – CTO

Yeah, right.

Unidentified Man

That's not the easy solution, though.

Unidentified Man

And Chris, I think, had an amendment to that answer as well.

Unidentified Man

Okay.

Chris Chute – Mayo Clinic – VC for Data Governments & HIT Standards

Yeah. Chris Chute; I'm a researcher at Mayo Clinic, and—

Unidentified Man

Oh, you're the guy who's going to help me into this.

Chris Chute – Mayo Clinic – VC for Data Governments & HIT Standards

Well, I [laugh]... it's not clear to me that the analytic infrastructure is the critical path piece. But more pertinently, as I think Floyd was saying, it's really the information interoperability. And I do want you to point you to, if you haven't already focused on it, the Clinical Research Tiger Team within HITSP that is starting to recognize that clinical research information standards really must align with clinical information standards, because if we have differences in those worlds, then at the end of the day, quality improvement is really a kind of research. The quality people don't always see it that way, but it is. And to the extent that we have comparability and consistency between the way they conceptualize information, and that—the way clinical trials folks conceptualize information, and the way that clinicians conceptualize information and have commonality across those domains, then, if you will, the inferencing analytic becomes frosting on top. It becomes almost arbitrary, because what is important is to insure that the underlying information is comparable.

Unidentified Man

Let's see; Gina?

Unidentified Man

Let me just add to that that just last week, having been at a Integrating the Healthcare Enterprise meeting (IHE) in Chicago or Oakbrook, we—it's been 2 years since there was a domain developed called "Quality Research and Public Health," trying to see how to coordinate the data among all three for use for research, quality measurement, and also clinical use. And it was a very interesting conversation that occurred when, for the first 2 years, it was discussion of "Clinical research needs these data. How do I map them to what's there?" And because of the Research Tiger Team, the comments came through. We really need to get research looking at data as its clinical use and not just map it. So there is a strong movement now to coordinate that, and I think HITSP's tiger team has helped.

Unidentified Man

Great. So Gina and then Kevin, and then we should move on to Jamie's presentation. So Gina.

Unidentified Man

Okay, great. Go ahead.

Gina Perez – DHIN – Executive Director

So I just wanted to go back to your point about the communication of the Policy Committee. I think it's—this discussion really emphasizes the need for health information exchange. And what I know very well is that hospitals and physician practices using EHRs are not necessarily capable, and probably won't be capable any time soon, of sending SNOMED transactions and so on and so forth. So I am very concerned about the environment, where it stands today, and the likelihood of us moving to a 2011 implementation. And I think it's really important that we communicate that to the Policy Committee and the role that the health information exchange can plan in standardizing that data as it comes in and being able to report that back in a standardized format. And I really want to make sure that we keep that in the forefront.

Unidentified Man

Right. So as Gina said, one of the important roles of the health information exchange is data normalization—that you'll get it in a variety of formats, sometimes coded, sometimes uncoded, sometimes proprietary, but they can provide a unified view.

Well, I know that administratively, Judy, you wanted us to take action on this presentation, and that is, would there be any objections to accepting this report as written, recognizing it's a work in progress and that there's additional work going forward—but the spirit of what has been done?

Unidentified Man

So moved.

Unidentified Man

Okay. Very good. Well, we will accept, then, by consensus. Thank you very much, Floyd, and let us move on to Jamie and clinical operations.

Unidentified Man

Oh, yes. Certainly.

Elizabeth Johnson – Tenet Healthcare – VP of Applied Clinical Informatics

I just want to ask a more generic question. This is Liz Johnson. We've talked about years in this committee. Last week or earlier—yeah, last week, Thursday, we heard “adoption year.” Are we going to do any correlation between 2011 and Adoption Year 1? John?

Unidentified Man

This is a discussion we actually recently had in our clinical operations meeting—is—that is—so John, you have, in the case of the HIT Policy Committee and Meaningful Use, had the sliding multiple years. Do standards slide as well, or do we really want to say, “SNOMED is actually a statutory requirement to have use by 2013”? You really can't slide that.

Unidentified Man

John, for the Web folks, you may want to use a microphone.

John Halamka – Harvard Medical School – CIO

I think, as you all consider, you have to consider the fast movers, and hence there will be a requirement up front that the fast movers who will be early—start early in '11 and be at a certain place in '13—if you're going to put requirements out on '13, you're more whetted to calendar year than meaningful use year. That's my suspicion, although I think you guys ought to debate. Does that make sense, Liz?

Unidentified Man

Right, and so when we've looked, as you'll see in Jamie's presentation, which we'll go through this in some detail, they, as written to date, are calendar years rather than meaningful use years.

John Halamka – Harvard Medical School – CIO

Because if you're going to guide product development and some people will be at '13 and Meaningful Use Year 3, then they'll have to be, you know, essentially able to conform to the standard here. So I don't know that you have my sense, although this is sort of—this is guidance that you all decide here. You're more whetted to calendar year than meaningful use year. Meaningful use year is more of a payment-related mechanism than it is when the vendor products or self-development or whatever the strategy is—when do they—essentially here. So if you're in Meaningful Use Year 3 and you say you ought to move from proprietary to a standard, then that has to be what you do in Meaningful Use Year 3, which may happen to be Calendar Year '13, which means if you're a vendor, you'd better be ready in Calendar Year '13, even if some of your customers are in Meaningful Use Year 1, if that made sense at all. No? [Laugh]

Unidentified Man

So basically, to summarize what he said—is, we, as you'll see in Jamie's presentation, say ICD-9 is an absolutely acceptable coding mechanism for 2011, and SNOMED would be great if you can do it. But by 2013, you know, you're going to be doing ICD-10 and SNOMED. So we've built calendar year progressions based on the statutory requirements that are going on with regard to certain changes like ICD-10.

Elizabeth Johnson – Tenet Healthcare – VP of Applied Clinical Informatics

So I'm going to ask the question slightly differently to be—I understand what you're saying, but the interpretation in the rest of the world was that when we talked about adoption year—that if you chose to make 2013 your adoption year, then the 20—what we're now calling 2011 standards would apply to 2013. If you look at the slide out of the meaningful use presentation, that's the way it showed. And so, I am confused.

Unidentified Man

I think Jodi had clarification on that.

Jodi Daniel – Office of Policy & Research – Director

Yeah, let me see if I can help clarify. What I heard the Policy Committee say was, there's two requirements for getting your incentive payment: one, that the entity has adopted a certified product that is certified as meeting criteria and standards; and the other is that they are a meaningful user of that product. So what I heard the Policy Committee talking about was the second half, just the meaningful use part, and saying—recommending that if somebody enters the—you know, begins to adopt in 2013—that that should be—they should meet the criteria for Meaningful Use Year 1, whatever that is, so what somebody else would have done in 2011. Now that doesn't necessarily—I didn't hear them say that the certification requirements should be different for the product. So let's assume that ICD-10 is the standard in 2013. Then somebody who starts adopting in 2011 would have to move to ICD-10 in 2013, as well as somebody who adopts in 2013 would have to be at ICD—would have to have a product that uses ICD-10.

Elizabeth Johnson – Tenet Healthcare – VP of Applied Clinical Informatics

And so, based on that interpretation, what relief was given?

Jodi Daniel – Office of Policy & Research – Director

So then, what I heard was, so if you're in your first year of adopting, you might not be able to report on, say, all of the quality measures because you're first just starting to get your system up and running and capturing data. So perhaps there's—you know, if there was a requirement to have the capability of reporting on a particular measure but not necessarily reporting in 2011, there would be relief in 2013 from having to kind of up the reporting requirements—the activity that they're doing. Or, for instance, if they had CPOE for 10 percent of orders in 2011 and CPOEs for 50 percent of orders in 2013, somebody who starts adoption at 2013 would only be held to the 10 percent.

Elizabeth Johnson – Tenet Healthcare – VP of Applied Clinical Informatics

Right, and that is how I interpret it. So that is relief, no question, but there—what I hear—I'm hearing from this committee, which may be our intent, is, there is no relief on the standards side. Is that correct? Because what we're saying is, you may get a relief on the CPOE adoption still following through by fourth year getting to 70 percent, for example. However, from a standards perspective, the way we report the data is going to continue to stair-step up, whether you start in '11 or '13. Is that correct?

Unidentified Man

Right, so that the measures would be by adoption year, but the standards would be by calendar year.

Unidentified Man

So Jamie, let us see your presentation, and then I'm sure we will have a lively discussion.

Jamie Ferguson – Kaiser Permanente – Executive Director

Thank you, or maybe not. I'm Jamie Ferguson from Kaiser Permanente. First, I'll just—I've got a slide listing the workgroup members, most of whom participated in a series of calls. We did have—similar to the Quality Workgroup, I think we actually had a couple of additional calls. We had some joint with them, and we have—we've had actually quite a number of hours on the phone in the last few weeks, coming up with these recommendations. So I just want to thank everyone for their participation.

First, I will just summarize what the whole presentation says. We've used a two-phased process, first to identify applicable EHR standards and then to assess the feasibility of implementation of those standards for widespread implementation according to 2011 versus 2013 versus 2015. And we addressed almost all of the measures. You'll see at the very end there are a couple of measures that we missed that—I'll for permission to go back and look at the same recommendations, as they may apply to those.

We started—as we were instructed, we started looking at the applicable department-adopted, recognized, or accepted standards. So that's what we're recommending for 2013 and for 2011 as they apply to these measures. We did identify some gaps in standards that may affect the use or the scope of these measures for 2011. And an example is that, in lab results, there are no adopted standards currently for blood bank, for surgical pathology, or for genetic test results. And so, how those kinds of results can be reported in a standard if there's no currently adopted standard is something that we're going to have to work through.

In general, also, while we're setting a level of standards that are the current adopted standards for the 2011 measures that we think should be required for 2013, for 2011, we're also allowing a degree of flexibility in our recommendation, in terms of the use of unstructured documents, including PDF and text, instead of structured continuity of care documents, also allowing for local and proprietary coding systems to be used instead of ICD and SNOMED and LOINC and RxNorm and so forth. So there is some flexibility, and I'll go through our reasoning for that. So that's my summary.

In terms of the process that we used, first, we did go through and reviewed the meaningful use objectives and measures. We did focus initially on the quality measures, and we only came later to the coordination of care measures. We then identified the existing EHR standards that could apply to those meaningful use measures. As I said, we looked at the existing HHS-adopted, recognized, and accepted standards first. Then we also looked at and listed other widely accepted and widely deployed standards that could potentially be alternatives, and we looked at and listed those as they may apply. And we also identified gaps in the standards for the measure. And we did this process looking at standards for the measure both in relationship to the text of the way the measure was written, but also looking at the quality datasets that we got from our joint work with the Quality Team identifying, well, what's in that measure the way it's calculated by the measure steward. We also then identified the feasibility of widespread implementation of these EHR standards by 2011 or 2013 or beyond. And in doing that, we followed the same taxonomy that we discussed in the last committee meeting, which was also referenced here earlier. And then finally, and throughout the process, we took a formal step of saying, "Well, what's our reality check on what we're recommending?" And we did make some additional notes—wanted to make sure that this was a realistic set of recommendations.

That's the process that we followed; I'll go through a particular example here in some detail. As Floyd said, the existing standards for quality reporting really are not geared to EHRs, and so the measures now will need to be calculated in terms of EHR standards in the future instead of, for example, administrative

financial reporting standards. And so, typically here, we're reusing standards that were adopted for a different purpose. So some standards that were chosen for clinical interoperability are now being recommended for quality reporting. And a particular exception to that is SNOMED CT, which is recommended actually for the same purpose that it was adopted for under the consolidated health informatics standards adoption, which predates HITSP, which is using SNOMED for clinical documentation.

So when you look at this matrix of recommendations, you'll see—or rather, when you look later at the matrix of recommendations, you'll see the same things that are here in these feasibility columns, but having been translated to the current document numbers of HITSP. And so, that's the translation between this process document and the actual recommendations. So, in this particular measure, we're looking at the patients at high risk for cardiac events on aspirin. We identified that, in terms of the adopted and recognized standards, we could use the standards that are referenced in the HITSP spec for continuity of care document—for e-prescribing and medication management. We didn't see that there were any other widely accepted standards that were needed or applicable to this particular one. We did identify a couple of gaps, so back to the Quality Workgroup. We need a way of identifying high-risk patients, but also we didn't—the measure itself included a calculation that, in part, was based on patient self-reporting of medications, and there wasn't a specific standard that was adopted for that purpose. So that was deemed to be a gap.

Then we thought that these standards, then, that are the recognized standards were widely feasible for implementation by 2013. And that's what we have in our 2013 column. But then for 2011, we thought that, in fact, local and propriety codes may have to be used. ICD-9 may have to be used in 2011. And so, at the same time, we don't want to penalize those who are able to get to the standards earlier than 2013. So you'll see in our recommendations, for each of the measures, we have basically the—in the 2011 column is the 2013 standard selection or recommendation and what we're recommending as the allowable variation in terms of the use of local and proprietary codes, unstructured documents—and those appear in almost all of them as an acceptable alternative for 2011, because we thought it just was not feasible for truly widespread implementation for everyone to get here to the 2013 recommendation.

And then you can see, in terms of our reality check, we saw that, for these particular standards, the adopted standards are not currently widely deployed for this use. So we had discussions about that. So as Floyd described, after these adopted standards are approved for this purpose, then it's back to the Quality Workgroup to oversee the detailed definitions of the actual code values for calculating each measure in the particular recommended standards.

We had a number of discussions, obviously, during this process. I just want to reprise some of them. We had a lot of concerns that were raised regarding the ability of those who've not yet implemented EHRs to get here to our recommendation, as well as a very—well, a lot of discussion about those who have already implemented legacy alternatives, and how are they going to get up to this level of recommended standards for meaningful use? And so, one of the main concerns that was represented for new implementers was ICD-10 doing all of this work at the same time. But the greater proportion of discussion was really about the legacy system implementations that are already in place and what it takes to get to standards.

And so, just as a sidebar, in Kaiser Permanente, when we brought together our different, independent regions to migrate to common systems and standards ourselves, we found that the loudest objections really came from the organizations that had already made the greatest commitment and investment in local proprietary systems and in alternative standards. And so, I wouldn't expect necessarily to see anything different here. And we did have discussions on that. And what we really talked about was the

fact that the longer the legacy systems are in place—the longer the proprietary alternatives are in place, the more gets built up around them and then the—essentially the greater their cost of upgrading to the standards. And that was part of our discussion on making these recommendations. So we believe we considered that fully, and that's part of why we're allowing this degree of variation, especially for 2011 and 2012 reporting.

To summarize our recommendations, then, we're saying that meaningful use, based on the standards that are in the recognized and accepted HITSP capabilities, which are all detailed in the attachments, is recommended for 2013 and for 2011 implementation of the 2011 measures. And this, as you'll see when we go through the detail, or if you look at the detail that's in the attachment and in the actual HITSP documentation of these capabilities, there are many uses of the continuity of care document as a summary record. And the specifications that are in there—the use of LOINC labs, the RxNorm for drugs, and other standards—SNOMED is one of them. And I just want to point out that, in some of the conversation here in earlier parts of this meeting, some folks said that we were recommending that SNOMED would be required for 2013. That's not correct. We are saying that SNOMED or ICD-9 for 2011 is recommended, and SNOMED or ICD-10 is recommended for 2013. And so, we anticipate the certification criteria should match the recommended standards, and we did not have any lengthy discussions on the certification criteria or the process in particular.

I'm going to go through a single example—detailed example of the recommendations, which is the percent of diabetics with A1c under control. So you'll see here HITSP capabilities. If you—so you have to look at the attachment and this list of HITSP numbers to get the full context. The 1—HITSP capabilities 117 and 18 are inpatient and ambulatory prescribing; 119 and 120 are structured and unstructured documents; 126 and 127 are lab results. And so, you can see that this is a translation of what we had when we went through our process. We documented things as—for example, we would say “CCD and HITSP labs.” And so, here in our actual recommendation, we've translated that into the current document numbers that are used in the accepted and recognized standards. And so, when we say that ICD-9 or SNOMED must be used for this measure, we're not specifying how the data are stored or managed internally within the entity, but we are saying that you must be able to represent your data in ICD-9 or SNOMED for this purpose. And so, that principle was the subject of a lot of discussion, and it really applies to all the recommendations.

Now, another thing that I'll point out on this detailed example is—so you can see here that we have local and proprietary codes, and unstructured documents are recommended as allowable for this meaningful use measure in 2011, as alternatives to basically what we're calling the 2013 standards. Those are removed from the 2013 recommendation for this 2011 measure. Also in 2013, we're recommending that ICD-9 replaces ICD-10, and that's consistent with the CMS time frame for ICD-10 implementation in the current—in the final rule from CMS. And then, instead of having a 2015 column per se, we have what we're calling a directional statement of intent, which is the direction that we think 2015 should go in. And it is a recommendation of that direction, but we didn't want to be prescriptive, essentially, that far out.

And so—now in some cases, remote device monitoring—there's a lot of standards work under way for home health device monitoring and so forth. And so, it may be possible to add those standards to the specification for the measure in 2013; but almost certainly by 2015, that should be added to this particular measure. And then SNOMED CT—so SNOMED problem list for clinical documentation, we believe, is the target and should be used by 2015. But we didn't want to be completely prescriptive about that, so we're calling it our directional statement of intent—is that clinical documentation, really, of problems for this purpose should be done in SNOMED CT and no longer in ICD by 2015, but not for 2013.

And that was our—so we had long discussions about the feasibility of changing that documentation and also about using—this is really about EHR implementation, where—as I think everybody here probably knows, ICD really is a classification system for administrative purposes. And even if you read—I think it's in the preamble to the final rule from CMS: CMS describes that SNOMED CT is appropriate for clinical documentation; ICD is for administrative classification and billing purposes. So that's—you know, we wanted to maintain that split, and here we really are talking about clinical documentation of problems in a health record used by physicians and hospitals. So that's why SNOMED really is the adopted standard for that particular purpose.

To summarize our recommendations, then, we are requesting—so the detailed recommendations are all attached in the matrix. We can go through those to the extent that folks want to. We're requesting committee approval of these recommendations for 2011 measures to be forwarded to ONC. Also, we missed a couple, and so these are in the second bullet here—so percent of encounters where med reconciliation was performed, percent of reportable lab results submitted electronically—that's for public health—and the 30-day readmission rate.

Now of those, the 30-day readmission rate—we deliberately delayed that one, because we thought it would take too much time, and we wanted to get our recommendations on the table. The other ones—sorry we missed them, so we're asking for permission to go back and see if the body of standards that we're recommending are suitable. And to the extent they are suitable for these purposes, then, we could—we're asking for approval to go ahead and recommend those, but not to go outside of those and, you know, create new stuff, essentially. And then we also realized that gaps have to be filled somehow, and so we wanted to ask ONC to determine what is the process for filling these gaps and to get that work under way.

Unidentified Man

Thanks very much. Just a couple of comments: You have at your desk, and you received electronically, this HITSP document that identifies all these capabilities. So when you see Jamie use those numbers, you'll see them referred to in the index. This is fully available in electronic form as a PDF. But as of this morning, all the HITSP work is now available as indexed HTML that's fully navigatable. You'll find it at wiki.hitsp.org. That just went live this morning—makes a whole lot of this documentation easier to navigate, because it's HTML based.

Marc Overhage – Regenstrief Institute – Director

Marc Overhage with the [inaudible].

John Halamka – Harvard Medical School – CIO

Okay, very good. Gaps—I think you've heard Jamie highlight this, and I think—important that—coming out of today's meeting, because there are a series of gaps identified that we'll work with ONC—and that ONC would want to make sure that these gaps are addressed by HITSP or standards development organizations, as is appropriate, because we want to make sure that we fill those.

It's important to see the division of labor between Clinical Operations and Clinical Quality. So you saw, Floyd came up with the measures, Jamie came up with the mechanism by which the data is gathered, but then Floyd will once again come up with the specific code values. So when we say, "ICD-9 will be used," you tell us that "250.XX" or "SNOMED concept" this or that, and so there'll be very good coordination and interplay.

You also heard Jamie talk about structured and unstructured data. Now, again, this is the escalator all over again. Wouldn't it be fabulous if every patient in America had a fully codified, structured problem list;

an RxNorm-encoded medication list; a completely structured allergy list with UNII chemical designations on every substance they were allergic to—food, medicine, or component—and every encounter broken down into a nice history of present illness with chief complaint and review of systems, etc.? Alas, we are not there today, and in 2011 it would be a stretch. So what you'll see in the recommendations to the committee is, they had said, "2011 structured, great; unstructured, okay." If you can take a PDF of the encounter that happens to have a human-readable problem list, medication list, and note, that's okay. But by 2013, we really want to get atomic and granular, so there's this roadmap of getting us there.

So with that, I would like to open it up to questions. Marc Overhage, you have the floor.

Marc Overhage – Regenstrief Institute – Director

Thanks, John. I guess I have a very fundamental question that I must have missed somewhere along the story here. We talked a lot about what standards and what HITSP constructs might be adopted. It wasn't clear to me, because on the one hand, in the—a little bit earlier in the conversation, we talked about—we're not worried about what codes and structures are used within an organization, but only when it hits the barrier. So are these the standards for transmitting—because in some ways, the measures that we're describing are things like "Okay, what's the percentage of patients that have adequately controlled glycosylated hemoglobins based on some criteria?" And—but we're talking about CCDs and things like that, which doesn't really—I don't understand that. So maybe somebody can straighten me out.

Jamie Ferguson – Kaiser Permanente – Executive Director

Okay. So, Marc, this is Jamie. We're talking about the list of standards, for example—so within CCD, HITSP has made it—there are a number of different specifications within each template, and so—same thing if we look at labs: there are a number of different specifications within that. And so, what we're saying is that the standards that are referenced in those specifications should be the ones that—in this case, that the Quality Workgroup specifies the code values in for calculation of the measure. So we're not saying that this is the way that the data have to be represented in an internal database or anything of that nature, but we're saying that it does have to be able to be—whether through translation or mapping or other means, it does have to be reliably used for calculation of the measure in the specified code set.

Marc Overhage – Regenstrief Institute – Director

Understand the code sets. The CCD is the part that throws me.

John Halamka – Harvard Medical School – CIO

Right, so just to—from my perspective, Marc, the transmission of data between two organizations, whether that is a provider-to-provider or whether that's a provider-to-biosurveillance or provider-to-quality metrics organization—these are the standards the workgroup has proposed for those transmissions between organizations, not for use within an organization.

Marc Overhage – Regenstrief Institute – Director

Okay.

Jamie Ferguson – Kaiser Permanente – Executive Director

I'll also say that, in terms of our use of CCD in recommendations, many of the—or a number of the recommendations have to do with coordination of care, both providing summary records—for example, encounter summaries, longitudinal summaries—both to other providers and to patients. And for that purpose, we are saying that CCD is essentially the format for transmission. But we're not—but in other cases, we're using the terminologies that are referenced within the HITSP standards as those that should be used for calculation of the measures.

Marc Overhage – Regenstrief Institute – Director

So just to be clear here, though—so first of all, when we talk about transmitting these quality measures, we're talking about sending, for example, a percentage of diabetics that are controlled. There is no accepted standard for doing that. There is ongoing work; there's discussion; it's clearly Level 2, maybe Level 3 standards—or Category 3—whatever—for that purpose.

John Halamka – Harvard Medical School – CIO

And so, Floyd or Jamie, do you want to talk about QRDA?

Marc Overhage – Regenstrief Institute – Director

QRDA is work in progress, right?

John Halamka – Harvard Medical School – CIO

Why, of course [laugh].

Floyd Eisenberg – NQF – Senior VP for HIT

QRDA is the draft standard for trial use from HL7. The patient-level report, which is all of the data, is Level 1, and that's not calculated "What is your performance?" It's just this—"For each patient, do they—what are all the data elements?" Level 2, as you said, Marc, is more an aggregate, and 3 is a higher-level aggregate. So Level 2 and 3 is in a—it's still in testing. And even Level 1 is still a work in progress, but it is a draft standard, and it uses CDA format.

Jamie Ferguson – Kaiser Permanente – Executive Director

Yeah. I'll just—I'll also add that what's in our recommendations is not the actual transmission of the measure with patient-level data. What we're talking about is the calculation of the numerator and the denominator by a meaningful user.

Marc Overhage – Regenstrief Institute – Director

I don't understand what that has to do with CVA or CCD.

John Halamka – Harvard Medical School – CIO

Right, and so, to summarize—and certainly, Jamie and Floyd, jump in—that we want to do a couple of things. There is clinical care coordination, which requires the summary, problem list, medication list, and laboratory information between organizations, and that is the CCD. There is the measurement of an individual's performance, process, outcomes with regard to a quality measure, and you have specified the vocabularies that are needed to do that. There is the transmission of numerators and denominators, which is very much still a work in process. I mean, that is, as you've said, Marc, QRDA—very, very early in the standards harmonization or standards creation process. So those are the three levels of standards that we're looking at in the committee.

Marc Overhage – Regenstrief Institute – Director

So I guess my point is, I think it is very premature and inappropriate to include CDA/CCD under those bullet items that are quality-reporting bullet items. Certainly appropriate for sharing information between organizations, although I think everyone would admit CCD is still fairly early in terms of ability to deploy it in the real world.

John Halamka – Harvard Medical School – CIO

Right, and so, certainly, CDA is widely used; CCD is emerging. And the question, I guess, coming back to the committee, is, we've specified the vocabularies that would be used, and you will come up with the code sets and values, but the transmission of the actual patient-identified data to a quality registry—

that's, I think, getting to the heart of Marc's question. Do you see that as a CCD document per patient, or do you see that as a different kind of message, or is that work still to be done?

Jamie Ferguson – Kaiser Permanente – Executive Director

We haven't spec—we haven't considered that question, and we haven't specified it in these recommendations.

Marc Overhage – Regenstrief Institute – Director

I guess I was keying off the inclusion of CDA under the standards.

Jamie Ferguson – Kaiser Permanente – Executive Director

So—and in that case, for example, the HITSP C32 implementation guide for CCD includes some terminology and vocabulary standards in the relevant sections. And so, that's—those are the ones that would be relevant to the calculation of some of these measures, not talking about it as a means of transmitting patient-level data to a quality data recipient.

Marc Overhage – Regenstrief Institute – Director

So I would suggest that we can clarify that to avoid confusion by others by removing that reference. I do have another comment, but I'll get back in the queue, John.

John Halamka – Harvard Medical School – CIO

Okay, great. So I think what we have is the work for the committee to clarify, once a measure at a patient level has been done, or once an observation has been made, how is that transmitted to a quality registry?

John Halamka – Harvard Medical School – CIO

Okay, so David.

David McCallie – Cerner Corporation – VP of Medical Informatics

Yes, David McCallie. At risk of piling on, I want to agree with Marc's point that the use of CCD, in this context, is extremely confusing, because CCD is a data standard for transmission of a snapshot in time, and very—there's no specification on what the snapshot has to be. It could be a single encounter; it could be the last year. And it's really for moving data from place to place; it doesn't represent an internal state about a patient. Now, a CDA, describing a clinical document—per se a specific visit—might have encoded data in it that is specific instance, you know, just once. But the CCD would not work in that context. And I think that clarification's really important. Otherwise, vendors may assume that you're trying to imply that the CCD is some kind of a data structure to be used in the database, which it obviously is not. It's just a transmission structure.

John Halamka – Harvard Medical School – CIO

And absolutely, yeah, there is no intent that CCD would be a data structure as a transmission vehicle, but—

Jamie Ferguson – Kaiser Permanente – Executive Director

So we'll look at opportunities to clarify our documentation.

John Halamka – Harvard Medical School – CIO

[Laugh] Yes. Chris.

Chris Chute – Mayo Clinic – VC for Data Governments & HIT Standards

As Chair of the ICD revision process for the World Health Organization, I'm painfully aware of the limitations of ICD. That being said, I have angst about SNOMED. And specifically, while there is, in the

HITSP documentation, a clinical problem enumeration that is the Kaiser VA list, it's not actively maintained—best I can tell. And it is widely acknowledged to—by its developers to have significant gaps—for example, it doesn't really deal with pediatric information at all—and has other—how do we phrase this politely?—shortcomings.

Furthermore, as many of us noticed, the National Library of Medicine yesterday released a clinical problem subset of SNOMED. They are the nationally designated center for SNOMED implementation. And while I personally haven't examined it, Bob Dolan has suggested to me that they're different. So we're—since the SNOMED clinical problem enumeration is such a core component of these recommendations, and very few clinical organizations have implemented SNOMED and even the maintenance of what constitutes clinical problems within SNOMED is—how do we phrase this?—a tad fuzzy in the United States. How do you see the reconciliation of the resolution of this, moving forward, as bearing upon SNOMED?

Jamie Ferguson – Kaiser Permanente – Executive Director

Well, I think that obviously, there's going to have to be a maintenance process for the specification of not just SNOMED but also the list of LOINC labs and RxNorm drugs and so forth. And I really thought that that was out of scope for our particular workgroup. But the current list that is an adopted standard is the list that is used by the Kaiser VA, but it's also used by the Food & Drug Administration for structured product labeling and other purposes. And my understanding is that NLM will be maintaining the—a problem list and that the HITSP—whether it's through HITSP or another mechanism, there will be an adopted standard for problem lists, and that's what we should be using. So in terms of the maintenance of it and the degree to which it—if it doesn't meet the needs of the code values that are identified by the Quality Workgroup for these particular measures, then it'll have to be updated for that purpose.

So I think it does raise the question of the maintenance process, certainly for the terminologies and their subsets. But, you know, there is a broader question about maintenance, actually, of all of the standards that we're recommending. But starting from the CHI work where SNOMED was first adopted, and through the HITSP and FDA use of that problem list subset, that's what we're keying off of. So I'm not disagreeing that it has to be maintained, but we selected what's there now.

John Halamka – Harvard Medical School – CIO

And so, the question is, given that we have this rather long, multiyear ramp-up, will we be able to achieve the clarity that you ask in these multiyears? I just received the NLM's problem list subset, because we're going to be an implementer and a tester at Beth Israel Deaconess over the next year. So certainly, I would be able to report back in 2010 how that is going and how it might actually reflect on a 2013 certification.

Now, Linda, I think your card fell, which I imply—I imagine meant [laugh] you had a comment.

Linda Dillman – Wal-Mart – VP of Benefits & Risk Management

Just a recommendation to the subgroup to go ahead and invite Betsy Humphreys from the National Library of Medicine to come and talk to you. You're referencing a number of things that are taking place in the Federal space. You know, I've done standards in a long—for a long time in the Federal space, and nobody has paid any attention. Now all of a sudden, it's quite—getting quite a bit of attention, and so there should be some fixes coming to some of the Federal activities that are taking place. And the more verbal you are and, significantly, the more we have providers doing that feedback with places like the National Library of Medicine, we'll be able to advance quite quickly. So keep those communication lines open.

John Halamka – Harvard Medical School – CIO

Okay, very good advice. Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This is a bit of a subject change, but as part of the deliberations on the subcommittee, you know, there is the column there that is sort of “What’s the feasibility and the timing appropriate for these?” And in that deliberation, the question that comes to my mind is sort of “What is the target we’re shooting for? Feasible for what percent of the population or for what percent of people who are implementing systems?”

And it’s not—it—this is really not a question as much as it is an—well, a question, I guess, not in the sense of—for the subcommittee, but a question for the—for policy or even maybe some insight into those who pass the legislation to say, “Was—is the intent that we should set feasibility, in that sense, at a level that we think 90 percent of the institutions would be able to benefit from the incentive or 75 percent or 50 per—?” You know, we’re sort of shooting for sort of an unknown target when we say whether this is feasible, because, you know, there’s such a spectrum of capability in the country that you could set the standard where, you know, leading institutions like Mayo and some other places would be able to meet almost any standard. And others, you know, that are basically not automated at all—you’re setting a standard that, you know, could—and so I’m asking, I guess, if there’s any direction that could be offered about whether we’re trying to shoot for 90 percent of people being able to achieve this if they work hard, or 75 percent, or 100 percent, or 50 percent. Is there any direction that you could give about how hard we’re trying to make this?

John Halamka – Harvard Medical School – CIO

Right. And I think, at our last meeting, there was the question to David Blumenthal, “Are you willing to place a number? Because it has been discussed previously that 70 percent of all hospitals and 90 percent of all doctors will have an electronic health record by 2014. Are those the number that we should use? And John, are you willing to make a comment on the 80/20 scale? Should we be shooting for 20 percent? Should we—or 80 percent?”

John Glaser – Partners HealthCare System – VP & CIO

I think the better part of valor would be to repeat David’s response at the last meeting, which is that there’s no number on the table that says we’re shooting for this, that, or the other. And I think there’s a judgment call, both here and in the Policy Committee, about what represents terrific progress but doesn’t, you know, using the escalator analogy, cause the vast majority of the field to say, “I’m not on this thing.” So I think with a—it’s a judgment call. The ideal—there would be a number, but there legislatively is not, and I think it’s a hard one to pick, even if you picked it to justify it—to say, “Here’s how we arrived at this number versus that number,” etc.

I think the other thing I was thinking—that goes back to one of Wes’s comments earlier on the certification. What I’m listening to—although there are standards directed specifically to an EHR versus the capabilities of an organization to a mass data and report—and so it’s not necessarily EHR centric; it is organizational centric versus standards that are more for the exchange between. So there’s really three categories at play simultaneously. We get them blurred from time to time.

And so, part of the question is, well, if we’re going to certify against an EHR, what exactly are we certifying here? Because we’ve got three categories that are going on. And do you roll them all into the EHR and say, “You, the vendor of an EHR or module in aggregate, have to do all of these things”? And I suspect, well, the reason that’s sort of relevant in this particular percentage conversation is, organizations may, in a modular sense, particularly larger ones, say, “From EHR, from my quality reporting apparatus,

and from my exchange apparatus, I can meet the standards even on translating a variety of ways along the way. But I have a modular approach to achieving what you all come up with here, even if my specific item, the EHR per se, doesn't pass all of it." I think you'd probably still have to think about having the EHR pass all of these things. For those organizations, that's what they've got. I mean, they won't have the larger apparatus; they will rely on a vendor to do all three categories here. But nonetheless, I think—but we'll—we don't have—longwinded way of saying, Stan, I don't think we have a percentage; we're not going to have a percentage. Use your judgment call. And I think we'll have to rely on the industry doing a lot of thinking and innovating about how best to go after that and finding ways that are clever—meet the legislative and criteria requirements but nonetheless do pretty well by and large across the board. So a longwinded way of saying we don't have a number for you.

John Halamka – Harvard Medical School – CIO

Right, and what we came up with in our taxonomy was highly mature—was—20 percent of the industry has deployed it. And ready for introduction was a 2; well-developed was a 3. So, in a sense, what we said was, "Gee, hey, 20 percent of the industry of the industry has already deployed it. It's at the tipping point. It's at the Gartner threshold, where the hockey stick will likely occur." And so, we have not, to this point, come up with a—oh, we think it's 80 percent achievable. We just think it's mature enough for introduction.

Okay, so we have several others. Let's go ahead with Doug.

Doug Fridsma – Arizona State University – Associate Professor

So one of the things that sort of occurs to me as I'm looking at the detailed example here is that there are seven capabilities, local codes, unstructured documents, ICD-9, and SNOMED for the percentage of diabetes. And one of the charges of the quality group is that we have to come up with value sets that will help define those quality metrics. So ICD-7 and the number of com—IC—not 7. There's five or six different kind of standards that might feed into this quality metric and a variety of different value sets associated with them. And some people might have RxNorm, or they might have NDC, or they might have SNOMED, or they might have, you know, ICD-9. And so, there's a whole number of different permutations that this particular standard sort of—that the Quality Group needs to sort of take a look at.

So when I look at that—and I'm not even sure exactly how to interpret local and proprietary codes. I don't know if that's something that then we would define as what that would be or if that would come from the local system. So I guess, operationally, as I'm looking at this and trying to figure out the impact that has on the Clinical Quality Group, it would seem to me that, at least, we need to identify a couple of these measures, and we need to kind of go and flesh them out in detail—not all of them necessarily right away, but at least one or two of them in detail to really just see what the impact of the Operations Group in terms of defining those data elements—how that's going to impact the quality metrics and the number of possible equations that we have to define, both in terms of numerator and denominator to support those standards.

John Halamka – Harvard Medical School – CIO

Let me just ask, Floyd, do you want to make a comment on that?

Floyd Eisenberg – NQF – Senior VP of HIT

[Inaudible] comment on that. Anna, you're on that workgroup. When I saw the local codes and the free text pretty much, my assumption was, the value sets that we come up with for those measures will be—we would expect that someone locally is going to use some analysis to take the free text or to map the local codes to the value sets provided, rather than expecting that we would be able to provide some value set based on all local codes, as an example. But—and I also—I think we—I discussed with Jamie earlier that we wouldn't necessarily—if we came up, say, with the SNOMED value set, we would expect locally

that could be mapped to ICD-9 and use their local ICD-9 codes in order to do the appropriate reporting. Is that in agreement with where you are in the Operations Group, Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director

Well, our thinking was that where we specify it as an example—ICD-9 as an alternative to SNOMED, we were hoping that the Quality Workgroup would define the specific ICD-9 value—you know, code values that would be used for calculation of the measure and not leave it up to local implementation.

Floyd Eisenberg – NQF – Senior VP of HIT

And I'll add to that, for retooling, we would expect to do that. My—the caveat is for those that have been retooled under the HITSP work effort, like the Stroke 3—they have been retooled with SNOMED, so that would take extra effort to add the ICD-9 list.

John Halamka – Harvard Medical School – CIO

Right, and so, just to reflect on this, I think what's being said is very reasonable. For certain kinds of data exchanges, for clinical care coordination, I think we understand structured and unstructured makes complete sense, recognizing that decision support will be better if it's structured, but, hey, it's human readable; unstructured's okay. For quality reporting, maybe we can't be quite as loose as saying, "Oh, any local code set could be used, because then there's not a code set that can cleanly map to it"—that we may need to get a little bit more restrictive saying, "Hey, in 2011, we recognize if it's a problem... well, diagnosis is a proxy for a problem list; ICD-9 is acceptable. If it's a med, well, we know RxNorm—not widely deployed. We will accept NDC as an alternative." So then there's this finite amount of code sets that you would have to provide.

Jamie Ferguson – Kaiser Permanente – Executive Director

And I just want to emphasize that I think there's a lot of value in actually taking these and driving them down and taking a look at one or two of these as examples, because I think, in that process, we're going to learn an awful lot about even interaction between the standards that we construct. It could be the combination of ICD-9 and NDC, you know—I'm making this up, but it's better than SNOMED and RxNorm or whatever, you know, because we're able to better identify certain aspects because of the way in which those coding systems work in terms of identifying numerator and denominator. But I really think that we need to do that. We will learn a lot in that process about informing the rest of the work that goes forward.

John Halamka – Harvard Medical School – CIO

Right, so—next call of the Clinical Quality Group and Clinical Operations. Maybe we want to consider a joint call in that regard.

Floyd Eisenberg – NQF – Senior VP of HIT

One more comment on that, and that is that, in the process of doing that, we need to do it with the developer of the original measure, because often there are concepts that aren't necessarily written in the specification that led to the choice of the set of values that they're using. That's the experience we've had, and we can show some examples from what's been done in the HITSP effort for the inpatient measures so far—that you can read a paragraph of what they're looking for, but there's some nuances to it that only the developer—the measurer knows in order to come out with that result, so we'd have them at the table as well.

John Halamka – Harvard Medical School – CIO

Very good. Nancy?

Nancy Orvis – DoD – Chief of Health Affairs

Hi, John. This is Nancy Orvis from DoD. In this discussion and having—you know, as this committee starts to mature—I mean, it ha—in its meetings, I'd like to ask if we could clarify what role this committee has in identifying standards that need to be evergreened or that need to be fleshed out in more detail as soon as possible to meet 2013 or whatever. What do we do about where we see gaps? We know that HITSP has some roles in there, but there's some broader perspectives that we're already dealing with and HITSP hasn't done with. And I would also say, as an example—is for organizations, as we try to implement ICD-10, this discussion is the detail granular concepts of SNOMED CT, which for quality—which is probably the right direction, because there's specific context to use it. And how do you map that up to a coarser categorization of ICD, which has been a big problem, because it's very difficult to go from ICD level down to the SNOMED?

John Halamka – Harvard Medical School – CIO

Right.

Nancy Orvis – DoD – Chief of Health Affairs

We've proved that in the NIM demonstrations and internally. Our organization had to call in a group of people and say, "Well, what do you think this problem is [laugh], you know, in SNOMED CT terms versus, you know, what it would be in ICD?" I think one of the—many organizations use extender codes for the ICD-9 today [inaudible]—you know, like unique extender codes. And I think many organizations are trying to grapple with "Are we going to have to do the same thing with ICD-10, or is there better granularity in those categorizations—ICD-10, or should we use SNOMED CT?"

I think it's—these quality measures and those issues will be—if we could give some guidance in that area, that would help quite a few people. I know my clinical analytic staff is struggling right now. How are we going to collect this data for these quality measures? Well, we'll probably just have to add more extender codes to ICD-10 in the future. And I think we could very well help organizations—say, "We recommend that you do this in the SNOMED CT context and/or do this in there," because it's very expensive to think of continuing organizational unique extender codes in the ICD environment, because if you've tried to buy a CAHPS product and you want to continue that and then you know that every year you're going to have to continue to do organizational modifications, you're looking at a grim process. I—from experience.

So my two questions are, what role do we have in helping identify gaps and where there should be rapid evergreening? And what—and second, what do we do about maybe helping codify, should organizations look at the ICD and SNOMED CT relationship for documenting?

John Halamka – Harvard Medical School – CIO

Sure. So in the org chart that we were given from ONC that shows the interrelationship of all of these various groups—that the HIT Standards Committee certainly identifies gaps—can consult with HITSP and other SDOs as is necessary to gain implementation guides and harmonize standards. Presumably, too, we would work directly back with ONC, and ONC could commission standards to be harmonized or created as necessary.

Nancy Orvis – DoD – Chief of Health Affairs

Or create these value sets, I think, which is, I think—you're going to be testing these 6,000 problems in the problem list, and I think that's a very cogent problem, right?

John Halamka – Harvard Medical School – CIO

So I think the answer is, it's up to us to identify gaps, work closely with ONC, and together figure out how best to apportion them to be closed.

Jamie Ferguson – Kaiser Permanente – Executive Director

Also, just, Nancy, to reflect back on your questions about gaps and evergreen standards, part of our recommendation is, in fact, to ask ONC for guidance on how to deal with gaps. What's the process for dealing with gaps, and how should that be addressed? What I've heard in a couple of different comments here so far, Chris's and others', were about "How do standards get maintained? How do specifications get expanded for additional measures?" And I think that relates directly to this and should be, in my view, a recommendation that we make as a committee—is, again, probably to ONC to request guidance on how to deal with the need for standards maintenance, which—I would call that all different aspects of standards maintenance.

Nancy Orvis – DoD – Chief of Health Affairs

And it's a multitiered effort, because not only do you have to add to the content of the standard; you then have to then continue to maintain the specifications and the updates—the specifications for the use of that content. So yes, that would be—thanks.

John Halamka – Harvard Medical School – CIO

Anne.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Thank you. Anne Castro. I cannot emphasize enough the slippery slope of proprietary coding to be involved in any of what we're doing. Because of the fact that we're relying on this to grow in the future, we need standard coding—officially recognized coding with an official maintenance process with a regularly expected release schedule so that we don't end up having every implementation of our EMRs or EHRs into a physician's office take 8 months because of the proprietary coding that has to be installed. That is—I cannot emphasize enough—strongly enough—to where I wouldn't approve with the wording of "proprietary coding" in the clinical operations. We have really got to stay with standard coding, whatever standard ones exist, and then work with whatever entity maintains them.

John Halamka – Harvard Medical School – CIO

So what you're suggesting, is the ICD-9, the NDC's 2011, migrating to RxNorm and SNOMED in 2013.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Exactly.

Jamie Ferguson – Kaiser Permanente – Executive Director

Yeah, and to the extent that our recommendations do specify flexibility in allowing for use of local and proprietary coding for 2011, I think that's a recognition based on our discussions that it just not—it's not feasible for a widespread implementation of all of these standards by 2011 in that time frame and that—so those who can get there, we certainly want to encourage and not penalize. But at the same time, for calculation of the measures, not everyone can get to all of the standards in that time frame.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

I respectfully, totally disagree. It is a slippery slope that will not recover after the 2011. If we can't meet the requirement, then we should back off on the quality standard that we're trying to measure if we didn't have a coding structure to support it.

I have a question on the aside. I think I've made that point; I can move on. I need to understand the incentive process. There's two different incentives as I know of. One is for you to get financial support to install an EHR, and the other is Medicare payments being less or more, depending on if you have one. Is

the meaningful use tied to both of them? Do you have to have an EHR that's certified for meaningful use in order to gain the payment incentive down the road? And I ask this because of a comment that you made earlier, and that was that hospitals can have anything out there. There are providers or doctors who will not participate in a certified EHR. But if they were able to somehow pull the data together by whatever means they could, do they then qualify without a certified EHR for the incentive payments?

Jamie Ferguson – Kaiser Permanente – Executive Director

Sure. And so, this is really—

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

That helps me understand how the two are tied.

Jamie Ferguson – Kaiser Permanente – Executive Director

And so, I'll defer to ONC a bit on this one, but there's Medicare and Medicaid incentives. Neither—the Medicare incentives do not fund you to go out and buy an HER; they are paying you starting in 2011 for the meaningful use of an HER. And a meaningful use of an HER, obviously, is a set of functional—

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Has a standard certification.

Jamie Ferguson – Kaiser Permanente – Executive Director

—a set of functional criteria, but the definition of what a certified EHR is is evolving. So what we could say is, certainly we have seen, in the latest meaningful use iteration, you must have 10 percent of your transactions in a hospital entered through an electronic ordering system. Whether that is a self-built ordering system or whether it is a commercial product, at the moment, I don't think, has been specified. So, I mean, just to clarify, to my knowledge, there aren't any incentives to acquire an EHR other than that Medicaid, I believe, does allow some early acceleration of some of the funds if you have greater than 30 percent Medicaid patients that might assist with the acquisition of such systems.

Jonathan Perlin – HCA – CMO & President

I want to be sure that we don't overstep our purview. I think your questions are good. And I'm going to take your questions in the spirit of trying to understand the relationship to the specifications, which is, I believe, your intent.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

That's where I'm coming from.

Jonathan Perlin – HCA – CMO & President

And—but it's clear from your comments there's still ambiguity hovering over the last discussion. So let's parse that into a couple pieces. Okay, from the last discussion, I think—recognize that there is no singular system, at least that I'm aware of, that would answer all the different utilities. It also—it appears to be that there is envisioned a certification process that is evolving that will define certain components that are going to be fundamental. I think the final policy and rulemaking through HHS will define that relationship between the certified piece and the meaningful use piece. I think we would be overstepping, and I'll defer to Jodi Daniels for any elaboration. Is that a fair working approach at this juncture?

Jodi Daniel – Office of Policy & Research – Director

Yes.

Jonathan Perlin – HCA – CMO & President

Okay. So let me step out of my role as Chair and say, “How am I approaching this?” My interpretation of what would seem logical is that a certified EHR would be a very core piece, and there would be certain actions like provider order entry that would be a component of that. For the quality reporting, it’s likely, as Wes brought up, that many of those systems, however wonderfully functional they are in terms of that utility—many of the quality measures are derivative of data that are entered from a variety of sources—for example, order entry, plus the pharmacy system or a lab system. And the conjunction of data necessary to some sort of derivative calculation, thus coming from those other systems, may live in a data repository. That piece may not. So that’s at least how, not as Chair, just as an individual, I’m thinking about this relationship and looking forward as well to that policy. And [inaudible]—

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

That was helpful. Thank you.

Jonathan Perlin – HCA – CMO & President

So I also want to be a little bit cognizant of time. I want to make sure—there’s been extraordinary work done by privacy and security. And I think these conversations are also incredibly helpful, because if we’re not clear on these points—and so, I really appreciate you bringing it out; I don’t think that anyone else likely is either—so I appreciate that piece. John, let me turn it back to you, and [inaudible]—

Unidentified Woman

[Inaudible] anomaly [laugh].

John Halamka – Harvard Medical School – CIO

Wes, please.

Wes Rishel – Gartner – VP & Distinguished Analyst

As far as standard codes, I want to quote my favorite philosopher, Mama Gump, who I think said, “Clinical standards is as clinical standards does.” Isn’t that what she said? And what I mean by that is that the whole issue of standard coding has come a long way over the last few years. We’ve gone from not—being afraid we couldn’t afford the code sets we had in some cases; having code sets that were so big, it was hard to say how to use them; to applications where people are now talking about identifying standard subsets of code sets. We’ve figured out how to pay for SNOMED, but people are identifying standard subsets of code sets.

There is no doubt in my mind that somebody starting anew would prefer to go with standard code sets rather than try to make all that stuff up again. Even though it’s not trivial, you still have a lot of work to do. But it wasn’t there before, and we have our most astute use of IT in—being done by places that had to improvise along the way. So I have been thinking about “How do you deal with that, and how you deal with all of the other stuff I think about?”

It strikes me that we really are talking about three kinds of interoperability and one kind of intra-operability here, okay. We’re talking about the interoperability that is conveying to hospitals and physicians what we mean by a clinical standard—that is, the reverse direction. And we’re—there has been a lot of work done to—both in HITSP and other committees and in this particular workgroup to nail down what we mean by that. Some of the research in this workgroup was to look at what other standards were out in use in order to inform what could be used to express quality standards. Can you really state in terms of ICD-10 now, ICD-9 now—things like that, just to give the unambiguous, or as unambiguous as possible, explanation of what you mean by a quality measure?

There's the interoperability of sending data about quality out, either to a registry or to a quality organization. There we have more work to do. And there are measures for meaningful use that are more about just getting the information from one physician to another to support a transition in care regardless of how well a computer can deal with it. We don't actually have a lot of studies, I think, that show that that's useful. Certainly we know it's useful in the ED environment. We expect it's—the lack of information, we see, is killing people going into nursing homes and all kinds of things.

But I wouldn't want to do anything towards measuring quality that got in the way of enabling that easy stuff as a step on the escalator—as a position on the escalator. And if that means I'm anti-code, I'll go fight Mama Gump.

The—I was interested in Capability 120 in your document, which, in effect, says, you know, for now at least—I mean, the way it's used—would say, for now at least, you can send it as text or a PDF. What it doesn't say, which I would like to give feedback—should be considered, is if you can send it as an image of a document. There are a number of EHRs now that have some scanned documents, some structured data in them. It seems like being able to access that information that's in scanned data, at least for a while, makes a lot of sense.

Jamie Ferguson – Kaiser Permanente – Executive Director

And that's also in Capability 120.

Wes Rishel – Gartner – VP & Distinguished Analyst

It just doesn't say it in the document, then. Okay.

Jamie Ferguson – Kaiser Permanente – Executive Director

So I think you have to go to the next level of detail, which is the thicker document—

Wes Rishel – Gartner – VP & Distinguished Analyst

Oh, there's a thicker document.

Jamie Ferguson – Kaiser Permanente – Executive Director

—[inaudible] posted.

Wes Rishel – Gartner – VP & Distinguished Analyst

Okay.

Jonathan Perlin – HCA – CMO & President

So let me summarize all of this very good discussion. I think there's some elements of confusion between those standards that are used for the continuity and coordination of care—those that are used for the transmission of quality measures at a detailed level or quality measures at a numerator and denominator level. There's some concern about the flexibility for proprietary and local codes, and we've heard arguments pro and con. You know, one argument said, "At least state ICD-9, NDC—something basic for 2011, and then march up from there." The other is, "My God, huge innovation has happened with proprietary code sets, and it's worked in the past. How do we actually figure out how to leverage that? Maybe it's good for care coordination, but it's hard for quality, and so what do we do? Do we defer the quality measure?"

It seems to me—and I want to get the consensus of the group here—that based on all the comments that we've heard, there needs to be some revision done to this work so that it's a little bit more clear to all of our stakeholders. And, you know, again—sort of would ask a point of order from the ONC folks. If what

we wanted to do was digest all of this and revise this and bring it back at the next meeting incorporating all of these comments, how might we do that? Do we do an interim acceptance pending the revisions? Do we say we'll table it until the next meeting and we'll bring the revisions back? What has been done in the past?

Judy Sparrow – ONC – Executive Director

Yeah, that's a good question. What the Policy Committee did when they wanted to go back on meaningful use is, they tabled it and came back. Our timing is such that—you know, that it's going to be challenging, because we—in order to get final regulations written and published by December, we're—you know, we're kind of starting to get our heads down and trying to get our heads around this, or we won't make our deadline. So I would say, if there's anything that you're comfortable with forwarding on in the interim, that would be helpful. You know, obviously, if you want to think more about it, that's your decision, and we would be happy to hear your kind of more refined thoughts on—you know, on these recommendations, so...

Jamie Ferguson – Kaiser Permanente – Executive Director

Great. Jon?

Jonathan Perlin – HCA – CMO & President

Let's just think about the work that's been done? I think—again, a terrific and very illuminating discussion. It's interesting, because I'm not hearing a lot of objection to the sort of granular data standards. Where I'm hearing concern is the application of the data standards—some of the derivative uses, especially as they reply—apply to complex determinations of performance.

And so, I wonder if there's a way to parse this into two pieces. One is to ratify the standards, but also—but set for ourselves, as an agenda item, ongoing discussion on that relationship to the use of the standards for the quality measures. And just with one sort of asterisk out there—is that the performance level for any of the metrics, which won't be set by us, may ultimately resolve the issue of when things are ready for adoption.

And again, I believe the entire thrust of this effort is to help make people succeed. So I start with a very—with a frame that all this is coming together. It's really in the interest of propelling the health IT. And so, whatever the performance levels, whatever the different pieces, they're not meant to be barriers; they're really—I think this is where the privacy and security has done such an incredible contribution: It's all framed as elements of support.

So here's my suggestion: that we—if the group feels ready to adopt the granular elements of the data standards in a general sense; come back to the use of the data standards for the derivative functions, particularly with quality reporting; and recognize, thirdly, that whatever the outcome of that second piece—is ultimately going to be calibrated to performance levels that are identified elsewhere. Does that sound like a proposition given, you know, essentially what we set out to do and the timetable that's really been our framing?

Unidentified Man

I'm going to try to make very specific recommendations to say that we agree as a group that the continuity of care document is an appropriate means of sending a summary from place-to-place for care coordination, that we have as a goal to use RxNorm and LOINC and SNOMED as the vocabulary, and that we do some additional work to describe the path to get to there. Is that what you're suggesting?

Unidentified Man

If I can just point out, I think that's actually what we have in our recommendations—is exactly what you're saying. And so, I think what you're suggesting is, in fact, that the recommendations would be adopted as they stand, but that we would have to come back and review the application of the recommended standards to quality reporting and transmission of quality data.

Jonathan Perlin – HCA – CMO & President

The Chair accepts that as a motion. I heard a second [laugh]. Let me ask, is there anyone who has strong concerns about that as an approach? I see a lot of heads nodding positively.

Marc Overhage – Regenstrief Institute – Director

I—this is Marc. I have a strong concern, because I don't think the CCD reaches our Level 1—or Category 1 standards requirement.

Jonathan Perlin – HCA – CMO & President

All right, and so, Marc, your concern is that the notion of using CCD for care coordination data exchange in 2011 would be a concern?

Marc Overhage – Regenstrief Institute – Director

Yes, to the extent that we've said, you know, Category 1 standards are those that are at that, you know, adoptable level. I think it's pretty hard to make the argument it's there.

Jonathan Perlin – HCA – CMO & President

Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director

And just to point out—our recommendation is that that would be a 2013 requirement and that in 2011, unstructured documents, including free text and PDF, also could be—and images of documents also could be used.

Jonathan Perlin – HCA – CMO & President

And so, Marc, with the understanding that this Capability 120, which offers the unstructured option, which could be text, PDF, image—conceivably could also be—I mean, Jamie, let's just ask—HL7 2.X OBR, which is a text transmission of an observation; or CCD in 2011, with then CCD in 2013. Marc, would that meet your criteria?

Marc Overhage – Regenstrief Institute – Director

I think that's at least conceivable [laugh].

Jamie Ferguson – Kaiser Permanente – Executive Director

Okay. So then what we have is the motion on the table with—that has been seconded—of adopting these standards and recognizing that, as they articulate with the quality measures, there will be qualification made.

Jonathan Perlin – HCA – CMO & President

Let me, then, call the question again, and that would [inaudible]—that your points, Marc, were noted. There was, I think, a lot of—a consensus with the trajectory of the discussion following. And with that, are we in agreement?

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

I still have my issue with proprietary coding, because I don't know how it relates to you—

Jonathan Perlin – HCA – CMO & President

And let's make that sure that that's noted in the record of the meeting.

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

Right, and I understand the majority.

Jonathan Perlin – HCA – CMO & President

Okay. Good. Any others?

Jodi Daniel – Office of Policy & Research – Director

Can I just ask—

Jonathan Perlin – HCA – CMO & President

Jodi.

Jodi Daniel – Office of Policy & Research – Director

I just want to, for clarification purposes—so does this—does what you're saying mean that the table that we have, where it says "Recommendations for definitive 2011 implementation," is basically those that are recommendations that we're talking about, correct?

Jamie Ferguson – Kaiser Permanente – Executive Director

Right. Our recommendations are the 2011 and 2013.

Jodi Daniel – Office of Policy & Research – Director

And 2013, okay.

Jamie Ferguson – Kaiser Permanente – Executive Director

Right.

Jonathan Perlin – HCA – CMO & President

Thanks.

Jodi Daniel – Office of Policy & Research – Director

That are in the attached table.

Jamie Ferguson – Kaiser Permanente – Executive Director

That are in the attached table. Right.

Jodi Daniel – Office of Policy & Research – Director

Okay. Thank you for that.

Jonathan Perlin – HCA – CMO & President

And we will work diligently over the next month to clean up language to incorporate clarification of the discussion.

Jamie Ferguson – Kaiser Permanente – Executive Director

And just, I guess, a friendly amendment to the motion is, we're also recommending that we continue to finish up—clean up the last couple of measures that we didn't get to and see if these standards can also be used for that purpose in the same way. And then we're also recommending that ONC determine the process for filling the gaps.

Jonathan Perlin – HCA – CMO & President

Okay, with that... [Pause]

Wes Rishel – Gartner – VP & Distinguished Analyst

I look at—the question was whether we’re approving the PowerPoint or the matrix. If we’re approving the matrix, I see a line here that says—hard to tell, because you’ve got read the page before—“percentage of all”—this is page 7, okay—“percentage of all medications entered into EHR as generic when the generic options exist in the relevant drug class.” Okay. Then I see “recommended for definitive 2011 implementation, C32 continuity of care document, *and*” a number of other things—doesn’t say “or.” I don’t even know what this column means. I mean, does it mean that the EHR has to do all of these things? I just don’t know how these—how this applies to that measure. I mean, if I understood—if it was informing the discussion on whether the measure was feasible, I understood that, okay. If it is implying that there’s a requirement to either certify or use these standards to achieve meaningful use, (1) it seems to contradict the statement that C32 isn’t required in 2011, and (2) I don’t—I’m having a hard time—you know, I don’t know that RxNorm is available in 2011.

Jonathan Perlin – HCA – CMO & President

Right, so let me clarify this, because it’s the “and” that’s confusing you. It’s saying that—“*and* the unstructured documents may be used, *and* a local or proprietary code set may be used.” So I think it’s the wording that’s confusing you. RxNorm is not required until 2013. Structured documents aren’t required to 2013. It’s the fact that the exceptions are added to the end of this list that is confusing.

Jamie Ferguson – Kaiser Permanente – Executive Director

Right, so the way the wording also is developed is that the “and” says that, in the specification of the measure that will be done by the—overseen by the Quality Workgroup, they will use the standards that are referenced here in the “and” statements. Perhaps it would be clearer if—and we did go back and forth; it has been suggested that these should all be “ors.” So I’m not—if we want to consider these all as “ors,” that is a—

Wes Rishel – Gartner – VP & Distinguished Analyst

I wonder if the original mover who didn’t know he was making a motion at the time—would tell the Chair, “Accept it as a motion”—would consider a friendly amendment that the substance of the documents are available—be available for ONC staff to use, but that there be a revised publication that clarifies these issues. I think it’s easy enough to explain it to staff; it’s really hard to explain it to people who aren’t here today and who are going to pick these up and—

Jonathan Perlin – HCA – CMO & President

Right, I think it’s very fair. Floyd?

Floyd Eisenberg – NQF – Senior VP of HIT

I just wanted to be clear that I don’t think we’re going to see the Quality Workgroup come out with a list of proprietary local codes that could be used with the measures or how to determine something out of a PDF. So when we develop any of our value sets, they might be ICD-9 and SNOMED, but they’re not going to be using local codes. That wouldn’t be feasible.

Jonathan Perlin – HCA – CMO & President

Right, okay.

Floyd Eisenberg – NQF – Senior VP of HIT

It’s just the “ands”: the way that was worded makes it seem as if that could happen.

Unidentified Man

Right. So I think in—the spirit of what we’re getting at is contained in the PowerPoints. The wording that is in the matrix with the “ands”—confusing, the understanding being that C32 would be used to coordinate care and, in 2011, a PDF or unstructured text format might be used for the coordination of care for recognizing you’re coming up with value sets—ICD-9, NDC, RxNorm, SNOMED—structured values will be used. And we’ll continue to work on the refinement of the mapping of the standards to the quality transmission.

Very good. Well, I know we are behind time, and we want to give time to Dixie. But I also am guessing that there are some biology breaks that may need to take place. Chair, Mr. Chairman?

Jonathan Perlin – HCA – CMO & President

I want to recommend a 5-minute break, and then—but let’s convene right at 5 minutes, understanding—appreciate the very good discussion. So I just want to recap the bidding on this: that the general matrix concepts at the granular data element accepted the work to come back in terms of the use—the derivative uses for quality—that this discussion will be captured; points made by Wes, by Anne, and others actually interpreted; and ONC staff will work with John and Jamie to capture that in an iterated and revised document, but that we have directionality. So appreciate that and...

Jamie Ferguson – Kaiser Permanente – Executive Director HIT

So basically, the—as I understand it, the recommendations are approved, but we have to go and revise our documentation to clarify the points that Wes and others have made here, right? Okay.

Jonathan Perlin – HCA – CMO & President

Okay. We stand adjourn for 5 minutes. Let’s reconvene shortly. Thanks. [Break]

Jonathan Perlin – HCA – CMO & President

Okay. Thank you all for sticking to a tight schedule on break, and again, appreciate the dialog. That was an interesting discussion, and obviously a lot of issues that require continuing work—and so, just please understand that the commitment is that the Clinical Operations Workgroup will be addressing all of those issues that were identified for further work. And then, obviously, they’ll have an interface with the Clinical Quality Workgroup, and I think the sense of the group about the uses of the standards in particular situations was very clearly expressed. So I appreciate that discussion.

Someone left me a note here, and honestly I cannot read it, so [laugh] I think it’s apocryphal.

Unidentified Man

“The Microsoft rep has requested she can make a public comment.” I’m a doctor; I can read this stuff [laugh].

Jonathan Perlin – HCA – CMO & President

I just thought it was just wonderful demonstration—object lesson for the importance of electronic health records in the transmission of information. So sorry to whomever’s handwriting that was. Thanks very much. And we will, of course, move to public comment after the next session. So let me turn back to you, John, to moderate this final piece of the workgroup.

John Halamka – Harvard Medical School – CIO

Very good. Well, so Dixie and Steve will present the standards for security and privacy, as well as give some insight into their impact on the consumer. Why will all of this make lives better for us as patients? Dixie.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

I'm actually going to be the brief warm-up act to Dixie. And in the interest of time, I'll take less time than we planned on the consumer part. We wanted to put a little bit of this in context. First I want to thank the members of the workgroup—the active members who were on two, three, four, five calls over the last couple of weeks—and especially thank Dixie, who was fearless and tireless and did an enormous amount of this work on her own, late at night and on airplanes and all that sort of thing, as she was shuffling around the country. So we owe her a deep debt of gratitude.

We wanted to do—establish a little bit of context here, just a few minutes before Dixie dives into the technicalities. One is, we're obviously seeing lots of polling and surveys in the last months on health care reform, some in response to the proposals that have emerged in Congress—negativity appearing in some of those. This is just—orients us to a survey that was released last week, which reminds us of the dissatisfaction with our health care system.

And move to the next one on the subject that we're addressing today in the context of the discussions. This was part of the same survey, again, released last week. Very sobering for all of us, the basic finding here is—and this is consistent with other surveys we've seen—this one finds that 68 percent in 2009 were not at all—this is a survey of the public, obviously, not vendors or doctors or anything—68 percent in 2009 were not at all confident that their EHRs will be secure and protect their privacy. Only 12 percent were confident they'd be secure. And particularly note the jump, sobering for all of us, in—from 2008 to 2009, from 38 percent to 51 percent of 1,000 people who responded to this saying they're not at all confident that their electronic health records would be secure. On to the next slide.

So just a reminder, really, as we dive in before Dixie dives in, that we are living in a world that's unacceptable, both in terms of our health system and in terms of the paper-based and faxed-based system we have. We need to move to a system that is going to solve that problem. I think I feel confident that the work that Dixie has done and this committee has done—this workgroup is going to move us to a better place in terms of security and privacy.

I would make an addition to the points that are made here—the—you can read them; I won't read them in the interest of time—that I think we'll be better-enabled, because electronic health records that are protected will be—enable consumers to participate in decisions about their care and improve their doctor-patient relationship. Next slide.

Well, as we all know, the use of computers and networks introduce new risk to personal privacy. I won't belabor the points here again. The main three reasons, from a consumer and patient perspective, that we need to do this are listed there. And again, I won't read them.

On a personal note, I have learned a lot—participating on this workgroup. It's been a very interesting series of discussions, much like the one that we had just half an hour ago or so. I still don't—won't claim to know the difference between IHEs, OASIS, HL7, LOINC, and SNOMED, but at John's tutelage and others on the committee, I'm sort of getting there.

My big plea—and I've made this to our group—is that we have to pay attention to communicating this stuff to folks beyond our realm. I make a commitment to do that as best I can, but we all really should. So turning to Dixie for the technicalities. Thanks.

Dixie Baker – Science Applications International Corporation – CTO

Okay. To encourage the broad adoption of EHR, the stimulus bill, ARRA, offers reimbursement to eligible providers who meet two different but complementary requirements. First of all, they have to acquire a certified EHR product or service; and secondly, they have to demonstrate that he or she is using that product or service meaningfully.

So the Standards Committee, all of us here, need to recommend both criteria for certifying products and criteria for demonstrating that an applicant is using that product meaningfully. I think we too often get those two confused and think we're simultaneously certifying both a product and its use, and they really are two separate steps and, in fact, two separate sets of criteria.

For privacy and security in particular, certification that a defined function or service meets a—certification criteria is not sufficient to demonstrate that it's being used meaningfully or even that it's being used at all. In particular, for example—let me give you an example: I'm certain that the certification criteria for EHR products undoubtedly will include a requirement for an audit capability—the ability to record auditable actions. But it's—as anybody who has ever worked on a system knows, you can turn off auditing.

A second example is encryption. You know, you may—I'm sure that these products will be capable of encrypting information. But if the EHR is used within the health informa—a hospital that's physically protected, you know, in all likelihood, you probably won't need to use the encryption. But if you host that system on a laptop that you carry around the community, you probably will. So it's important that we keep—that the Security and Privacy Workgroup specify both of these types of criteria.

So we've adopted an approach that addresses both the certification of products and the demonstration that the—that a user is using the certified product meaningfully. And in these two slides, I show you the approach that we used. We started with the ARRA priority areas of focus, the ARRA 8. There are eight priority areas of focus that are identified in the law. And we extracted those—identified those that are particularly relevant and—to security and privacy and that security and privacy can speak to. Then we looked at the HITSP constructs and the ref—and the standards that are referenced in the HITSP constructs, and the standards that are referenced in the standards that are referenced in the HITSP construct. And we identified standards, and we identified gaps. So ultimately, out of this, we will have services that are required, certification criteria, the standards that are required; and then, if a product meets all those certification criteria, it is certified.

Now, moving on to the meaningful use, we anticipate identifying a subset of those requirements for product that would be—are absolutely required for use or may be required for use in the following set of circumstances. And then that will become part of the meaningful use criteria, along with security IT infrastructure that's required and secure operations. For example, we want to make sure that the risk assessment that's required by the HIPAA law and the security standard—the security rule are—is current and up to date and that the risk management approach is current and up to date, as well as the current contingency plan, because as we pointed out—Steve pointed out in the introductory remarks, security does more than protect confidential information. It's equally important to protecting the integrity of data and the availability of services and critical information at the point of care. So we want to make sure that the contingency plan that specifies the backup and recovery of information, the continuity of operations plan, and emergency operations plan are all current. And all of these are really important to assuring that that product can be used in a meaningful way. Okay.

So using this approach, we—the following two slides, I think, identify the eight ARRA priority areas of focus. The first one is technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive, individually identifiable health information. In order to—now, this one particular area of focus is very specifically security. And some of the later ones—or one of the later ones that are very relevant to security is not as straightforward. So this area of focus requires just about every privacy and security service out there. It requires identity management, which is assuring that a person, when they're given an account on a system, is who they claim to be, so that's a process as well as technology. User entity authentication—once you know the identity of the individual, they have to provide—or an entity, they have to provide proof that they are who they claim they are. Identity and role-based access control—access control itself as a service determines what resources an entity or user can access as well as what actions they can perform with that resource.

So there are basically three types of access control. One is identity-based, which is—says that Dixie Baker can access this resource. Role-based says that the administrator of this system can perform the following operations. So identity- and role-based access control—one of those two—or both of those two are present in most systems today, even on your desktop system. The label-based access control is a type of access control where the access is based not on the identity of the user but on a clearance that that user has been given. They are clear to see top-secret information and then matching the clearance that that user has with the sensitivity label that is associated with the resource they're attempting to access. Now, of course, this—that label-based access control really came out of the Department of Defense and the intelligence community, but it's also being used in other industries now. So that's a third kind of access control.

Consent management has to do with consumers consent, and consent is sort of a loaded word because that includes both my authorizations to use or look at my private information, but it also has to do with informed consent on what actions I've given my consent to happen, you know, what procedures can be performed, what research databases my name can be in, and even what clinical trials I might participate in. So managing all of those types of consent is another requirement here.

Transmission integrity is really important to safety, to patient safety. You know, a good example is if you look at me. If somebody modifies my weight in my health record and makes it 180 instead of 80, I could die from that modification in my health record. So the integrity of data is very, very important. Then, finally, the transmission of confidentiality protection—so the protection of confidential information when it's transmitted.

You see in the right-hand column, whether the HITSP standards address these security and privacy services. You can see that they do not address label based access control, and I do want to caveat that because the priority area of focus mentions the segmentation of information. And, to me, segmentation means label based access control. It means segmenting the highly sensitive information, information that's traditionally been known as deniable information like HIV/AIDS, STDs, that kind of information. But actually, it's up to the Policy Committee to really make that – set forth that definition, which they haven't done yet.

Consent management, I'm going to talk a bit more about later. It's partially addressed because consent management is a really complex challenge, and there are standards that are in HITSP that address part of the problem, but we don't think it's addressed in total.

The second area of focus is a nationwide health information technology infrastructure for the electronic use and exchange of electronic health records. So this requires a secure communications channel, one that protects both the integrity of the data, as well as the sensitivity of information, and secure e-mail, and both of those are addressed in HITSP standards. We expect this one, as we move forward and get into the era of HIEs, in later years we will identify more security services associated with that.

The third one is EHR certification. And of course, all of these security services address certification.

Technologies that, as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity; so this requires auditing, auditing of actions on an individual system is what auditing refers to, but auditing is certainly not the total picture. To capture an accurate audit record you have to have a consistent time source, especially if you're auditing across multiple systems or between systems, as an enterprise traceability. Inner enterprise traceability is my term for what ARRA requires, which is the accounting of all disclosures, so as information passes from entity to entity we need to maintain a traceability of what happens to it and who accesses it.

Finally, nonrepudiation: Non-repudiations are measures that prevent someone from denying having taken some action. The most commonly used technology in this arena is the digital signature, but there are others as well.

Three of the four of those are addressed by the HITSP standards. The inner-enterprise traceability is not beyond auditing.

The use of certified electronic health records to improve the quality of healthcare, that's number five. Security is often equated as a privacy mechanism, but in truth it's absolutely essential for assuring the quality of healthcare in that it protects the integrity of information and it provides assurances that information and services will be available when they're needed. The HITSP standards address integrity protection, transmission integrity protection and non-repudiation, all three of those. Service availability, the HIPAA standards address service availability, but it's not clear how we will ultimately define that one.

The sixth one is technologies that allow individually identifiable health information to be rendered unusable, unreadable or undecipherable to an authorized individual. This requires that transmissions be protected or encrypted. It also requires de-identification, anonymization or pseudonymization. These are three approaches that are used, particularly the last two are used in public health. De-identification is clearly defined in the privacy rule, exactly what 18 elements one needs to remove to render information de-identified. Anonymization and pseudonymization are, as I say, methods that are used. They don't fully de-identify information, but anonymization takes the obvious identifiers out. Pseudonymization inserts a link so that the data can be re-identified at a later time if it's necessary.

Finally, the limited dataset, which is anonymized and then it's also of the minimal data set as well. As far as HITSP standards, HITSP addresses the transmission confidentiality, de-identification and anonymization, but pseudonymization is partially; the partial is not really in HITSP; it's more in the HIPAA privacy rule and the limited data set is really not defined at this point.

The Privacy and Security Committee Workgroup made a number of general recommendations, the first of which is that certification criteria should not dictate policy beyond what is specified in ARRA and the HIPAA security and privacy rules. So what we need to do is we need to specify standards such that a doctor can configure the product to its individual policy based on its own risk profile. We don't want to tell everybody exactly what they need to implement, but we need to tell them what standards they should use and give them flexibility to configure it according to their own needs.

Second is that product certification should address both functional requirements, which are the services provided and the assurance levels. Assurance levels are really orthogonal for services, but it's really important to assess the strength of the mechanism that they use to implement the standards and secondly, the implementation itself, the strength of the implementation itself. For example, you might have a standard that requires authentication. Two factors is a stronger mechanism to meet authentication than single factor authentication. How the authentication is integrated with the products is a measure of the assurance level. Assurance level is also measured by penetration testing, conscious efforts to break security mechanisms. It's really important. The strength of the protection is certainly equally as important as the functions that the protection provides.

We're recommending the common criteria use the international standard for information technology security evaluation. The common criteria specifies a number of evaluation assurance levels and we're recommending that the ONC look at the common criteria and recommend evaluation assurance levels for specific use cases.

Third: For greater openness and broader interoperability we recommend that the ONC prefers standards that are developed by international standards development organizations or SDOs. There are plenty of them. HL7 is an international standard. ISO is an international standard. We think that this is really important.

The next recommendation is that certification criteria and standards should enable design possibilities that leverage fundamental principles and open standards. Once again, we don't want to lock anyone into solutions. We want to recommend open standards that allow them to apply fundamental, generally accepted design principles to develop their own solutions.

Product certification criteria should build toward full interoperability with both healthcare partners and consumers. This is what people have been referring to all day as the escalator approach. We believe it makes sense to start for 2011 with securing the enterprises themselves in accordance with HIPAA security and privacy standards, which is what the Policy Committee recommended, plus some simple shared sharing with healthcare partners and consumers. We think that secure exchanges with healthcare partners and HIEs is better to look toward 2013. In 2015 we think that full integration with consumer preferences with Enterprise and Exchange access controls is a good target. I would add that the 2011 recommendation there is consistent with what the Meaningful Use Working Group recommended that John Glaser went over earlier.

Next, we believe that the meaningful use criteria should be rules based and should specify what certified features must be used and how within the context of defined operational use cases. As I said earlier, if you're a hospital and physically secured you're going to have a different use case than if you're a doctor traveling between hospitals and home and carrying your laptop with you.

We think the criteria for meaningful use should include at least required, certified features and their configuration within the applicable use cases. Secure IT infrastructure; the current HIPAA risk management and risk analysis and the current HIPAA contingency plan, as I mentioned earlier.

The widest and perhaps most urgent gap that we identified may be consent management. Consent management involves several functions. As I mentioned before, it's a very complex, technical, as well as operational problem or challenge. First, it involves recording patient elections, their privacy authorizations and their informed consents in a consistent way such that both humans and computers can interpret the elections consistently across systems and across organizations.

It requires transferring these elections among entities that handle the PHIs so that basically the elections should persist with the data elements that they refer to.

Third, it involves translating these elections into access control rules. It's not sufficient to have the elections on a piece of paper filed in a filing cabinet when the information itself is being sent from provider to provider or to labs and to payers.

Then finally, it involves managing the continually changing elections. You know that the law allows that for someone to change their mind I might say anybody can see my information, but then the next week I may be diagnosed with a condition that I don't want people to know and I may go back and change that election, so this is a moving, evolving kind of consent.

There is some work under way and work that has been done, some good work, some very good work that's been done in this area. I think what's needed more than anything is some glue to bring some of these efforts together. HL7 is developing a consent; as you might know, the reference information model for version three includes the sensitivity label and HL7 is developing in the process, developing a hierarchical set of consent vocabulary that can be used.

John Halamka himself has done some work and has kind of postulated a consent assertion markup language. The HITSP TP-30 includes the IHE basic patient privacy consent profile, the BPPC. The BPPC captures patient consent and defines a method to enforce it. The one that I didn't put up here is XACML, which is a standard being developed by OASIS, which has a great deal of potential. XACML enables the capture of both enterprise security policy and access rules, as well as access rules associated with individual consumer consent.

We believe that these pieces need to be brought together. In particular, none of these efforts really address the way, a real standard way. BPPC talks about a method to enforce, but there's no real standard for translating access control from consumers into access control rules enforced by the system. So I see this as just bringing the OASIS, the HL7 and the BPPC together.

Consumers, as Steve mentioned, are beginning to play a much, much greater role in defining how their information is used and shared and so it's really important that we take the initiative and that ONC step up, I believe, to take this on. So we're encouraging the ONC to encourage and support the rapid, well informed development of consent management standards that comprehensively address all four of the points that I went over.

As John Halamka mentioned, we have assigned these readiness ratings to the standards that we've identified. They range from one to four. I think Marc Overhage was the one that put forth these four definitions at our last meeting and we thought that they were good and applicable. A rating of one is a mature standard, widely used using the Gartner kind of measure of at least 20 percent of industry; not the industry, not just healthcare, but industry in general has adopted it.

A rating of two is that it's ready for introduction, but it's not probably on our 2011 list.

A rating of three is it's well developed; work is in progress. It might get a 2013 or it might get a 2015.

Four is kind of blue sky. We think this is needed; standards are needed here. Somebody started it, but it's not real yet.

I'm certainly not going to go over all of these listings, but you do have three pages in your slides of standards that we're recommending. As I mentioned before the OASIS' extensible access control, XCMAL here, is an approved standard, but it's not at all widely used in any industry. It's very powerful because it does provide a means of capturing both enterprise rules, as well as individual consents. We believe it has a lot of potential.

OASIS SAML, security assertion markup language, is one that's widely used within enterprises, but it's not widely used between enterprises, so we gave it a rating of one because it's used extensively within enterprises, but it's with that caveat.

Let me see: Some others I wanted to mention: ATNA, this one, Audit Trail and Node Authentication profiles and IT profile. That really defines basic security between nodes and it uses the TLS bi-directional, mutually authenticated between one node says authenticate yourself to the other and the second node authenticates it back, before the transmissions can occur or before exchanges can occur.

The Kerberos here was developed by MIT. This has been around a long time, a decade at least, maybe more than that. It's authentication between two entities and uses a trusted third party synchronous encryption, symmetric encryption. The important part of it, the reason I'm pointing that one out is it is actually incorporated. That's really what EUA uses, so there is some sort of quasi-duplication here, because EUA uses Kerberos, but Kerberos is the foundational standard. I think that's all I wanted to point out there.

We'll go to the next slide. I talked about the HL7 data consent, which is the vocabulary. It needs more work. I talked about BPPC. All of these are very standard industry standards for establishing a standard time element.

This one: There are several here; XDS is another one that was on a previous slide; that are really infrastructure standards. These standards, they're not exactly security, but they're not clinical operations either, so Jamie and I got together and decided we'd put them on the security and privacy list, but they're really infrastructure, fundamental infrastructure standards, XDSB.

Let me see: Are there any others I wanted to mention there? I don't want to keep you here forever.

Transport layer security. This is what is used every time you go to Amazon and buy a book. This is beyond one. It is very well used. It's also known as SSL, simple security layer I think it's called.

I think that's it.

Jonathan Perlin – HCA – CMO & President

Very, very good presentation. Thank you so much. Comments, questions from the room? You didn't raise your card. You scratched your head, so I wasn't quite sure what to make of that.

Wes Rishel – Gartner – VP & Distinguished Analyst

I'm really sheepish about making another comment.

Jonathan Perlin – HCA – CMO & President

Go right ahead, Wes.

Wes Rishel – Gartner – VP & Distinguished Analyst

In the interest of time I'm just going to ask. I have a number of questions, some of which I think are pretty important, like what is the cost of EAL certification, for example. Is this document going to be moved approval today or is there a chance to go off-line and get questions answered?

Jonathan Perlin – HCA – CMO & President

I think given the time frame that ONC is under that this document would be moved to approval, so certainly, the floor is open if there were particular concerns you had.

Wes Rishel – Gartner – VP & Distinguished Analyst

Okay. Well, just a question then; maybe there's an easy answer: The EAL approval, as far as I know, that requires an auditor, who has been approved to do common criteria certification. We know that CCHIT took a lot of gaff because it cost \$100,000 for vendors to be certified on all of the functionality, security and interoperability. What is the cost to a vendor of an enterprise system to be certified for EAL?

Dixie Baker – Science Applications International Corporation – CTO

It depends. There are six levels of assurance, EAL levels, six levels. The first level is strictly conformance testing. The first level is exactly what CCHIT has been doing all along and the common criteria does not specify who does the evaluation. That's specified by whoever develops the protection profile or specifies the EAL level. ISO doesn't specify who does the evaluation. It does specify that it's an independent, like level one has to be an independent tester, but ...

Wes Rishel – Gartner – VP & Distinguished Analyst

So to be an ISO 9000 certifier you have to be authorized as a certifier? That's not the case for the common criteria?

Dixie Baker – Science Applications International Corporation – CTO

Not that I know of, no. No. Now, in the case of the common criteria evaluations that are done within the U.S., they're all done by entities that are certified by NIST, which I...

Wes Rishel – Gartner – VP & Distinguished Analyst

So what I understand is that endorsing the use of the common criteria here we're not buying into endorsing a specific level and there's plenty of time to work out the issues of what this adds to the cost of...

Dixie Baker – Science Applications International Corporation – CTO

That's what I recommended; that the ONC specifies a specific level based on the use cases, because I think that there probably are cases, use cases in which a level one would be perfectly fine, but there are other use cases where it wouldn't be. I think that the way we've gone so far there hasn't been any flexibility to do that.

Wes Rishel – Gartner – VP & Distinguished Analyst

Okay. The next question is does your recommendation say yes, no, or is it silent on the issue of consent beyond the consent levels that are associated with HIPAA?

Dixie Baker – Science Applications International Corporation – CTO

It doesn't say.

Wes Rishel – Gartner – VP & Distinguished Analyst

It doesn't say.

Dixie Baker – Science Applications International Corporation – CTO

I take that back. I am recommending that when we capture consent that the approach that's used to capture consent be able to capture not only the privacy authorizations, which are HIPAA, but also other informed consents that are required in the delivery of care and in clinical trials.

Wes Rishel – Gartner – VP & Distinguished Analyst

So consent for release of information: I don't want this information to go to anyone, who is related to any of my doctors. I mean I'm talking about the granularity of consent for information release.

Dixie Baker – Science Applications International Corporation – CTO

I have personal opinions about that, but my working group hasn't discussed it. So let's say...

Wes Rishel – Gartner – VP & Distinguished Analyst

We're not buying into a specific level...

Unidentified Woman

Well, we said role based as a general...

Wes Rishel – Gartner – VP & Distinguished Analyst

Role based is different. I mean role based...

Dixie Baker – Science Applications International Corporation – CTO

Yes, that's different. He's talking about how much discretion a consumer can have to limit the use and disclosure of their health information.

Wes Rishel – Gartner – VP & Distinguished Analyst

Potentially to other practitioners, who might look at it in the course of giving them care, right?

Dixie Baker – Science Applications International Corporation – CTO

Right. We certainly have not gone beyond what's in HIPAA. Right.

Unidentified Man

To that point, I mean this is where the standards gaps exist, to say, "I consent to a given situation, a given set of disease states, a given institution or provider." We're not quite there yet... standards...

Dixie Baker – Science Applications International Corporation – CTO

Well, and I think that if the ONC takes our recommendation I think that what your question is really getting to will be the most difficult part of the whole thing, but I think it's also essential; that if we're going to be exchanging health information across the national health information network that everybody has to be able to understand what the consent that they receive means and that they be able to interpret it in a uniform way. Number one would be developing a uniform data model that could be implemented across the NHIN.

Wes Rishel – Gartner – VP & Distinguished Analyst

I'll recognize my main concern was we weren't sort of by default buying into something I didn't think we were ready to implement.

Lastly, there are specific topics in here, such as encrypted e-mail, that are called highly used that in effect are used in environments where there is a public e-infrastructure available. I'm questioning whether it's reasonable to assume there's a national public e-infrastructure available in evaluating standards for use.

Dixie Baker – Science Applications International Corporation – CTO

I think it's unreasonable to assume that, especially for 2011.

Unidentified Man

Yes.

Unidentified Man

Is it possible that there are ways to use TKI for secure interchange that don't require distribution of keys to every individual so that you can have portal to portal secure mail?

Unidentified Man

I agree completely with entity; end point ... checking is really e-mail that I was concerned about.

Unidentified Man

Why don't we discuss this? As you said, secure e-mail can mean many things. It can mean SMI, SMI gateways, PGP or it can mean Web based portals for data exchange using TLS.

W

Right.

Unidentified Man

So we did not assume there would be a national PKI.

Dixie Baker – Science Applications International Corporation – CTO

That's exactly what we were assuming it would be for 2011.

Unidentified Man

Okay. Fine. Fine.

Jamie Ferguson – Kaiser Permanente – Executive Director

My question is exactly on this topic of PKI, but also digital signature, which I noticed you put in category three. I'm wondering what was the thinking, because those are, I think, widely used. I'm wondering what's the thinking behind putting those in category three versus, perhaps, category two. Is there a question of certainty? In other words, are you saying we definitely want to go there, but it's going to take more time or is it really a question mark?

Dixie Baker – Science Applications International Corporation – CTO

No. I think we really want to get there, but it'll take more time. I mean we had a digital signature standard as part of HIPAA, you'll recall, in 1996. I don't see it today, so it's what Wes was pointing out; I don't see a health PKI growing up in the next two years.

Jamie Ferguson – Kaiser Permanente – Executive Director

Okay. So you think it's still unreasonable for 2013 then, to have a PKI infrastructure? I'm just wondering what the workgroup discussions were on that.

Dixie Baker – Science Applications International Corporation – CTO

I think it's plausible for 2013. I don't think it's a done deal. That's why we gave it a three. That's how we defined three.

Jonathan Perlin – HCA – CMO & President

Any other questions?

Unidentified Woman

We're evaluating Slides 13 all of the way through 21, which include recommendations, I believe, to ONC on how certification should deal with privacy and security, particular standards, as well as how standards should be selected and consumed. Is that true? Is that the scope of what we're recommending? I'm just trying to...

Unidentified Man

I mean the scope of the recommendations today are there is the matrix, which includes all of the selected standards, plus their level of maturity and there are specific recommendations for filling up gaps that we would want to work with ONC and then HITSP and ... as appropriate to fill. Anything else, Dixie, you would add to that?

Dixie Baker – Science Applications International Corporation – CTO

No, except that I read through all of these standards yesterday on a plane. There is some slight duplication that is an editorial type of thing that I'd like to fix, but yes. No, I think we're acting on the handout that has the complete citations of the standards.

Unidentified Woman

Okay.

Unidentified Man

... the recommendation, so any specific question beyond that ...

Unidentified Woman

So primarily 19, 20 and 21 is what we're looking at today?

Unidentified Man

Right.

Unidentified Woman

Okay.

Unidentified Man

Did you ... questions?

Unidentified Woman

There were some issues within the recommendation slides, but I guess we're not actually accepting those today in terms of looking primarily at international standards organizations. Yes, international use standards will definitely help what we're trying to do here, but we probably don't want to limit ourselves to just that. Also, using that constraint language actually would unintentionally probably bump out IHE. We've had a lot of work with IHE, which has been very useful for us as a provider organization, but in fact, I don't believe they actually are SDO certified.

Dixie Baker – Science Applications International Corporation – CTO

That's why we use the word prefer.

Unidentified Woman

Okay.

Dixie Baker – Science Applications International Corporation – CTO

That's exactly why that word is there instead of use.

Unidentified Woman

Okay. So we probably just want to do the internationally used standards. Why call it out if we're just going to then constrain it with a prefer in front of it?

Unidentified Man

For example ...

Unidentified Woman

But this is not part of what we're accepting today?

John Halamka – Harvard Medical School – CIO

For example, what HITSP says is when we can harmonize international standards good, if we have to go to a U.S. realm, fine. Certainly, when we think of SDO what is the definition of an SDO? Well, there's the strict standards development organization in the anti-sense, but there's also the implementation guide riders, etc. So I think your point was suggesting that we would want to use the internationally accepted standards to the extent possible as a preference.

Unidentified Woman

John, you're getting to then the other question in terms of divergence from HITSP. HITSP has been a wonderful success story within a very short period of time for the amount of harmonization that you've been able to do and so I appreciate, in Jamie's presentation that it looks very familiar. It looks very comfortable. It is very much following and is inter-digitized with the HITSP model. I don't see that in this presentation here and just want to get that assurance that in fact ...

John Halamka – Harvard Medical School – CIO

In fact, they've all been lifted from the HITSP capability.

Dixie Baker – Science Applications International Corporation – CTO

Yes all of them came from HITSP, but I would point out HITSP and its latest tiger teams did not identify capabilities for privacy and security. They assumed that privacy and security cut across the capabilities, but every bit of this work is based on HITSP.

Unidentified Woman

Okay. Great.

John Halamka – Harvard Medical School – CIO

Just so folks understand, sometimes you can say capability and it's assumed the whole variety of other constructs in the privacy and security. It's actually granular standards services components, etc. So this is all completely consistent.

With that, today we are looking forward to an acceptance of this report from the security and privacy workgroup and those standards, as named, in the last three slides and in your matrix; of course, these are some recommendations on gaps that we'd like to go forward with. Any objections to moving forward with accepting the work as submitted by Dixie and Steve? Okay. None being heard, we will then move forward.

Well, a wonderful array of presentations. We certainly do have refinements to do, but I think we've got some clear marching orders, so at this point I think we'd like to open it up to public comment. I'll return to Jon.

Jonathan Perlin – HCA – CMO & President

Thank you, John. Let me thank all of the committee members and the workgroups. I think everyone present appreciates the amount of work. I just want to reiterate that we hear pretty clearly and have some concerns in some areas for refinement and that process will go forward. I appreciate the latitude to allow the national coordinator to do the work they need to do, but I think the demarcation of where our comfort zone is and where there's further work is appreciated and understood and so I think everyone is working down that lane.

I apologize to the public members that this part of the session is delayed. It is, in my estimation, the singularly most important part that I have received feedback on a longer period next time and a better calendaring, but I think we all appreciate these are extremely complex issues.

If you would please identify yourself, name and organization and limit your comment and/or questions to no more than 2 minutes, please.

Mike Capital – McKesson Corporation

I'm Mike Capital with McKesson Corporation. I'd like to commend all of the workgroups. I think clearly the work products showed a very thorough and disciplined approach. However, I'd like to go back to a comment that Ms. Baker made in her presentation that she believes that occasionally this committee is confusing standards for meaningful use with certification standards. While I appreciate the very succinct analysis that privacy and security did to separate those two, I'd really like to see the work product from both, the clinical quality workgroup and the clinical operations group clarified as to what is designed for meaningful use versus what is suggested as certification criteria. I'm not sure that ONC can move forward with clear guidance. I'd just like to say that I don't believe that any stakeholder, whether it's patients or whether it's physicians, hospitals or any technology vendor, can move forward until we get this clarity. Thank you very much.

Jonathan Perlin – HCA – CMO & President

Thank you for your comments.

Kathleen Connor – Health Policy Analyst – Microsoft Health Solutions

I'm Kathleen Connor. I'm a Health Policy Analyst with the Microsoft Health Solutions group and I've been involved in standard setting organizations that we've talked about here today, including HL7 and HITSP. I've made contributions to the security and privacy and infrastructure workgroup and technical committee's product. I'm not an MD, so I didn't write that note.

On behalf of the Microsoft corporation I wanted to thank HHS, ONC and the committees for the rapid progress they've made on meeting the high tech requirements on such a short timeline. We remain really committed to promoting a future that liberates and leverages health data in ways that will empower both the consumers and providers to improve health outcomes. For these reasons we strongly support the HIT Policy Committee's positions on the following: A limited and flexible certification process focused squarely on validating that EHR technologies have appropriate security, privacy and data interchange capabilities and are able to report meaningful use measures.

A definition of meaningful use that is focused on outcomes rather than features and functions and proposals for the health information exchanges that recognize that timely adoption must leverage the interoperability infrastructure already in place.

To ensure that the goals of high tech are accomplished across diverse health information ecosystems, both current and emergent, it's imperative from our view that the meaningful use standards selected be technology neutral, platform independent and architecturally agnostic. Our concern is that much of this progress could be voided if the HIT Standards Committee unnecessarily narrows the standards selection process to those that support only comprehensive EHRs and document centric health information exchange. Such an approach would not recognize many other very effective standards that would be critical to ensure effective state and widespread data interchange.

HITSP standards have been primarily selected to address the limitation of legacy EHRs and that are, for the most part, inappropriate for alternative EHR and HIE technologies, such as those discussed by the HIT Policy Committee. These non-legacy HIT solutions, which are widely used by providers and consumers, include modular EHR components for medical devices and quality measure reporting, alternatives to document centric HIEs, such as the majority of the health information exchange organizations, which have not adopted the IHE document centric architecture; established networks for e-prescribing, public health reporting and laboratory orders and results, clearinghouses, which might also be able to support health information exchange and health platforms, such as Microsoft health wealth, Microsoft... for providers..., Google Health and other health applications on mobile devices.

These alternative EHR and HIE technologies can support meaningful use with non-HITSP standards, such as messaging standards, which are used in the e-prescribing and the lab reporting networks; there's NCPDP; there's eLinks, X-12 and HL7 messaging, such as the V-2 and V-3 messaging; these can convey the same data that is being put into the CDA profiles; the CCR, a widely used alternative document standard that is easier to implement than a CCD and is actually in use today to coordinate care. Computationally enforceable privacy standards that protect health information far better than what is possible with standards being proposed for use with legacy EHRs and more robust security standards than have been proposed by HITSP around secure node authentication and which may not be permitted under the NIST encryption standards for data in motion, as specified for safe harbor under the HHS breach notification guidance, which has not been adopted yet, but we know that it's likely to go forward.

Microsoft supports the selection of technology appropriate standards for meaningful use certification that promote availability of affordable and easy to adopt EHR technologies for low tech and non-tech providers in the green field market and want to augment the installed systems with innovative modules that will enable meaningful use.

We see diverse HIT technology ecosystems leveraging existing HIE infrastructures, enabling privacy protection and data liquidity for edge systems and providing interoperable on ramps to the ... so that meaningful use objectives can be met in the most efficacious and least burdensome way while promoting market innovation.

In closing, Microsoft thanks the HIT Standards Committee for considering our perspective. We ask you to consider recommending standards appropriate for alternative HIT products and services that offer the market lighter weight, agile and more cost effective meaningful use EHR technologies. We look forward to working with you more closely on this. To sum it up, we see the boundaries that you're talking about allowing enterprises to maintain the standards that they use. We also see those boundaries applying to health ecosystems, such as the networks that we are considering for HIE. Thank you.

Jonathan Perlin – HCA – CMO & President

Thank you very much for your comments.

John Knew – Director of Quality Management – Maryland Institute for Emergency Medical Services Systems

Good afternoon, committee members. Thank you for this opportunity. I'll be brief. My name is John Knew. I'm Director of Quality Management with the Maryland Institute for Emergency Medical Services Systems in Maryland. I'm here to represent our Executive Director, Dr. Robert Bass, and the National EMS officials. What they would like you to hear is that the pre-hospital care data set has a wonderful standard out there in the form of the national EMS information system data dictionary, NEMSIS. We would want you to consider using that as the standard for many, many reasons. It represents a consensus for many partners. It is well on the way of being out there, implemented. Our state is going over to that standard and I'm in that process as a project manager. That's the message that we would like to leave you today with. Thank you.

Jonathan Perlin – HCA – CMO & President

Thank you very much for your comments. Any comments on the phone?

Unidentified Woman

We do have a comment from Debra Peel. Ryan, would you open Debra Peel's line, please?

Debra Peel

Thank you so much. Patient privacy rights would like to suggest that even though this group just accepted the report from Dixie and Steve that their recommendations are so critical that there be a formal public comment period and a requirement that the workgroup address and include recommendations from the public for this incredibly important part of health information technology and health information exchange, because the health privacy advocacy community and the privacy advocacy community I know, for example, our coalition, which represents ten million Americans, hasn't seen this before. There are many peculiarities about it that really require some study and some comments. Even though you all have very tight deadlines, a part of the purpose of the committee was to ensure that there really is adequate public input. I think simply passing on the recommendations from the privacy and security workgroup does not give us adequate time for public comment. So we would recommend that you set this aside or develop a process to take in public comments and require that they be addressed and incorporated into the matrix and into the recommendations from the privacy and security workgroup. That's essentially my first comment.

The second comment or question that I would like to address to the committee is Dixie and Steve put up eight key areas of focus for privacy and security that came from ARRA. The most significant and historic consumer privacy protection in ARRA is the ban on sales of PHI, protected health information, without consent. We do not see that particular requirement of ARRA on the timetable for the health IT Standards Committee, so that's essentially my second question. When is that going to be addressed? That's essential protection. How can the privacy community, privacy advocates and the public interface more effectively with this committee in the development of key privacy and security standards?

Jonathan Perlin – HCA – CMO & President

Thank you very much for your comments. I don't know. Jodi Daniels from the Office of the National Coordinator might like to offer any comments.

Jodi Daniels – Office of Policy & Research – Director

Sure. I just wanted to respond to the one question about the provisions in ARRA about the sale of data. That is something that we are in conversation with the Office of Civil Rights on. It is something that would be incorporated into any modifications they did on the HIPAA regulations, so that is something that will absolutely be addressed as required by ARRA. I'm not sure that it's something necessarily that the Standards Committee would be looking at, because it's something that would end up being a legal requirement as opposed to a standard for electronic health records.

Debra Peel

Is there a process for the public to be involved with OCR and the development as that moves forward?

Jodi Daniels – Office of Policy & Research – Director

I can't represent the Office for Civil Rights. My understanding is that they would be going through rule making, which, by definition, incorporates a public comment period and the incorporation and consideration of those comments before coming up with final regulations.

Debra Peel

Thank you, Jodi. I hope someone could react to my question or concerns about the recommendations from the privacy and security workgroup.

Jonathan Perlin – HCA – CMO & President

I hope you were with us for the whole conference, because we've described it. There's been some discussion about the next phase of comment period and activity.

Debra Peel

I was.

Jonathan Perlin – HCA – CMO & President

I just wanted to make a couple of brief notes about some of the questions. Let me first ask if there are any other persons, either on-line or in the audience, who'd like to offer any comments.

Unidentified Man

We have no more comments on the phone at this time.

Jonathan Perlin – HCA – CMO & President

Thank you very much.

Robin Rayford – Eclipsys Corporation

Just one really quick. I'm Robin Rayford from Eclipsys Corporation, but my comment comes from previously being on the CCHIT Child Health Expert Panel. That futuristic, for 2013 or 2015, when you get into consent I just want to note that the examples given today were like human beings in charge of their own consent. Don't forget when you get into kids and you don't know where the egg came from; you don't know where the sperm came from; you're not sure who the daddy is; who knows where mommy is. They've got ... foster kids. Don't forget those layers of complexity with consent.

The other is disabled adults when they, perhaps, have consent for someone else. I just wanted to get that in the record. When you start peeling back the onion don't forget that group since that's one of the ARRA for the needs of the vulnerable.

Jonathan Perlin – HCA – CMO & President

Thank you for your comments. Any other comments? Okay.

First, let me start with the theme and that is the public comment period throughout the process. Of course, all of the meetings have been open, as required and really encouraged by the Federal Advisory Committee Act and its process. Jodi, it seems that there is still a great deal of interest. Could you describe what's more at the different threads of the ability for public comment? Because that's a rule making process it does include that in its next stage. I'll just preface it that anything that is recommended to CMS and CMS takes up will have its own public comment period in addition. Let me turn to you, Jodi Daniels, for that.

Jodi Daniels – Office of Policy & Research – Director

Sure. All of our activities in the area of standards and certification, all of the CMS activities in developing the incentive program and defining meaningful use, all of the provisions regarding modification to the HIPAA privacy rules that were in statute, which we haven't talked about until just the last comment, all of that will go through our normal rule making process.

The rule making process is designed to be a two-phase process where the agency comes out with their best proposal on a set of rules and then we look for comment. We are, in fact, required to review all of the public comments, consider all of the significant comments and inform the public of how we have addressed those comments or why we've chosen not to address particular comments in the final rule, so all of the activity that this committee and the Policy Committee are advising ONC and CMS and also some comments that might be directed toward OCR will go through that traditional administrative process to incorporate feedback. The ... process, as Jonathan mentioned, is also intentionally an open and transparent process where folks can be part of and hear the deliberations as well as be able to make comments on the record as folks just did at the end of this meeting, for the committee to hear.

I think in some ways we sort of confuse the process a little bit by having a separate comment period just on the Policy Committees initial thinking on meaningful use. That was not something that is necessarily required or that is frequently done, but it's something that was optional that the committee thought was important to do. So we supported the committee in doing that and received quite a lot of interest and fed that information back to the committee. At this point I don't think there was any intent to do other of these informal comments. If at some point in time the committees are interested in doing that we can discuss our ability to support that, but I haven't heard an outpouring from the committee chairs on doing that at this point.

So basically, just in sum, all of the things we're talking about will go through formal rule making. There will be public comment processes for that. Comments will be posted on the Web. It's very transparent and we will explain how we address all of the comments. Again, we encourage folks to participate in these meetings, to make public comments at these meetings, to give your voice to the committee members in their deliberations, etc.

Jonathan Perlin – HCA – CMO & President

Terrific. Thank you for that. I think in sum as well, the themes that we heard, I appreciate the privacy and security that given that there is such work to do in and around meaningful use that they chose as a process not to ... that, which is already ... law. I hope that that addresses one set of issues, because it's already dealt with a far more stringent set of criteria.

I think the comments that were also made were very helpful in reminding us about the importance of making sure that our work continues to facilitate innovation and that it is a work that addresses as well vulnerable populations and that addresses the needs of care delivery that are environments other than the hospital and doctor's office. I think we've heard that as well.

I think the point about the certification and meaningful use, there's a bit of a sequencing problem and indeed, a lot of work going in parallel on this. It's now the time for some of that work to come together, but all of those points are points that we, as a committee, have the obligation to reflect upon, incorporate into our next set of activities. We certainly have marching orders in and around the next level of the standards and their use and deriving measures of quality.

Let me just turn to the committee and ask are there any other issues or items that you'd like to put on the agenda? Anything for the good of the order before we break for today, reconvening on August 20—I believe is the date.

Unidentified Man

Just recognizing that standards are always a journey; I know that sounds a bit Zen or something like that, but what we'll do with each successive meeting is continually constrain the variability. That is I think we've learned today what are those comfort levels we all have. In the next meeting there will be more and the next meeting there will be more. I hope you all take this particular day as just a step in that journey. I look forward to working with you.

Jonathan Perlin – HCA – CMO & President

Well-said. A little to add to that: Let me again thank all of you and the members of your workgroups for truly heroic work. The number of hours is incalculable. It's just extraordinary to date. We know there's more work and we hope that our recommendations provide the intended utility to the Office of the National Coordinator, HHS and more importantly, to realize the aspirations of improved healthcare, safer, more effective, more efficient and by virtue of the ability to move the data, ultimately more compassionate and patient centered.

Thank you so much, everybody. Thank you to the ONC staff here. Great work.

Public Comments:

1. I am concerned about the lack of attention to sharing imaging data to avoid rescanning patients for duplicate tests (due to lack of access to the patient's imaging data)
2. This is a lot of standards just for security and privacy that we may be asking stakeholders to use...I was wondering if we could categorize these in 3 buckets: Minimum/Must Use, For Next level of Security, Advanced Security (or some other buckets). Where do NIST security standards fit that have been in use by many public health applications and other health apps? Thank you for allowing and including comments from practioners like me on this important topic that will shape much of HIT work in future.
3. For Dixie Baker: the key consumer privacy protection --ie the ban on sales of PHI without consent is not one of the 8 ARRA Privacy and Security Focus Areas. When will the Privacy and Security WG address this historic new consumer privacy protection?
4. I wonder if there is a plan to standardize EHR systems on the capability to create a copy of an EHR on a portable medium, as well as to display and incorporate an EHR created by another system?
5. This entire discussion does not get to Americans' rights to give informed specific consent for research, whether the research is called QI or clinical use, etc. When will this committee set standards for the use of electronic consent, either via the use of DRM technology or open source consent technology such as has been in use 8 years by the NDIIC for exchanging PHI between behavioral health organizations. Deborah C. Peel, MD, founder and Chair Patient Privacy Rights. This report should not be accepted as it does nothing to ensure the key "meaningful use" patients want to see in EHRs: the right to control personal information. How can the public meaningfully participate in discussion of proposals designed by industry to ensure they set standards that meet their interests, not the best interests and privacy rights of consumers. This entire process is much like what happened in the auto and banking industries: when foxes design hencoops, the chickens will pay dearly. This process is like the way the American auto industry fought all patient safety measures including seat belts and airbags. Would the paint industry ever eliminated the use of lead in appoint voluntarily? Finally, when will standards be written to end the sale of PHI without consent as mandated in ARRA? The entire health delivery system is based upon the willingness of the individual to trust a health care practitioner sufficiently to disclose to the practitioner the most intimate details of his or her life. An assurance of privacy of health information is necessary to secure effective, high quality health care.
6. HHS own findings are above REQUIRE privacy as an essential pre-condition for quality healthcare. When will this committee include standards for privacy, which HHS has found is required for quality healthcare? 65 Fed. Reg. at 82,467. These HHS quotes are HHS' own position on the connection between privacy and quality, yet no QI measures are concerned with privacy (ie patient control over data use). This committee is dominated by industry, as HITSP has been, and does not represent the public's legal and ethical rights to health privacy. Despite assurances that public input would be taken, typically the public cannot even have time to speak and there is as yet no evidence that any of the comments submitted by the public have even been seriously considered by the committee. The entire health delivery system is based upon the willingness of the individual to trust a health care practitioner sufficiently to disclose to the practitioner the most intimate details of his or her life. An assurance of privacy of health information is necessary to secure effective, high quality health care.