

**HIT Standards Committee Meeting  
Transcript  
June 23, 2009**

**Participants**

Janet Corrigan – National Quality Forum  
Jamie Ferguson – Kaiser Permanente  
Martin Harris – Cleveland Clinic  
Liz Johnson – Tennant Health Care  
John Klimek – National Council for Prescription Drug Programs, Inc. (NCPDP)  
Wes Rishel – Gartner  
Anne Castro – Blue Cross and Blue Shield of South Carolina  
John Halamka – Harvard Medical School and Beth Israel Deaconess Medical Center  
David Blumenthal – National Coordinator for Health Information Technology  
Jon Perlin – Hospital Corporation of America (HCA) Inc.  
Marc Overhage – Regenstrief Institute  
John Derr – Golden Living  
Jim Walker – Geisinger Health System  
Jodi Daniel – Office of the National Coordinator for Health Information Technology (ONC)  
Chris Chute – Mayo Clinic  
Dixie Baker – Science Applications International Corporation (SAIC)  
David McCallie – Cerner Corporation  
Steve Findlay – Consumers Union  
Linda Fischetti – Veterans Health Administration  
Cita Furlani – National Institute of Standards and Technology  
Anita – Wal-Mart  
Gina Perez – Delaware Health Information Network (DHIN)  
Sharon Terry – Genetic Alliance, Inc.  
Kevin Hutchinson – Prematics Inc.  
John Glaser – Partners HealthCare  
Rick Stephens – The Boeing Company

**Presentation**

**Judy Sparrow**

Okay. Good morning, everybody, and welcome to the second meeting of the Health Information Technology Standards Committee. Just a reminder that this is a Federal Advisory Committee. It is being held in the public. We have an audience here in the room as well as people dialing in on the telephone. And there will be an opportunity at the end of the meeting for the public to make comment, either here in the room or on the telephone. Also, members here in the room, please remember to identify yourselves as you speak; we are making a transcript of this meeting, which will also be posting on the ONC Web site in about 5 days.

Let's go around the room, and if you could briefly introduce yourselves—your name and your organization. I'll begin with Janet Corrigan.

**Janet Corrigan, National Quality Forum**

Janet Corrigan from the National Quality Forum.

**Jamie Ferguson, Kaiser Permanente**  
Jamie Ferguson, Kaiser Permanente.

**Martin Harris, Cleveland Clinic**  
Martin Harris, Cleveland Clinic.

**Liz Johnson, Tennant Health Care**  
Liz Johnson, Tennant Health Care.

**John Klimek, NCPDP**  
John Klimek with NCPDP.

**Wes Rishel, Gartner**  
Wes Rishel, Gartner.

**Anne Castro, Blue Cross and Blue Shield of South Carolina**  
Anne Castro, Blue Cross and Blue Shield of South Carolina.

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

**Dr. David Blumenthal, National Coordinator**  
David Blumenthal, National Coordinator for Health Information Technology.

**Dr. Jon Perlin, HCA Inc.**  
Morning. Jon Perlin, HCA Health Care.

**Marc Overhage, Regenstrief Institute**  
Marc Overhage for Regenstrief Institute.

**John Derr, Golden Living**  
John Derr, Golden Living.

**Jim Walker, Geisinger Health System**  
Jim Walker, Geisinger Health System.

**Jodi Daniel, ONC**  
Jodi Daniel, ONC.

**Chris Chute, Mayo Clinic**  
Chris Chute, Mayo Clinic.

**Dixie Baker, SAIC**  
Dixie Baker, SAIC.

**[Inaudible], Arizona State University**  
[Inaudible], Arizona State University.

**David McCallie, Cerner Corporation**  
David McCallie, Cerner Corporation.

**Steve Findlay, Consumers Union**  
Steve Findlay, Consumers Union.

**Linda Fischetti, Veterans Health Administration**  
Linda Fischetti, Veterans Health Administration.

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

Cita Furlani, National Institute of Standards and Technology.

**Judy Sparrow**

Sorry, Cita; didn't see you. We do have a number of members that will be joining late. And on the phone, we may have Rick Stephens from the Boeing Company. Rick, are you on the line? He'll be dialing in late—and Linda Dillman from Wal-Mart.

**W**

Yes, we have Anita for Linda, who will be joining us shortly.

**Judy Sparrow**

Thank you, Anita. With that, I'll turn it over to Dr. Blumenthal.

**Gina Perez**

Just want to note, this is Gina Perez on the phone as well.

**Dr. David Blumenthal, National Coordinator**

Good morning, everyone. David Blumenthal, National Coordinator. Again, I want to thank you all for being here; welcome you to Washington; thank you especially for those who had to find an alternative commute this morning because of the events last night on the Red Line; and also want to thank you, especially members of the committee and the Office of the National Coordinator staff, for the incredible amount of work and dedication that you all are showing to the very demanding requirements of the HITSP provisions of the Recovery Act and the very inspiring agenda that that piece of legislation has created for us. The importance of the work of this particular group, the Standards Committee, is becoming more and more evident as we get into the totality of the tasks that we face.

We have been doing a lot of things in the Office of the National Coordinator, which I expect will become more apparent to the public over time. One of those, which has already become public, is that we held a second meeting of the Health Information Technology Policy Committee about 10 days ago. That meeting was—the topic of that meeting was the working group—the HITSP Working Group's first overview and rendition of the meaningful use criteria that the working group thought should be considered by the Health Information Technology Policy Committee. That formulation was discussed in detail; a lot of suggestions were made. We are still entertaining public comments on those materials. And the Office of the National Coordinator and the Center for Medicare & Medicaid Services are right now involved in an extensive series of listening sessions based in the regional offices of the Center for Medicare & Medicaid Services, through which we are soliciting the views of providers and patients and institutions around the U.S. concerning their views of this working group view of the concept of meaningful use. That definition will be reviewed again—will be modified and reviewed again in the middle of July, July 16, by the Health Information Technology Policy Committee. It will, I expect, be modified and result in recommendations to the National Coordinator and to the Department of Health and Human Services, which will then be taken into account during a rulemaking process that will unfold over the following several months.

Nevertheless, that preliminary view, just part of an extensive process, does highlight the granular task that the standards-writing bodies that work in this field will have to undertake in order to make the definition of meaningful use a reality. And I know there have been discussions within this group, the Standards Committee, about where the gaps are—where standards exist for elements of the meaningful use concepts that were put forth by the working group. And I think those are illustrative of the tasks that this group will be asked to take on, and we are deeply grateful for that.

There are many other things going on in the Office of the National Coordinator. We are working hard on the best—what we think is the optimal allocation of the discretionary funds that are available to the Secretary under the HITSP Act to provide support for the adoption and meaningful use of health information technology, especially electronic health records. We hope that some of those programs will be announced over the summer. And already, we are—have gone public in the *Federal Register* with a

description of and extensions to the program, which will be the subject of one of those possible spending plans that is under discussion.

All this—the successful conclusion of all this work continues to depend on the voluntary help of so many people, including those of you around this table. We literally just cannot bring this off without an entire—the entire information technology community and many public and private groups coming to our aid. So this is a critical part of the success of this HITSP agenda and, in that sense, a critical part of the President's and the country's long-term agenda to make our health care system higher quality and more productive.

So with that, I'm going to turn over the proceedings to the two Johns, as I've come to call them, and—who have been providing terrific leadership not only here but in many other domains of information technology and health policy.

**Dr. Jon Perlin, HCA Inc.**

Well, thank you, Dr. Blumenthal. This is Dr. Jon Perlin. Let me add on behalf of John Halamka and myself our welcome to not only members of the Health IT Standards Committee but to all participants who are part of this great national dialog on really helping to achieve, as Dr. Blumenthal outlined, not just more rapid implementation of technology but technology that will lead to higher quality, greater safety, and greater productivity in health care.

We do have a number of new members to the committee and want to join the Office of the National Coordinator and Dr. Blumenthal in recognizing and welcoming these new additions. Linda Fischetti is the Chief Health Informatics Officer at the Veterans Health Administration—Nancy Orbus, Director of Health Standards Participation, Department of Defense. Cita Furlani is Director of Information Technology Laboratory at NIST—and Anis Chopra, Chief Technology Officer, Office of Science and Technology Policy. Welcome to all the new members, and thank you very much for adding to...

At the outset of the last meeting, we really described—Dr. Blumenthal described and we picked up the task of meeting a very ambitious agenda and Dave, I think I joked that this would be a highly caffeinated group, and the group lived to charge; indeed, your caffeine really propelled the work that, in retrospect, is quite remarkable. I want to commend not only the members of the workgroups and the parent committee but the Office of the National Coordinator. Just to describe the depth of activity, let me note that there were conference calls that started as early as 6 a.m. Eastern, 5 a.m. Central, and everyone was enthused about really meeting the task at hand.

When we set our activities, we also used the analogy from Wayne Gretzky that we would skate to where the puck would be, and we tried our best to anticipate; indeed, there has been convergence. I think we're directionally aligned with what's come forward in the first iteration from the Meaningful Use Workgroup and would add our appreciation to that workgroup for a terrific start. This is an ongoing dialogue, but there are two elements that I'd stress: first, that we need to, as, again, David said, be very granular today in our deliberations. We have our next meeting—I believe it's July 21<sup>st</sup>—and really need to be able to come together to describe standards that will support implementation specifications to really frame the aspirations for the 2011 tranche of work. We need to be clear about the gaps that exist, and we need to put our heads together about the certification process.

Now, I want to be also very clear on this: This is a working meeting. This is—things that we discuss today may or may not be ultimately anointed by the group itself, by the workgroups, by the Office of the National Coordinator, by the vetting process. In that regard, I would hope that this is really a great forum to bring together the work of the three workgroups that will present today as well as an update on the Meaningful Use Workgroup. But I can't overemphasize that no one should overread the discussions as definitive policy—really is just that, a working group, and, indeed, consistent with the purpose of the Federal Advisory Committee, is really meant to be open and transparent. And so those deliberations that all here and online are participating in—are really just that: They're formative; they're idea generation; they may be deliberational at times, but they're—most of it or much of the discussion, particularly the second half of the meeting, is really working around developing clarity that Dr. Blumenthal charged us with providing.

Let me conclude my opening remarks, again, by just thanking everybody not only for the work that has been done but in advance. I think you can tell by the task that's ahead of us that the pace—the up-tempo, if you will, that has been established will be one that continues. We'll hear from our workgroup Co-chairs today, and they deserve particular credit for their terrific leadership. I want to note Dixie Baker and her terrific work with the—Dr. Steven Findlay on privacy and security, and Janet Corrigan—just extraordinary leadership on quality—clinical operations—clinical quality [inaudible] clinical quality, and Jamie Ferguson and John Halamka organizing around the clinical operations. John Glaser continues to lead us well and will be describing for all of us to make sure that we have a shared understanding of the evolution of concepts of meaningful use and a preliminary definition of that. And then following these presentations, we'll go to deliberation about more granular aspects of 2011.

But Jamie Ferguson has had the able assistance, as I do, of an extraordinary individual who really brings so much domain expertise and subject matter expertise to this. It's my pleasure to not only thank but recognize Co-chair John Halamka. And John, let me invite you to any introductory comments as well.

John Halamka, Co-chair

Well, thanks very much. And yes, do want to thank everybody on the committee and the workgroups for the extraordinary amount of work that's been done since our last meeting. As John has said, today is really a discussion; it's a workgroup; it's predecisional. And so, certainly for members of the public and the press, don't take anything that you see in our presentations today as "It is going to be this way."

You'll hear a lot of straw man discussions. So for example, how do we decide what work is done by the Clinical Operations Workgroup versus the Clinical Quality Workgroup, because they're actually quite interrelated? How do we figure out not only the "what" of the standards but the "when"? It may very well be true that there are standards out there that describe the perfect way to exchange data from place to place; it's just that no one's ever implemented them. And so, deciding that, by 2011, those will be widely adopted is probably not realistic.

So much of what our discussion today will be is that framework. How do we decide if a meaningful use objective or measure is defined? What are the standards, and when will they be part of meaningful use? When are they ready? When will they be deployed or implemented in 2011, 2013, and 2015?

The work ahead for the next 30 days is going to be probably even faster paced than the last 30, because the folks at ONC tell me that they are looking for their guidance by, say, beginning of August, which implies our next meeting, July 21, we better have at least a glide path to the finish by the time we meet again. And so, between now and then, there will be a series of workgroup meetings and teleconferences to try to get us to that finished point. We're going to, sure, gather quite a lot of input and hear from many, many stakeholders because our challenge is really, as you said, focus on 2011. What can we do to get implementable standards that are ready for prime time, mature enough, that can be achieved widely in the United States by 2011?

And so today, I look forward to all of your thoughts on our frameworks, the trajectory we're setting for the next 30 days, and then after our break today, discussing "Well, where are the gaps? Where should we focus, and how do we get to August 1?" Thanks.

**M**

Well, thank you very much, John. We have adopted as a committee norm a disclosure of any conflicts of interest, real or perceived. And so, I'd like to just go around the room and either by an undisclosed or— indication of anything that could be real or perceived conflict of interest—just a declaration. And we'll start online. Linda Dillman?

**Judy Sparrow**

She's not in yet, so we'll refrain at this time.

**M**

Thanks. Janet Corrigan, we'll start at the left with you.

**Janet Corrigan, National Quality Forum**

I don't know if I have any conflicts, but did want to indicate that I work with the National Quality Forum, and we are the group that sponsors the HITEP (the Health Information Technology Expert Panel) and endorses measures that are input to this process.

**M**

No conflicts.

**Martin Harris, Cleveland Clinic**

Martin Harris, no conflicts.

**Kevin Hutchinson, Prematics Inc.**

Kevin Hutchinson, no conflicts.

**Liz Johnson, Tennant Health Care**

Liz Johnson, no conflicts.

**John Klimek, NCPDP**

John Klimek, no conflicts.

**Stan Huff**

Stan Huff. I don't have any conflicts, but I do work with HL7 and with LOINC, and I'm also on the SNOMED—one of the SNOMED committees. So I have, obviously, interest in those, though I have no financial interest in any of those organizations.

**Sharon Terry, Genetic Alliance, Inc.**

Sharon Terry, no conflicts.

**Wes Rishel, Gartner**

Wes Rishel, no financial conflicts; I am a trustee of CCHIT.

**Anne Castro, Blue Cross and Blue Shield of South Carolina**

Anne Castro, no conflicts.

**John Halamka, Co-chair**

John Halamka; I work for a provider organization, so recognize that may have some biases associated with it. I'm on the board of Envida Health, which is a decision support service provider. Otherwise, no conflicts.

**Dr. Jon Perlin, HCA Inc.**

Dr. Jon Perlin; I work for a provider organization as well, and I'm on board of National eHealth Collaborative.

**Marc Overhage, Regenstrief Institute**

Marc Overhage, no conflicts.

**John Derr, Golden Living**

John Derr, no financial conflicts, but I work for a provider. I'm also a Commissioner on CCHIT representing long-term and post-acute care.

**Jim Walker, Geisinger Health System**

Jim Walker, no financial conflict.

**Chris Chute, Mayo Clinic**

Chris Chute, no conflicts.

**Dixie Baker, SAIC**

Dixie Baker, no conflicts.

**[Inaudible], Arizona State University**

[Inaudible], no conflicts.

**David McCallie, Cerner Corporation**

David McCallie, no conflicts, though I work for a large HIT vendor

**Steve Findlay, Consumers Union**

Steve Findlay, no conflicts, but I am also on the board of the National eHealth Collaborative.

**Linda Fischetti, Veterans Health Administration**

Linda Fischetti, no financial conflicts. I do work for a provider organization. I'm a federal liaison for the National eHealth Collaborative. I'm on the board of HL7 until the end of this calendar year.

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

Cita Furlani, no conflicts.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Thank you very much, and I appreciate that. It is now time to begin to get into the substance of today's meeting, and my pleasure to introduce Dr. John Glaser to give us an overview of introduc—what's written here—overview of preliminary definition of meaningful use. And John, thank you very much, and to the Meaningful Use Workgroup as well, and the National Coordinator. Just amazing work—look forward to this overview.

**Dr. John Glaser, Partners HealthCare**

John, thank you. I may be coming down with a cold, so I'll consult with a number of you at the break about how best to treat this—appreciate that. I'm the ONC Lead to the Meaningful Use Workgroup of the Policy Committee, so I'm going to give you an overview of the Meaningful Use recommendations—or Workgroup recommendations that were presented at the HIT Policy Committee last week. As David noted in his comments, a meaningful use proposal was presented. It is under discussion through—as a result of public commentary. I had some conversations that occurred at the Policy Committee. So it is a great start, although it is still under discussion and potential revision in the weeks ahead.

David also mentioned in his comments the importance of the work that you all do in the workgroups surrounding the development of standards and certification criteria that will be necessary to ensure that both the clinical operations, the quality of measurement and reporting, and the privacy and security infrastructure that need to be the bedrock on the foundation for meaningful use are in place. What I was going to do is give an overview of or a sort of shortened version of the presentation that the Co-chairs of the workgroup, Farzad Mostashari and Paul Tang, gave at the last meeting. I will not do as good a job as they did at presenting this.

And the reason for going through this is that it may be that a number of you were not present at the meeting last week or did not have a chance to see the presentation and the outline of it. While recognizing it as a work in progress, it was suggested to the various workgroups that they center on this outline and to make sure that whatever standards and criteria—initial thoughts they had perhaps were linked to this framework and definition, again understanding that it will go through its evolution. So you will see the outline of the meaningful use approach that was presented last week appear in a wide variety of the initial thoughts and observations on the part of the workgroup. So I just thought we'd establish that, because, again, you'll see this multiple times.

So if I have the slides—I'm not sure who or how that is getting done; there is a clicker. [Pause] Thank you. So this is the—this is a brief overview of the composition of that workgroup. You can see the two Co-chairs listed and then a diverse array of quite talented, experienced, thoughtful, and also not shy

individuals who contributed to this conversation, so a terrific set of discussions that led to the slides that you will see here shortly.

I think a key point in the discussion is that, while obviously we're very centered on some very near-term challenges—2011, you know, figures front and center in a wide variety of our discussions—it should not be lost on all of us that the point really is to transform the health care system and to effect substantive change in our ability collectively to manage the health of a population of folks, but also the health of individuals within those populations.

So the term that's been used is this "North Star"—and make sure whatever we do for 2011, '13, '15, or subsequent years is moving as rapidly and as effectively as we possibly can to that North Star. So again, while we will get into fine-grained, close-to-the-ground conversations today and in meetings to come, let's not lose sight of the collective vision that we have.

You can see within that ultimate vision some key goals. These were adapted per the asterisk from the National Partnership. And these key goals were used as a framing set by the Meaningful Use Workgroup to make sure that whatever meaningful use objectives and measures were fronted—is that they were mapped to one or more of these key goals that you see listed here.

An example of an achievable vision to take the material on the prior slide and perhaps make it more concrete was to post this as a potential outcome. This is not necessarily the policy of the Federal Government, but just illustrates the type of gains and the type of improvements that we are capable of making as a country. And particularly, if we do our work well, in the—furthering the meaningful use of electronic health records and interoperates, we ought to be able to achieve a wide range of these outcomes that are listed here. I suspect all of us—if we were sitting here in a meeting in 2015 and we were to look back and say we actually accomplished the slide here, we would regard our work and those of all who were part of this process as being very, very well-done. So this is, again, to help us frame and be specific about what we might be able to do.

Now, in achieving that aspirational goals, there is a recognition that we have to evolve the industry—no need to repeat adoption rates that are out and about or even within your organizations that, quote, "adopted" Partners HealthCare at times, being an example where the use is not quite what it ought to be—is that we have to move the industry in stages and grow with them and both understand where we want to go but also understand the state of the industry at this point, and hence the workgroup recommendations where this is sort of viewing this as three stages with a fundamental orientation in 2011 of capturing data and sharing it, moving on in the subsequent years to advanced clinical processes, which—leading to improved outcomes. It's not inherently serial—doesn't preclude outcomes from occurring earlier than that, but nonetheless a sort of core emphasis we change by the meaningful use year here. And to show the effect or the relationship between some of the specifics that you'll see here shortly and the current reform agenda, which is not only zeroing in on access but also affordability, is that our work collectively, in addition to improving the quality of care, should be able to be leveraged to result in meaningful cost reduction, as you can see here, and also to provide the kinds of data and the kinds of analysis that will be necessary to truly understand the care processes and what's necessary to improve them.

This is a way of looking at this, and then we'll go into the specifics of 2011. I did not include in this presentation 2013 and 2015 recommendations that the workgroup put forward. You can find the full presentation that they gave along with some of the supporting material at the [healthit.hhs.gov](http://healthit.hhs.gov) Web site. As you can see, the reform arrow from left to right and then the—coming out in the—2011, 2013, and '15 a proposed meaningful use criteria, which, again, center on the evolutionary trajectory that had been presented in the prior slide.

Let me—again, this is the—Paul Tang used specifically this. We will not spend a lot of time on this, but again, just to make sure we're sort of framed to help you understand, in a variety of potential conclusions and interim discussions on the part of the workgroups, how these are being mapped. This—and you'll go back NTP goal, where the goals drafted from that have improved quality, safety, and efficiency. Within

that specific meaningful use objectives for 2011, you can see these being listed here—a heavy emphasis on capturing data in a coded format. We won't enumerate or list all of those, but you get the general idea. The—also is to make sure that there is an electronic documentation of the progress note with a proposal in 2011—is centering on the outpatient side, moving into provider order entry across a range of types, and then also some core abilities to manage populations, such as generate a list of patients by specific conditions and then following up with them to the degree that there is further care needs.

In addition to each objective that was listed in the workgroup's analysis, they also proposed some measures. And these are measures which are a mixture of quality measures, which we—are critically important to our efforts to reform the health system, but also measure that would be viewed as indications that affect meaningful use as occurring. And so, it's a combination of those two kinds of measures. You can see these here, with the first two bullets being more a reflection of meaningful use progress, and then the third bullet and all of its sub-bullets being more a reflection of improvements in care gains or at least identifying where care gains improvement are needed. Clearly, a lot of equality measures were required that a—or supported by the degree to which laboratory results, for example, are integrated well into the electronic health record.

Moving into the second category of Engaging Patients and Families, which is instrumental if we're going to make the kind of progress that we intend to make. You can see three bullets here, fewer bullets than the prior slide, but no less substantive in their impact. It's making sure that we provide patients with both access to educational materials—but also giving them access to the types of data—their medical records, their medical history, and findings surrounding their care. Again, you can see some measures that were associated with that. It measured the percentage of patients with access to these kinds of information or in which encounters are summarized.

Care coordination, which is a lot—where a lot of the exchange, particularly for routine care operations, will center, has these two major objectives for the 2011—and it has these proposed measures that would go with those objectives, both focusing on medication reconciliation, but also, for example, in the last bullet, percent of times in which a transition of care, which is—summary of care record is made available to receiving providers.

Population in public health has a couple of items here, both for contributions, immunization records—but also, going all the way to the bottom, syndromic surveillance, which, in the H1N1 crisis of the last multiple months, is made particularly salient to us. As it happens from time to time, this is the case. And again, you can see a set of measures that are associated with the achievement of those objectives.

And then last but clearly not least, because this is a bedrock upon which all of this rests, I often think that if we erode the trust of the patient for the care system, we can undermine virtually everything else we do if they're afraid to talk and afraid to engage in a candid conversation with those who are their partners in providing care. And so you can see the objectives that were listed here. We'll hear some commentary from Dixie and Steve a little bit later on about these, along with some basic measures that were presented here.

This is the last slide. And so, I didn't—I could not have possibly captured the full impact or thoughts that were conveyed during the Policy Committee meeting, but did want to make sure we all at least understood the framework—that we'll see a lot of the discussion occurring in the next couple minutes.

Here is the summary, which I think is important and well-targeted then and is today—is to realize that, obviously, this transformation requires that we engage in meaningful use. And in all the work of all of the workgroups and committees and everybody else come together in a reasonably coherent and tight and thoughtful way, we do have to evolve from where we are now to this as rapidly as we can, but also as thoughtfully as we can. And in turn, we should also leverage and not ignore the terrific work that has been done by a range of organizations leading into this conversation, both those involved in setting standard, but also providers who've been implemented these systems, etc.

And then, now you can see the last point, which is both stated by us but also stated by the President—is that if we were engaged in the reform we envision—that the work that we do and the technology we’re discussing and the meaningful use we envision is a fundamental bedrock to all of us. So with that, I am done. I don’t know, John, that there are any questions, or whether you want to move right into the panel discussion.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

I think we have—it’s a terrific overview, and thank you very much. I hope everyone shares a sense of excitement. This isn’t—you know, it’s really not about the technology. Technology is the vehicle. When I think of having reached the point where one advocates for others in their family, the difference between the health care as it exists today and health care that’s envisioned—this is really an exciting proposition. And I hope that beyond even national objectives, even at a personal level, people begin to interpret what that looks like—the difference between filling out repetitively that clipboard and not having that clipboard’s information get to the emergency encounter or even a scheduled encounter. So thank you very much for sharing that vision. Let’s ask if there are any clarifying comments or questions that the group might have. John, go ahead; you might want to—

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Sure. So one of the interesting aspects of meaningful use is that it will evolve over the next 60 days. And we, as a Standards Committee and as workgroups, have to come up with the standards and certification criteria that will support an evolving definition. And so, this is, of course, getting back to getting where the puck will be. John, I may need to comment on—over the course of the next 30 days, there’s going to be additional deliberation by the HIT Policy Committee and its workgroups—any guidance you might have for the Committee recognizing this will be an evolving set of criteria.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

I think—continue on—[inaudible] kind of trite, but it’s true— is the amount of work that’s been done in the last week is exceptional. And so, that kind of pace and that kind of quality is—whatever you’re doing or however you’re doing it, continue to do that. Obviously, what we need to do in ONC is to make sure that the meaningful use conversation that the workgroup plays through as it digests the public comment that it’s going to receive and to the degree it begins to alter its recommendations is to make sure that there is close coordination with you all and such that, if there’s a pathing added, let’s talk about that, because obviously we need to make sure that we give you guys an opportunity to contribute to that—to the [inaudible] path is being moved from year to year.

Whatever it is, we need tight interaction between the—both committees at the committee level, but also at the workgroup level. So that is our obligation, and we will keep you guys as closely in the loop as we can as they make their moves and incorporate their evolution and thought formulae. So—and that is one of the—I suspect we’ll see some short-cycle iteration between the groups as we collectively converge on a set of recommendations that they will make. And again, as David reminds us, these are recommendations to HHS, but nonetheless—is to make sure that the resulting set of recommendations that come from this group and also from the Meaningful Use Workgroup coordinate well. So anyway, we have a lot of cross-coordination that we will engage with you all in over the course of the next several days and weeks.

**Dr. David Blumenthal, National Coordinator**

Let me just add a word to that. We are all engaged in a process; it’s going to be a very open process; it’s going to be a very responsive process. The Health Information Technology Policy Committee will make recommendations to us and to you. Those recommendations will provide important guidance but not definitive guidance. They will then be part of the material that goes into a rulemaking process, which will extend over months. There is, unfortunately, no way we can give you closure around a set of specifications that you should write standards for.

On the other hand, I suspect that as you listen closely and observe, being the very knowledgeable observers that you are—that you will begin to see a kind of consensus forming, a direction, a set of things that get mentioned a lot and mentioned by lots of parties. And those, I hope, will provide you enough sort

of direction so that you can make truly useful contributions. But, you know, you can't, obviously, cover every eventuality. And so, this is—we're somewhat playing a percentage game here trying to find the sweet spot. But I think that you will—if you follow that set of directions—that set of rules, you will nevertheless be able to make a very important contribution.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Thanks, David. Questions/comments from the group? Okay, then let me—just one. Let me just back—introduce Jim Walker.

**Jim Walker, Geisinger Health System**

Jim Walker. As we plan both what meaningful use means and what the standards are going to be to support that, I think it'd be useful if we remembered that the way this is going to hit health care organizations is as a project plan that will have a timeline and costs. And the better we can do in terms of designing so that this will be—this can be transformed into a realistic project plan—in fact, I think we could use a project plan as a way of structuring our thinking. I think it will increase the likelihood that particularly small practices and small hospitals actually can execute this by 2011.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

I would agree, Jim. And sitting as a—having two hats here, one of the ONC but the other, like, a number of years being in a provider organization, is, you've got to get concrete at some point, and the sooner the better for all kinds of reasons here. I think that takes two forms in your-all's deliberations. And realizing some of the comments that David just made, one is that the clarity of direction—and so, it's sort of clear what we're going to or what needs to be done, etc. The second is, you balance—suggestion is, you balance the various criteria and standards, etc.—that which can be affected now versus that which will require more discussion, more work.

And so, obviously, 2 years is not a lot of time. And so, without undermining the whole process, the closer we get to that which exists and can be affected now, the better. I wouldn't want you to say, "Well, unless it exists, we can't touch it." That's not the point. You know, the point is that, you know, we have to make sure that there's a balance and a recognition that they—in addition to clarity of direction and clarity of actionability that you're going to actually act on some of this kind of stuff here, and I think that will factor into the conversation about—which is targeted for '11 versus '13 and '15.

Obviously, in the years that follow, there's more time to engage in conversations where we were not in consensus as an industry or to the degree that vendors have not had been a—enough time to bring this into their products. And so, that'll be part of the balance: on the one hand, pushing the system so that it sweats as it moves more upstream, but also, it's getting the bar that is achievable for the wide range of stakeholders that we have.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Just one follow-up to that. As we're planning all of this, we probably have some rough idea in our heads—maybe we don't—what percent of health care organizations we expect to succeed in 2011. And I would think that would be a measure of success for us. Do we expect it to be 95 percent of health care organizations that meet meaningful use by 2011? Do we expect it to be 70 percent or expect it to be 40 percent?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

You know, first, let me come back to your first point that—the idea of a project plan. That resonates very well with Anne Castro's point at the last meeting. And I think the graphic of the whole thing provided a sort of peeling off—helps to—specific concrete objectives in 2011, 2013, and 2015. It helps to provide the first iteration of a project plan. And I think your point about project plan—your point about success or integrative length—people need to know where they're going, and I think that that graphic is a metaphor for translating a set of—from what may feel, at certain times, like ambiguity but nevertheless embraces a set of principles—helps to define, with some degree, the opportunity for standards. And I think we see that first iteration very successfully in the workgroup activities, which, to be sure, needs another cut in terms of granularity. I think it's beyond the purview of this committee to identify, but I think what's within

this purview of this committee and Policy Committee is that—the idea is to embrace a set of standards that support meaningful use such that we can help support a transformation to health care.

Getting back to the metaphor that we've been kicking around a little bit, Paul Tang and I discussed the idea that the initial is really—describes the use of technology. And you saw in John Glaser's description that you have to have a technical infrastructure for things to occur. And the later pull is reform by achieving higher-value health care, described as higher quality and safety, greater productivity, etc.

I think, unless we can come up with the degree of specificity we need to, we don't set the stage for people to achieve the goals of transformation which are intended. I mean, in a perfect world, everyone will achieve. What we want to come up with are a set of standards that are clear—that motivated organizations and motivated community of vendors and an environment that embraces consumers can adopt, because it's a rational pathway towards putting in the infrastructure for not just meaningful use but purpose-directed meaningful use for—toward better health care.

I don't think it's possible to state, you know, "This is a goal," because we want to gain traction. We don't gain traction, we haven't supported the Office of the National Coordinator with our recommendations. If we don't define standards or we choose areas for 2011 that are gaps, not existing standards, we don't support organizations with the capacity for implementation. And so, we want to make it not just theoretically but practical for motivated organizations and individuals to be part of the use of technology toward better health care.

And I don't know that there is perfect. It will have to satisfy us. And I think part of the reason for the constitution of this group, with broad constituency and a very open process, is to put good minds together and formed in a very open way about a pathway that supports an aspiration, a very granular level of detail that can get the maximal achievement and remains practicable. That's—to say that we're practicable means it's not only practical, but the technologies exist to make it possible within that time period.

I wish I could be more specific on that, and I really don't think I can. And I also don't think, you know, that we can or would be able to ask others to define. I think our goal is to be as clear, as granular, and as effective to attract the greatest progress—the greatest capacity for adoption possible. [Inaudible], anything you want to add?

**M**

Did you want to comment on the actual numbers you'd like to achieve? I mean, wasn't there something in AARA that said something like "70 percent of all hospitals and 90 percent of all doctors achieving meaningful use by 2014"? What are your words [laugh]?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Well, the goals that have been laid out by the legislation are, all Americans will have access to electronic health records by 2014. But we, I think, in the Office of the National Coordinator, feel an obligation to get as many providers as possible a fair crack at the incentives that become available in 2011. So we want to service as many providers as we possibly can, but without sacrificing the long-term goal of changing the—improving the performance of our health system. So we have—there's a tension there, but I think it would be premature at this point to try to resolve that tension by putting out a specific number.

**Rick Stephens, The Boeing Company**

So this is Rick Stephens, and I apologize; I'm on the phone, so I can't see the dynamics in the room. But what is our process as a Standards Committee to document what our measures of success are, recognizing they're going to continue to evolve? And as I struggle as a committee member, I don't know where that information is. Am I missing something, or we've just not put it on paper? But what is our plan to go do that?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

I think our charge, quite specifically, is to support the Health IT Policy Committee's input and the charge from the National Coordinator, in return, to identify standards as well as gaps that support or need further

work for 2011, 2013, and 2015. I think you beg the obvious question: It's been alluded to that, you know, the connection between meaningful use and incentives is a hurdle, and there is an operational aspect of implementation. And really, that's not only beyond our immediate consideration, but I think it's fair to say it's—that the Office of the National Coordinator—the Policy Committee providing input will have to assess guidance in terms of metrics. In a broad sense, I think it goes right back to Jim Walker's point that we—and Dr. Blumenthal's commentary that we want to provide the framework for the most people—not just provider-side but all stakeholders—to succeed in supporting not only the use but the use pulling toward improved health care, embracing consumers, incorporating privacy, and advancing quality specifically.

**Rick Stephens, The Boeing Company**

And I appreciate that. I guess where my struggle is—I'm just a guy with a business that's got 160,000 people, recognizing we're trying to influence several million across the Nation. And we need some—in my view, some greater specificity, because as one looks as a system architect—that's the business I'm in; we architect—we have some top-level requirements, and we start flowing those down. And so, I'm struggling with our process about how we are going to, in fact, work our way down to get to the greater level of specificity, because the point that was raised earlier—eventually, this has to turn into a program plan that's going to get implemented by, you know, health care providers, doctors, employers, payers—and I'm—again, I'm struggling with the process.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Thanks, Rick. I think those are good points. And you know, just, again, to sort of take the first highlight—is that our task today is really be very granular and very specific about standards that then support the immediate tasks of 2011 as really described in the meaningful use. Let me turn to John Glaser to perhaps give another cut on levels of specificity.

Dr. John Glaser, Partners HealthCare

Yeah, I think it's a fair question and an appropriate conversation for this committee to devise ways by which it would measure its success and its contributions to the agenda, realizing that there's a broader set of reform conversations and health care outcomes, etc. But how does this committee know whether it's doing well and whether its recommendations, etc. are getting the kind of traction and adoption? I think that's a fair discussion.

We are, at this point, both in this committee and in the Policy Committee, in an anomalous time; and that is, we're trying to get a large amount of work done in a short period of time for the 2011. And so, to a large degree, for example—and I suspect you all will discuss—that might mean that standards and criteria largely exist. And so, we're going to sort of, quote, “pull it off the shelf” and put it in play. And there's a very immediate, very near-term goal, as was mentioned earlier, which is the end of August, to get some conclusions done. I think once we get to that point—that it would be appropriate to step back and say, “Well, in the years ahead, as we examine '13, '15, and the subsequent years, how is it we want to measure our success and our traction in the work that we are being asked to do and to the degree that we're now shifting from a mode of pulling stuff off the shelf to creating new standards or new criteria or whatever? You know, how does one—what's the process for that?” —I think, is—would merit some discussion. But that is, I think, a sort of—a tack that might be, you know, early fall or something along those lines. It might be useful to engage in.

**Dr. David Blumenthal, National Coordinator**

This is David Blumenthal. Let me add another bit of perspective. I would encourage the committee not to take the weight of the world on its shoulders but to define a doable task and judge itself according to that doable task. And I think the immediate task ahead of us is to write the standards that are required to implement the definition of meaningful use, which is an evolving definition. I don't think this committee has to decide the mega-policy about health reform, how many providers ought to adopt, what constitutes success for the Office of the National Coordinator or the President. If you can just define a set of objectives around developing standards that enable the implementation of a definition of meaningful use, help us think about the certification process, help us think about the implementation of the certification process—those would be incredibly important accomplishments about which you could feel very good.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Marc Overhage?

**Marc Overhage, Regenstrief Institute**

This is Marc Overhage, and I think, just to put words in Jim's mouth, in doing that task of trying to do that modestly scoped definitive objectives that you describe, one of the factors that we have to consider is how far we want people to get, because they interact; they're not independent. In other words, the standards and measurements that we end up recommending would be different if we are willing to accept a 10 percent—just making up numbers in the air—versus a 90 percent goal; they will be different. And I think that's perhaps where Jim and some others were coming from in terms of that aspect of our thinking.

**M**

And what I—the response I would make is, advise us of the consequences of your recommendations.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Sure. To that point—and one of the things we'll chat about today in our next agenda item is grading the standard's readiness of clinical operational standards and grading where we can achieve meaningful quality measurement. So this point about actually asking not only the "what" but the "when" and how mature is it and how can we achieve the maximal meaningful use—because, I mean—and this is just—be open about the discussions that I've had with several members of the group: If we were to declare, per the charge of the workgroup on clinical operations, laboratory, radiology, report exchange, e-prescribing—I think we would all—and again, this is going to be our work today—think, "You know, there are ways to achieve that in a reasonable short term. There are national organizations that could assist with that." If we require a fully functional health information exchange for every community in America by 2011, that may be setting the bar a little high. And so hence, as we put the matrix together that looks at meaningful use, the capabilities, and then a gradation sort of a score of "What is the likelihood that we could achieve this by 2011?"—that help us figure out what really goes into 2011, '13, and '15. It will get us to more meaningful use. And one would suggest, though it may not be our charge, because our charge is to deliver advice to you, that a measure of success would be implementation. How many folks are achieving meaningful use? How many transactions are flowing?

**M**

Well, I think this discussion is incredibly productive in terms of segueing to the next set of discussions, because really, you know, in one sense I feel the struggle of trying to define things in the abstract. And I know there's been good interplay between the workgroups and really appreciate committee—the workgroup Chairs assuring that because there is an interaction—interoperability between those concepts. So let's take one last comment on this and then segue so we move from an abstract description to other—and I'll come back with a couple comments of why I think this is so useful to the next set of activities. So Anne Castro?

**Anne Castro, Blue Cross and Blue Shield of South Carolina**

Thank you. I just wanted to observe that the meaningful use description, as it is today, looks like a 2015 for 2011. I think the problem of how do we fit everything into the time period that we have allotted and our need for project management and our desperate attempt to see the elephant so we can eat it one bite at a time, is that this sounds like the world. And when we're in our workgroups, I'm only responding to privacy and security; I'm not responding to the whole thing unless I go to the public comment. And my perspective is that this is huge for 2011 and what it impacts from my impression of the system requirements, the burden on the vendors—forget the standards. I think we're going to be fine on the standards; we're going to find the gaps, and we're going to put them together, because there are thousands of people working hard on this topic that we don't even know or see. But I am—I have a big concern about the whole context of the meaningful use by 2011, and I don't know when we're going to talk about that.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Well, that is the perfect segue, because that's exactly where we're headed [laugh].

**Anne Castro, Blue Cross and Blue Shield of South Carolina**

Thank you.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

John, did you want to make a comment?

Dr. John Glaser, Partners HealthCare

Just one comment, and then I'll get offstage here. Obviously, we're getting a fair amount of comments from the public at large across a range of opinions. So just talking to our official tally takers, there's about 150 comment letters we received to date, and I suspect we'll see a flurry before the week is up—and covering a range of perspectives on this thing.

I think if you—if one works on—if, to the degree at all—and I don't whether it will or won't step from 2011 to '13 to '15, and you all do the work—that says, "If it were to stay at '11, here's what we do"—that work is safe, because that becomes the work that you can then leverage whenever it occurs, whether it's in '11 or a subsequent year. So I think, while that conversation goes on of what's the right balance, the work that you have is good work that will carry forward, I think, virtually intact, regardless of the conversation that occurs in the meaningful use series of discussions we'll have in the weeks ahead.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Great. Well, as the famous philosopher Yogi Berra advised, "If you don't know where you're going, you may not get there." And in 2015, you know, it really does set a direction there; it's very aspirational. Our work, as John Glaser just offered, is really very concrete in terms of 2011—what some of the component pieces are. I think we've heard with great clarity we need a roadmap. We heard that from Rick Stephens. In terms of the operational realities, you need to tell us where you're going.

So this needs to be sort of reduced to some of the incremental pieces. And I think the graphic that Paul Tang and Farzad provided for us really gives some branches—some forks in that roadmap that get attached in 2011 to more concrete standards and 2013 and 2015 to things that are respectively concrete—2013, more aspirational; 2015 and—to your point.

I think David Blumenthal has been very constructive in his advice to us: Don't try to boil the ocean. Don't try to resolve the mega-issues of health reform. We have a pretty formidable task, and so it's reassuring to know that that limits our work only 24 hours a day instead of beyond [laugh]. So with that in mind, we—with cognizance and Jim Walker and Marc Overhage's point that the ambition of the measures themselves may determine capacity for adoption, it's really now our charge to advise the readiness to facilitate adoption in 2011.

I'm going to turn back to John Glaser to introduce the charges for the three workgroups and the Co-chairs of all those groups as we now embark on that exercise and report for—and to your point, not just the work—the extension of the work that's been going on between the Co-chairs and a number of individuals who're sort of cross-pollinating but for, again, today to reemphasize that this is a working meeting; to reconcile some of those interactivities and then have discussion on what's been accomplished; and, in the second half of the meeting, to really dive deeper into the feasibility and concrete readiness for adoption. So John Glaser, let me turn to you.

Dr. John Glaser, Partners HealthCare

Yes. What I wouldn't mind is—I don't know to what degree the various Co-chairs want to sit here versus sit where you are. You don't care? [Pause] Okay. It's kind of lonely up here, so [laugh]—and you're—

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

The workgroup Chairs actually [inaudible] do that, but the rest of the group can have dialog, because you may not be able to see people to your left or right. And so, I think it would be an easier dynamic.

Dr. John Glaser, Partners HealthCare

And you're a scary-looking group, so I don't mind having some colleagues up here.

**Wes Rishel, Gartner**

[Inaudible].

**Dr. John Glaser, Partners HealthCare**

Thanks, Wes; I appreciate that. Let me make sure I've got the sequence here right. Okay.

Let me walk through the charges and the members of the three groups, and then we'll turn over the program to the Chairs and Co-chairs who'll lead us through. This is the Clinical Operations Workgroup, with Jamie Ferguson and John Halamka Chair and Co-chair, respectively. You can see the members that are listed there—a number of folks drawn from the committee here—in addition, some individuals who've been added to the committee to round out the base of expertise and the types of experience that are necessary to do the work that we have in front of us. And then you can see the always popular John Glaser is ONC Lead there.

You'll see pretty broad similarity in both the broad and specific charges that exist for these workgroups. And so, we're looking for the recommendations coming out of them to you all regarding standards, implementation specifications, and certification criteria related to clinical operations. And there's going to be a little fuzziness to the boundaries, but a clinical operation, for example, would be documenting care or writing a prescription or a transition of care, so to speak—processes that underlie the day-in and day-out activities at the hospitals, physician practices, and other care facilities that we all serve.

And there are specific requirements that we have, which is what we engage in right now. And that is to, given a preliminary outline of meaningful use—is to identify the certification criteria, standards, and implementation specifications not only for that initial description of meaningful use but also to recognize that there was, in the legislation, eight national priorities for the country in health care, and they are required to map also into that work there. And so, we have the relatively short time frame of 2 months that needs to occur.

Janet Corrigan, who is the Chair of the Clinical Quality Workgroup—again, a terrific set of individuals who are working with her to undertake the charge that they have in front of them—and a similar broad charge with the major substitution being, rather than clinical operations—is to deal with the measures which should be both gathered but also reported and also, more importantly, used by providers and others engaged in the health care system to effect the kinds of care that we intend to make here. They also, like all the workgroups, have a verily short-term charge, which is to get a number of recommendations in place, as we mentioned before, by the end of July.

Then the last but by no means, obviously, the least is the Privacy and Security, with Dixie Baker as Chair, Steve Findlay as Co-chair, and again a nice lineup of great talent working with them. And there, there's Jodi being the ONC Lead for that group; and again, a similar charge, this time centered on the privacy and security; and again, a similar mapping—so very parallel broad and specific charges, all of them focused on—at least the specific—on the very near-term work that have; and again, extraordinary Chairs and Co-chairs, but also team members. And so, with that, I'm going to turn it over to the core of the conversation here, which will be led by my colleagues and your colleagues to my right.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So why don't we start with the Clinical Operations Workgroup? And Jamie will give you an overview of the two meetings that we've had. Generally, there's four bodies of work. We want to take that meaningful use matrix and then add to it the actual granular standards that describe work that's been done by HITSP, by implementation guide writers and SBOs, and there's some new work specific to AARA that HITSP has been working on for the last 60 days called "capabilities." These are services that are very reusable. So list that granular detail, and then put in measure of maturity and industry readiness. We've been talking about readiness this morning in order to actually achieve implementation. And then really understand what work the Clinical Operations versus the Clinical Quality Workgroup should do, because so many data elements in clinical quality actually come out of clinical operations.

And so today, we plan to outline not a finished work product—remember, it's a working session—but a straw man of how we're thinking through the framework and some examples. I'll turn it over to Jamie.

Jamie Ferguson, Kaiser Permanente

Thank you, John. Well, I think John has just gone through essentially the work—the streams of work that we have in process. We have held two meetings to date. I'm going to dig into one of the ideas that we've been discussing, which is about the relationships of the different tasks and deliverables of the respective workgroups. And the basic idea of this chart, which is included in the materials, takes the measures and objectives across the top in those top circles and says that, well, in the Clinical Quality Workgroup, they will devise the standards to certification criteria for the clinical quality meaningful use measures, but that there are aspects of clinical quality measures and objectives that have to be supported by EHR operational standards that would be determined by the Clinical Operations Workgroup and also by privacy and security standards that would be determined by the Privacy and Security Workgroup.

And so, in this case, the clinical quality obviously has aspects of the standards that would be developed directly by that workgroup, but there would be aspects of those clinical quality measures that would also be developed by each of the other workgroups in a supporting role. Similarly, in terms of clinical operations, we in the Clinical Operations Workgroup would have primary responsibility for the standards and certification criteria for our own measures, but there's a good—there are a good number of related standards in the privacy and security arena where we would rely on the work of the Privacy and Security Workgroup to support our particular measures. And so then, essentially, the sum of all of those would form a cohesive body of standards and certification criteria.

So that's the basic framework for the relationship of these that we've been discussing in the Clinical Operations Workgroup. And to some extent, we've had discussions with some members of the Quality Workgroup on that. I'll go into that in more detail shortly.

In terms of the taxonomy of readiness and ability to implement the standards, it's been subject to some of the discussion here today. Actually, John, if you don't mind, I'll turn it back to you to describe the actual taxonomy here, since it was your brainchild. But I'll just say a couple words that the taxonomy here is based on the maturity of standards and our estimated ability of the industry to deploy the standards within these various 2-year, 4-year, 6-year time frames. But it's also important to note that, in terms of things that might be implemented in 2011 or 2013, according to our recommendations, we're not only looking at what's widely used today but that can also include stretch goals. So it's not just things that are slam dunks, essentially.

#### **Dr. John Glaser, Partners HealthCare**

Great. So just to put this in simple terms, imagine—let's say, Marc, I would ask you, "Just how widely used is HL7 2.X and LOINC in the industry today?" You would probably say, "You know, those are pretty mature standards, and yeah, actually, they're pretty widely deployed." So the first Tier 1 would be, you know, if we list this as part of the meaningful use matrix, there won't be a lot of argument from payers, providers, folks in the industry, FDOs. This is a standard that's very mature, and it's been shaken out in use. There are millions of transactions—you know, NCPDP transactions for e-prescribing—sorts of things.

Now, there may be a category, too, where the standards harmonization has been done. So let's say it was done 2 years ago and that there are rollouts that are beginning, and there are good implementations that exist, but if you were to ask most of the EHR manufacturers, payers, providers, "You know, are you exchanging those transactions every day?" what they say is "It's in the project plan, and we'll be getting to it in a couple of months. You know, it's almost there." And then there's the "We actually harmonized the standard yesterday. You know, we have the standard; it just—it's never actually been tested in the real world; it's not out in the marketplace yet." And then there's the gleam in the eye: "We know we need a standard for that, and we have no idea how we're going to get there, but, you know, another year or 2, I'm sure we'll have something." And so if we put these one through four categories next to what our recommendations may be, that really will give us a sense of what we do in 2011, 2013, 2015, and what are the gaps.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Thank you. The—on the next slide, I show an example of applying this taxonomy to the actual selection and recommendation of standards. So I've taken the liberty here of adding several columns to the meaningful use matrix that was distributed. And so, as John mentioned earlier, in addition to showing the specific candidate standards in terms of the accepted and recognized HITSP constructs, I've added a column for the HITSP capabilities, which is the newer work of HITSP—essentially the newer version of the same standards—a column for gaps, where there are known gaps for meeting the particular measure—I'll go into that a little bit—and then four columns for the different categories of standards, where—to implement this measure what are the different standards that could be considered in Categories 1–4?

Now, just a couple words on the example here. The example that I've put up is to generate permissible prescriptions electronically. There's—there are HITSP constructs and HITSP capabilities that define standards for ambulatory inpatients as well as long-term care prescribing. I've got controlled substance orders listed in the gaps. Now, some people would say that, well, that's not permissible. There is some discussion about variability in terms of State boards of pharmacy, and so I've listed that as a gap to be determined—not trying to wade into the DEA rule quagmire, but just to say that, you know, there may be some determination standards that need to be made there.

And then there's also been some discussion about the completeness of the standards in terms of immunization orders, so I've got that listed as a possible gap. And then, because the standards—NCPDP SCRIPT and so forth—are generally well-defined, very well-accepted, that would go into Category 1. In Category 2 would be possible refinements for immunization orders. And then somewhere between Category 3 and 4, either 2013 or 2015, would be the controlled substance orders, to the extent that those are permissible. So that's our example of applying this taxonomy to a particular measure.

Dr. John Glaser, Partners HealthCare

So, for example, if the DEA or other agencies decided that to write a controlled substance prescription, the physician would need to get a message to their cell phone with a PIN code—therefore it's not only something that you know, a password, but it's something that you have, a device—well, then there'd be a set of standards around that. And are there well-described standards for secure messaging on cell phone? There are, but we've not actually tried to harmonize that, because we don't know the workflow yet.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So we're hoping for discussion on this concept—this idea later in the meeting here. And our proposal would be that all workgroups could adopt this format or something similar for drafting the standard selections.

One other thing that we wanted to—sorry, yes.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

I have a question about the concept of deployability, which is necessarily a judgment about how fast something that is agreed upon can be made practical. And I wonder how you think about that time frame issue, because obviously, as you said—you used some illustrations, John, where you said, "We've had it for 2 years, but no one's using it." So maybe that's a reason to put it off to 2013. But maybe in the new world of high tech, people can learn to use things faster. I don't know. How do you make that judgment?

Dr. John Glaser, Partners HealthCare

So a lot of this is the subjective judgment call of the wisdom of the committee based on their experience in the industry. And yeah, you could ask, certainly, technology questions. Is the nature of the technology of the standard very close to things that widely in use, and therefore it's just a small incremental improvement, therefore it's easy, or it's something so new there's just not a lot of learning yet, and there's not a lot of products that will be able to support it? I mean, I wish I could come up with completely objective criteria for how we classify each of these four. I think the answer will be—1 will be pretty clear,

because they're widely used. The 2 and the 3 will be judgment calls based on the experience of the people in this room.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Jim Walker, I think, had a question.

**Jim Walker, Geisinger Health System**

Yes, Jim Walker. I love the categorization. I suggest another dimension for Category 1 and 2. In our experience, one of the critical things about a standard is how much it requires on lots of other people using the standard—how much control we have. So there's some standards that are—and they're both mature standards, but some we can implement; we plug them in, and they just run. There are others, like e-prescribing—actually, the most work we did setting up e-transmission—we were already doing electronic entry—was preparing pharmacies to use the standards. And so, I think that's an important dimension. Is this something that's pretty much plug-and-play, or is this something that's entirely mature as a standard, but there are issues around the standard that will make deployment require a lot more resource?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

That's a very good point, and that's generally what we meant when we talked about if it's seen as deployable. Those are certainly some of those considerations.

**Jim Walker, Geisinger Health System**

But I would say “deployed.” I would say there's a big difference between a standard that is widely deployed—so everybody knows how much it costs, what you're going to have to do, and you just do it, and you're done—versus one that's deployable, and then when you start deploying it, you realize it's deployable, but lots of other people haven't deployed it—don't understand how to use it. You end up teaching them—or all of the issues that can be around that in terms of effective use.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So it just—it sounds to me as if those are considerations for the determination between what's 2011 and 2013 that we'll have discussions on.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So, for example, I think of HIPAA and when we initially all had to do administrative simplification, benefits eligibility as a transaction—well, a lot of people did that, and, you know, we'd use the standard—the X1240-10 standard. And therefore we started with that; it was low-hanging fruit—was probably a Tier 1. But then there were things like referral authorization and claims status inquiry and all these other transactions in HIPAA that, to your point, required a lot of interaction among a lot of parties. And so, although there was a standard and it was not so different than benefits eligibility, there was an ecosystem issue. And it took a couple of years for us to get all that interoperability implemented widely. So I think those judgments will be taken into account as we debate these categorizations.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Let's take some comments here. We'll go around with these three comments. Wes Rishel, Liz Johnson, Kevin Hutchinson, and Dixie [inaudible]—Dixie, I'm sorry.

**Dixie Baker, SAIC**

[Inaudible] Hutchinson.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Yes, well, why don't you start, Dixie?

**Dixie Baker, SAIC**

[Inaudible]—oh, there are also dependencies between standards that need to be—and there are dependencies between standards in architecture, especially in privacy and security. You know, there are,

like, SAML—you know, the TC20 depends on SAML, you know, and SAML is good for some architectures but not all architectures. And somehow, we need to capture those as well.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Great point. So we'll go Wes, Liz, Kevin, and then Doug Fridsma. And I think the convention of helping your tent card on the edge is a good way to...

**Wes Rishel, Gartner**

I think there are two kinds of barriers to be overcome in creating interoperability and implementing interchange of information. One is the distinction between that which looks really good—there have been some trials—and that which is widely used. Gartner, across all kinds of technologies, not just standards, generally makes the judgment that when 20 percent of the market is using a technology, it has reached what we call the plateau of productivity, which means that it's implementable for a predictable cost and a predictable time frame. The element of adventure has gone out of implementing it. They—that's a pretty high—by today's standards, that's a pretty high benchmark to meet for any kind of interoperability, but it's a cautionary tale that if we set a date for a criterion for meaningful use, even those standards that are—that look really good have that potential risk associated with them.

The second one that Jim commented on is the ecosystem issue. Anyone who's been in any meeting with Farzad in the last 6 weeks has probably heard about his adventures getting lab results to his e-clinical works users. The vendor handles it; the lab handles it; he has about 38 percent of his physicians getting lab results. And the reason is that—there are various reasons why the lab vendor insists on a very elaborate certification process that they won't even undertake the practices that don't generate a lot of lab orders.

So here's the question: Do we penalize the practice that has the right software, is working with the right partner, but still isn't able to get that interoperability going? Or do we incent them to try harder and pick the right partner and pick the right software by penalizing them? That is, you could argue—one of the problems Farzad has is that it sometimes takes six callbacks to get a practice to fill out the paperwork to get the data to the lab. So an incentive ought to incent people to do the things that it takes to achieve interoperability, even though it's not easy and it's not—it's easier to buy something on Amazon.com than get lab results.

But it's a variable I think we have to take into account, to which you would hope—is that the meaningful use incentives will get clinicians motivated to get the EHRs interoperability that we are going to decide together implemented. And hospitals and regional health care IT extension centers and others in the ecosystem that want to connect—we'll help these folks. So one hopes that we can set a metric for interoperability that's achievable, based on existing technology and the partners in the ecosystem, and create incentives for people to get the work done.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Yeah, I think we have a choice between how much incentive is helpful and how much incentive is disincenting. I mean, you know, [inaudible].

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Liz?

**Liz Johnson, Tennant Health Care**

Hi. My comment is about being deployable and cumulative effect. I think we need to be concerned—oh, I'm sorry. I think we need to be concerned about—not that we can determine the standards of the technology available; I think we can clearly articulate and put that forward. I think we need to look at cumulative effect on the providers that are going to need all of these new technologies and all of these new standards simultaneously to get the incentives and, more importantly, to get the quality we hope for. So what I'm saying is, if you have 25 pages of new standards that need to be—even though they're available in technology and the standards have been set, if they've never used them before, you're not asking them just to receive lab results or just to do e-prescribing; you're asking about a cumulative

change in work process. So as we set forward the standards, keeping in mind meaningful use and which year, we need to take truly into account cumulative effect.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Okay, thanks. Kevin?

**Kevin Hutchinson, Prematics Inc.**

My comment's just going back to the concept that David is bringing up around deployable versus use. And then Category 1 talks about deployable, and we were discussing e-prescribing. And just to give an example of that difference between deployable and use, there are vendors that have implemented standards to do e-prescribing in the pharmacy world that represent 95–98 percent of all pharmacies in the United States. About 85 percent of all pharmacies in the U.S. have actually implemented those standards in their stores and are activated and exchanging prescriptions electronically.

There are approximately around 120,000 physicians now on the SureScripts network being able to do prescriptions now electronically. So clearly, the standards around the subset, I should say—the standards around e-prescribing have been deployed so far—are deployable, but the use is very different. And while we have to be careful about the standards and making sure that use is part of our standards, I think our charge is to make sure that they are deployable, because next year, we'll probably have somewhere around the range of 10–12 percent of prescriptions that will go electronically in 2010—or 2009, actually. Probably this year, we'll run about 10–12 percent of prescriptions that will go electronically.

So while you have 120,000 physicians, while you have—85 percent of all pharmacies in the United States have implemented these standards, and while you have the availability of these standards to be deployable, use is still rather low.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

[Inaudible] e-prescribing is—as we think about the actual granularity of individual standards, NCPDP SCRIPT—very widely deployed. Well, how do you describe the actual med? NDC—well, that's widely deployed but not perfect for doctors to use. RxNorm—oh, that one's got a lot of promise, and it's been deployed, but not broadly. How about Structured Fig for how to take the med? Well, we probably need that; it's a good standard, but yet not implemented widely. So these are the kind of debates we're going to have to have.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Let's comment on this, and we'll go back to the presentation [inaudible]. Doug?

**Doug Fritzman**

Sure. So there's—a lot of this has been mentioned already, but I just wanted to make sure: When we think about this notion of “deployable,” sometimes it's not just about technology. And although that is sort of our charge, I think it's important to recognize that there are social, cultural, and workflow issues involved with this. And I look at least one of them in which we want to be able to compare drug formulary as one of our criteria. If somebody comes in and you haven't verified their insurance, you do a drug formulary check, and then you discover later that their insurance has changed in some way or the formulary has changed, you've got a workflow issue in which you don't have the information at the time you need to be able to make that check. And so we really have to think about this in a systems way and not simply in a sort of an isolated standards way.

**Dr. David Blumenthal, National Coordinator**

I'm going to have to leave shortly, because I have a downtown obligation, but I—before I go, I want to thank you all again, and this discussion's been very useful—very informative. The distinction between available and deployable is very important one, and your insights into what's deployable and what's not and the reasons for that would be extremely valuable.

I would encourage you, though, not to put off the writing of standards because you don't think that the standard is deployable in its current form. I think we have to at least hold open the possibility that, with the

availability of incentives and with the availability of support through extension centers and other means—that things that were deployable only with years of effort in the past could be deployable more quickly in the future, and that therefore we shouldn't constrain ourselves in writing standards that make possible change by a historical assessment of what—the timeline implementations. I would just—knowing your judgment about those two is extremely important, but don't constrain the world of possibilities by your sense of what the individual or cumulative effect of implementing the standards might be. What we have committed to doing is making those standards available to those who wish to take on this task. If some people want to push the envelope, our job is to make it possible for them to do that. And there may be people who wish to push the envelope. So let's make it possible for them to do that.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Well, David, let me just thank you, Dr. David Blumenthal, for your leadership and the great support from the Office of the National Coordinator. And I think that summary is a terrific segue back. I think we've seen the utility of the taxonomy, and I think this discussion has provided great insight into a number of others for characteristics that will be considered not only in this afternoon's work but certainly in the ongoing work of the workgroups: deployability versus availability and use; the ecosystem cumulative effect on the ability of the incentives to drive adoption; and really remembering that those incentives—may create a different social construct than the historical construct; and the point was made that it's not just the technology but the broader social aspects, including workflow and everything else that surrounds the implementation.

So I think those are good asterisks to add to a taxonomy that's very practical for the exercise that we have this afternoon and in the next tranche of work. And let me turn back to John and Jamie to continue on with this, and we'll take some comments again. I want to make sure that we have time not only to get through the stage setting, but actually to do the work that is meant to follow.

**Jamie Ferguson, Kaiser Permanente**

Thank you. There's one other idea that I wanted to present to the committee. And this is getting back to the—that previous diagram slide showing the relationships of the work of the different workgroups to each other. And this is an example of how that might be used in a practical sense. So in this case—this particular example, we have a measure of the percentage of reportable lab results that are submitted electronically. And then we looked at what's the delineation of the tasks and deliverables for that measure between the Clinical Operations Workgroup and the Clinical Quality Workgroup. And so, what we would say is that because of the charge of clinical operations having to do with EHRs and clinical operations—that the actual lab results messages, the document standards, the test coding standards, as well as the actual monitoring protocol would be a responsibility of the Clinical Operations Workgroup to determine the relevant standards; but that the Quality Workgroup would then be responsible, in this example, for defining reportable labs and the threshold percentages for the reporting of the measure.

And so, rather than devising essentially a one-size-fits-all set of rules to define the responsibilities of each of the workgroups, we are suggesting that we could very quickly agree on the division of tasks on a measure-by-measure basis in joint workgroup meetings and that we could walk through all of the proposed measures for meaningful use and split things out in a manner similar to this, probably very quickly so we can get on with our work inside of each of the workgroups.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

And to that point, so the chairs come together, and with the advice of some of you, say—you know, just generally, things that are the measure and the framework of devising the measure—well, that's probably clinical quality. The transmission of the granular data elements—the lab, the med, the date/time stamp—oh, that's probably clinical operations. And then you guys are going to have to decide together if there were a summary standard with numerators and denominators. You know, is that operations, or is it quality? And so I'm certain that we could achieve, in very short order, a nice division of labor in our work ahead. We have a month to finish this. We'll proceed rapidly.

**Jamie Ferguson, Kaiser Permanente**

So just to wrap up, then, in terms of the Clinical Operations Workgroup, we—in terms of our next steps, we would like to reach agreement on our approach to these workgroup activities, including taxonomy, the discussion that we've just had; our approach to documenting the standard selection, if we can use the extended matrix with the extra columns in a consistent way; and then if we can agree on the deliverables and tasks and how they're coordinated in terms of dividing the responsibilities across the workgroups. That would set the stage for both cross-workgroup sessions for that—for determining that coordination and then our workgroup sessions to actually craft the recommendations that, as John just said, are due in a month.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So comments? [Pause, inaudible] a lot of comment from Jim Walker, so let me apologize to Jim and bring him in, and then I think we're going to be—quality—or maybe one more comment, and we'll go to quality. I want to make sure we preserve time for the next tranche of work. Jim?

**Jim Walker, Geisinger Health System**

Thanks, John. You know, maybe one of the ways we can categorize standards is the likelihood that an organization that wants to execute them can. So in Farzad's experience, which has got to be one of the best-put-together organizations in the country, far better than the bulk of the people that will be trying to meet these standards, only, what, 62 percent of the people who do everything they need to do to receive lab reports electronically can do so.... I'm sorry? I thought it was 38 percent didn't have it.... Okay, only 38 percent can *do* it. It's worse than I thought.

You know, the 15 percent of pharmacies that aren't participating—I can tell you who they are; Kevin can correct me: They're rural, independent pharmacies that don't have resources and are unlikely to be any more connected in 5 years than they are now. Many of them will just go out of business if that becomes the breakpoint for them. And so, if we could sort of identify what—the likelihood that a willing organization who puts a reasonable amount of effort into it can execute a standard and then think in terms of how are we going to let these people document that, sort of like when I don't give an aspirin to a patient because they decline the aspirin—how do I document that and still get credit for performance? I think those would be two useful ways to approach the sort of meta-data about these standards.

And by the way, you know, we build every standard that is either mature or in development in our health information exchange area. It charts 100 percent of all orders, 100 percent of all notes—100 percent of everything that happens in our organization is done electronically. We have, well, almost 100 percent of e-transmission of medications. We can't do it for mail order pharmacies.

So this isn't—I mean, we're very grateful for your harmonization—the development of standards, and we regard it as critical to going forward. My concern is about organizations that don't have remotely as much resource as we do, knowing how hard it is and how much resource it takes for us to implement standards so that, as we roll this out, we are nuancing it in a way that really does get us where we want to go as fast as possible.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Dixie, did you have a comment before we go to Janet and the Quality Committee?

**Dixie Baker**

Yes. This may be a security-specific concern, but it may not be as well. There are standards that would be applied to a product that's implemented, like security standards that are applied to an EHR product that's sold. And there are standards that would be applied to the infrastructure in which that product would be integrated. And I think the maturity of those two may be—we may be allowed a little difference between the two, you know. And I think that may apply to all three; I'm not sure. But I know it applies to security.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Right. And so, to Dixie's point, you know, if you listen to her presentation, if an EHR had a complex authentication mechanism but you're using one username and password for everyone in your

organization, I think all of us would agree that's horrific and it's wrong. It's not a product fault; it's an implementation fault. And so we have to actually provide some best-practice guidance as well.

**Dixie Baker**

Right, and the standards for those best practices, as well as standards for the technology that they implement. You know, you should make it a little easier, especially for large—for small practices. You know, we need to think about how easy it is for them to implement versus a product company.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

And certainly based on—

**Dixie Baker**

Not to make it harder on the product companies, but—

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Based on the definition of medical use and the standards necessary, we will end up, even in clinical operations, declaring best practices, because if you need a coded problem list, you'd better start doing electronic problem lists that aren't free text. So it probably will go across all of our organizations. If you want a cord blood pressure, you actually have to put it in real numerical text and not, you know, "120 mm Hg" or something that is not personable.

**Dixie Baker**

Yes, two environments.

**M**

Right.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Well, I think, if we weren't certain that this is a dynamic process, a great example of that. Let's move now on to really the area that is the point, which is the improvement of health care. And I first want to thank Jimmy Ferguson and John Halamka for work today and all the members of your workgroup. And obviously, I know we had some discussion earlier about interactions and relationships. And so, in addition to the value-added by the taxonomy and the discussion that's superimposed, there's a great diagram in particular that shows the interrelationships and the work that's ongoing, augmented by today—I think is very valuable.

Janet Corrigan brings not just the recent work with the Clinical Quality Group but the HITEP and the terrific segue of work that's ongoing in Quality. And Janet, thank you so much for the leadership that you provided to Clinical Quality and—look forward to your reports—discussion.

**Janet Corrigan, National Quality Forum**

Thanks very much, John. Let me also thank the workgroup members of the Quality Workgroup. It's been a terrific group. We have had two calls so far, and I'm sure there's going to be quite a few more in the next—this month or so, because we've got our work cut out for us.

The work of the Quality Workgroup is focused to a great extent on identifying those standardized quality measures that can be used to operationalize the sort of the measure descriptions or concepts that the Policy Committee put forward. For those of you who are not as familiar with the sort of the quality measurement world, the National Quality Forum endorses standardized quality measures that are then used extensively by public and private purchasers, Federal/State Governments, and others. There are about 500 standardized quality measures that have been endorsed by NQF, and for the most part, those measures have not been specified properly to be used in an EHR environment. So the numerators, the denominators, the exclusionary criteria—a good deal of work needs to be done to retool or re-specify those measures to be able to operationalize them using EHRs and PHRs.

Fortunately, over the last year and a half or so, the Health Information Technology Expert Panel, under the guidance of Paul Tang, who chairs that for us—and some of the members of the Standards Committee sit on HITEP and are very familiar with its work. They have been working now for about a year and a half. They're essentially in the second phase of their work to identify not only what data types need to be captured within electronic health records to be able to support quality measurement, but also to specify in much greater detail, in many ways to define, a quality measure and its various characteristics that can then be used as feedback to the stewards of these measures to go through the process of retooling and re-specifying. So as we pursue our work here, there is a parallel effort and a lot of activity going on to ready those measures, to retool the standardized measures that will in turn be used to operationalize meaningful use.

What I'm going to cover today are really three things in my comments. First, I'm going to touch a little bit more on the work of the Health Information Technology Expert Panel and where it is at and how it feeds into—directly to the Quality Workgroup. Then second, we're going to talk a little bit about a meaningful use matrix that is being constructed by the workgroup that essentially takes the quality measure concept that the Policy Committee gave to us, identifies specific endorsed standardized quality measures that correspond to it, and in turn then trace that over to the HITSP capabilities and eventually to the certification criteria that will be needed. And then third, I'll give a couple examples of measures and where we're at in the process. I want to emphasize that, once again, this is still early in the game. This is the current thinking of the workgroup and it undoubtedly will evolve as we go forward.

The HITEP, so far in its first phase of its work—it essentially took high-priority measures, a subset of measures, a few dozen or so that have been used extensively—are currently being used by CMS for pay-for-performance and public reporting purposes. And it then traced down to particular data categories and data types that are needed within the electronic health records/PHRs to be able to support calculation/generation of that measurement information. And essentially, there were 11 categories of data that were defined during this first phase, and in turn there were also 38 data types. And this is really what needs to be there to be able to support quality measurement.

In addition to this, a lot of work has been done in the last 6–8 months or so to identify a standardized quality data element. And this is really the core work that's needed to provide guidance to all of the measure stewards, and there are dozens of groups that own the various—and take responsibility for maintaining the various standardized measures that are used by public- and private-sector programs.

A quality data element—and this is an example of one that corresponds to the standard element of diagnosis, in this case giving the example of diabetes. And here what you see is that there's a quality data type, whether it's an active or an inactive diagnosis of diabetes. And in turn, it also involves specifying a code set, which is the ICD-9 in this case, and a code list that then are used to fully specify that quality data element.

Work is also under way to identify where and how in the data flow of actual work this information should be captured. So then, using once again the example of diabetes, here we not only need to know that we need to do this in ICD-9, the code set, but in addition to that, what the group is doing, what HITEP is doing is to identify the best source of this information (in this case, it's the clinician), the—who should be responsible for recording the information (once again, it's the clinician), the setting to which it is applicable (here the example is ambulatory), and exactly where one would find this information—what field. And in this case, it would come from the problem list.

There's other examples here that you see, where we're talking about diabetes and medication dispense. Here, using RxNorm, the source is the pharmacist; the recorder is the pharmacist; the setting is ambulatory; the field is the medication list. Diabetes also involving laboratory results, here using LOINC: The source is the lab device; the recorder's lab device; the setting is ambulatory; the field is lab results. So really going to a detail to identify, in the data flow overall, source, recorder, setting and health record field.

Now, what the Quality Workgroup has been doing is to start to construct what we call the Meaningful Use Evaluation Matrix. And here, what you see in the first three columns are ones that come from the policy matrix, the care goals, the 2011 objectives, and the 2011 brief measure description. What we have done now is to then look to see where there are existing and QF-endorsed performance measures. And many of those are listed here as an example. In this particular case—and those measures in great detail what the numerator—the denominator is and the exclusionary list—and then, in turn, also to translate that over into the HITEP quality dataset data types that will be needed in order to support this—and last but not least, the HITSP capabilities that correspond as well.

And let me take you through an example for a particular measure. Now, here we have the HITSP measure—meaningful use measure, which is percent of hypertensive patients with blood pressure under control. Now here, there is an existing performance measure that has been used extensively controlling high blood pressure. The description of the measure is the percent of patients with their last blood pressure less than 140/80. This particular measure is owned by the National Committee for Quality Assurance. And you see the description of the numerator: patients with last blood pressure measurement adequately controlled to systolic blood pressure less than 140, diastolic blood pressure less than 80 during the measurement year. The denominator is all patients greater than 18 years of age with a diagnosis of hypertension in the first 6 months of the measurement year or any time prior. Now this, in turn—in order to be able to support this measure, what’s needed in the quality dataset data types, we’ve got to have age, hypertension diagnosis, ambulatory encounter, systolic blood pressure results—and then the HITSP capability is the communication structure documents using CDA.

The second example would be the percent of permissible prescriptions transmitted electronically. This particular measure is the adoption of medication. “E-prescribing” is the title. It documents whether a provider has adopted a qualified e-prescribing system and the extent of use in the ambulatory setting. The particular measure steward or owner is CMS, and it’s a structural measure: a G-code for each patient for whom e-prescription is written. Now, in order for this measure to be retooled and used with electronic health records, essentially the EHRs need to capture. The e-prescribing system needs to be present and performed—system reasons for not using e-prescribing. The HITSP capability would be the communication of structure documents using CDA, issue ambulatory and long-term prescriptions, and issue hospital prescription.

So that’s essentially two examples of measures. We are going to be going through dozens and dozens of measures over the next week or 2. The next steps will be to identify a complete set of measures and determine which ones can be retooled to meet anticipated time frames. We’ll have to then map those over to the HITEP data types and the necessary HITSP capabilities and identify certification criteria.

Now, as Jamie indicated, there’s a lot of collaborative work that needs to be done here and clear handoff. The focus of the Quality Workgroup heavily will be, obviously, on identifying these specific measures to be used and where they’re at in the retooling process, because that needs to be taking place in parallel. And there are a subset of measures that are—have been retooled by the measure stewards and others that are under development, and we’re attempting to coordinate that work. And probably, what we’ll have is a joint meeting of the two workgroups to be able to make sure that we coordinate extensively, especially when it comes to the HITSP and the certification criteria component of this work.

I want to acknowledge the contributions of all the Workgroup members, but in particular Floyd Eisenberg, who happens to be leading the HITEP work, which is very convenient to have him as a member. And Floyd did the lion’s share of the work on some of our initial evaluation matrix as well as going in and identifying the very specific endorsed measures that could be used to operationalize these concepts. So thank you, Floyd, for your contribution. Glad to take any questions.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Absolutely terrific. Thank you very much for that. And Chris Chute has his card up first, so we’ll start over there.

**Chris Chute, Mayo Clinic**

Thank you. That was actually a very illuminating overview, and I'm actually impressed with the degree of organization and thought that has gone into these high-tech specifications. That being said, it does raise, from where I sit in a more—how do I phrase this—technical-standards-perspective the obviously dissonance between what you're characterizing as data types and what you're characterizing as these quality-identified units with what, in my simple head, I see as data types coming out of, say, the template world, the archetype world, the HL7 data type world.

And what I would hope to see—and perhaps this could be the basis, Jamie, of our interaction with Quality—is, “All right, how do these HITSP data types, as you're calling them, really map and correspond to what I think of as the nuts and bolts of EMR specifications, which gets down to dorky things like value sets and units of measure and very, very detailed specification of how exactly does that data type unfold?” Because if you treat them as these large aggregates—I mean, you have a lovely page here of 11 categories and 38 data types that, in my mind, are actually very complex entities that have within them specified data types and components, but I can't see my way clear from this level of specificity to what I would consider to be a clinically interoperable specificity. And furthermore—and I'm certainly aware of your connections with HITSP, and I've been out of HITSP for a little while, so I may be dated; but to embrace only CDA document interoperability as a HITSP element seems regrettable, given the opportunity, I think, to take much more detailed and much more specific elements that could perhaps be bound in a CDA, but it hopefully would be much deeper than that.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Why don't I start with a response to that question? And that is, we recognize there are two general kinds of standards: those that are messaging standards, a transient message that goes from place to place like a routable e-prescription; those that are a persistent document. When you look at the data types, they map to both kinds. So when you talk about, say, medication—say, medication order—is probably a transient message; a medication administration may be a document. I mean, the fact that there are multiple constructs within HITSP that have supported these data types—Floyd, Jamie, and others have worked together over the last year on a variety—interoperability specifications of these mappings. And I think the work that has to be done between these two folks over the course of the next month is to make sure, given the nine specific quality measures and the work that you do from HITEP, that it does map to both the CDA document and the more granular messages, NCPDP, X12, etc.

**M**

Any other comments you'd like?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

The other comment I would make, Chris, in response is that I think when we get into the—looking at the detailed work that supports what Janet has just presented and looking at that for all the measures, I think you'll be favorably impressed with the level of detail and specificity that's in there. At the same time, I think it'll be some of the work of our Workgroup, from an EHR clinical operations perspective, to make determination/recommendations on what can be implemented in, for example, 2011 versus 2013 and also to do any where we see gaps.

**M**

I just wanted to comment: We've been talking about readiness. I think we would agree that lab transactions today using messaging standards are probably ready. E-prescribing using messaging center—probably ready. The use of widespread deployed clinical document architecture may be pushing the envelope a bit. So the question we'll also have to ask is, “How many of these metrics can easily be achievable with the lab, RAD, the typical e-prescribing, the kinds of things that are already flowing so ubiquitously today?”

**M**

Thanks. And I think, at a more broader level, the implication of “matrix” is really to go from the emerging concept down to this—a granular level so that the representation is effective and all dimensions the group just outlined. Wes?

**Wes Rishel, Gartner**

Yeah, just a quick response to Chris and then a question for Janet: I think this sort of dissonance between what a researcher calls a data element and what a computer nerd like me calls a data element is about as profound as what you see when you go to a football game in Dallas or London. And I know a lot of great work is going on systematically, bridging that gap. My fear is, we look at the measures that Jamie described for implementability; in the early years, we will be looking for ad hoc methods of bridging that gap rather than systematic methods, which means a lot of detailed specifications.

I—Janet, in your presentation, there was a measure—all of the patients in the—all of the patients who had had a diagnosis of hypertension at least 6 months into the year or any time in the past. And I think as we look at meaningful use criteria for EMRs, the def—as opposed to four organizations or regions or whatever, the definition of all—what—you know, what—do we have a—what it is—what is this issue here with “all”? Is it—typically, if you look at the stuff that’s done in California, a payer defines the population. A patient is in the population for a provider because the payer has signed up to that provider, presumably with the patient—at the patient’s request. And then you have access to patients who aren’t going to the doctor. And that’s really a lot of what you want with hypertension, with a lot of measures. But if we are measuring meaningful use of an EMR by a practice, is it simply all the patients they’ve seen, or is it all the patients they’ve been assigned? And if so, how do we put that definition under their control to create the divisor? Thanks.

**Janet Corrigan, National Quality Forum**

Well, it’s a great question, Wes, and as you might imagine, it is a bit of a hot button in the quality world as well. Essentially, it’s—we call it the issue of attribution: who decides whether or not a provider is responsible for what population they are responsible for. And it goes even further—the debate in the Quality community, because even though that patient may have come in, there’s a real debate about whether or not the provider can and should be held accountable for whether or not their blood pressure is under control, because some of that is in the control of the individual patient and their compliance with the treatment program—so the whole set of issues around attribution. It’s done differently by different payers, and it’s done differently for different purposes and objectives. You might have different attribution rules if you’re just publicly reporting the data versus if you’re imbedding it in pay-for-performance programs. In this case, you might have different attribution rules depending upon—for the meaningful use and the incentives that are associated with AARA. So I think that that’s an issue that has to be thought through in terms of how the measures are defined as specifically for AARA. You know, that’s a very important issue—can be done in multiple—in different ways.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

John Glaser, I know you’ve wanted to comment.

**John Glaser, Partners HealthCare**

A sort of suggestion [inaudible] question, Janet: Some of the feedback we received already from the public comment on the sort of material presented last week is in—twofold. One is that a lot of the measures these areas centered on primary care, which is a fair discussion. And there’s been a couple of threads about “Are there a set of measures which are physician invariant?” So whether you’re primary care or an ophthalmologist or a surgeon, these would be measures you would have consistently across the board. So you might have a core physician-oriented set of measures with a class devoted to primary care, a class devoted to surgery, etc.

The other thing to be mindful of in our case is the Medicaid incentives, which can also go to other health care professionals—nurse practitioners, physician assistants here—and whether or not there are measures there. So part of it is—and I don’t know how far we can get in the course of the conversations that you all are having—is, in addition to the response to the set that is there—is whether there’s a subset that is physician invariant. Is there a subset which is provider, period, including the range of Medicaid- and Medicare-eligible folks? And particularly for the specialists is whether there’s an additional set or how far along we are in the additional set of specialty-specific measures. Now, that may be boiling too much to take on all at once, but I’d be interested in your sort of initial reactions to that stratification, so to speak.

**Janet Corrigan, National Quality Forum**

I think it's going to take us to the next level as sort of analysis and selection of measures. There are measures that clearly—that are more neutral and not specific to a particular specialty area, in things like patient engagement to understanding of their treatment plan, care coordination measures and handoffs—all of those really are going to be important, whether you're primary care or you're in a specialty area.

There—and we have also made considerable progress in the last year and a half or 2 on measures that are specialty and subspecialty specific. There aren't large numbers, but for most of the major specialty areas, there are two or three that are applicable and in use by CMS and others. So we'll have to go back through and take a pass at it through that lens.

And there are also many measures that are applicable to the full care team, whether it's the nurse practitioner or others. And indeed, we try very hard to encourage measures to be specified and applied that way, especially if you're in a setting where there is a well-defined care team and it's not just an individual clinician on their own. So many of the measures are neutral to the specific provider.

But I think it's a great point, John, and we didn't really look at it through that lens in this first initial pass as we started pulling out measures. We'll have to go back through—as I said, there's about 500 endorsed measures that we have and probably 200 in the pipeline. So this is an on—growing area that will evolve if we can't hit—if we can't get the right set—a complete set of measures that addresses all those concerns for 2011, and we won't be able to. There will clearly be gaps for many specialty and subspecialty areas. We clearly can begin to achieve that, I think, though, in the subsequent years.

**Dr. Jon Perlin, HCA Inc.**

What a terrific dialogue there. And I just see a couple more columns in the matrix as the provider types that are applicable—and, you know, I know it's tempting—and used an example. And again, I just want to stress really for all listening today that this is really a set of examples, not definitive in terms of specifics. But it's tempting when thinking of quality and measures to think of process measures with numerators and denominators affecting something like blood pressure, medication or an immunization, etc. But your point, Jim—and I think it's so well-taken—that there are also measures about the intent of this—the continuity of care between environments that engage many provider types and also get at other aspects of quality and better-coordinated health care more broadly.

Let's take a last comment here from David McCallie, and then I want to get to our privacy and security discussion before we get to the work of the second half of the meeting. David?

**David McCallie, Cerner Corporation**

Thank you, Jonathan. In the distinction between a message and a document, in either case, something has to trigger the actual capture of the event that gets measured. And I wonder if you are leaning towards suppositions about where that capture occurs and what those triggers would be. Is the accumulation of the measure something that is likely to be done within the EMR system, or would it require transmission to an external system? Would it require the existence of an HIE, for example, as the point of capture? It's important, obviously, to define what you're capturing first. But are you beginning to move towards assumptions about when and where and how the data will be accumulated?

**Janet Corrigan, National Quality Forum**

Certainly there is, yes, quite a bit of work in HITEP to try to think through from who—the source, the recorder, the setting, and the specific field you'd find it in. So I think if you go back to the earlier example that was given here, you'll see that as that work progresses, taking, for example, the medication dispensed, it does begin to identify who the source—being the pharmacist—the recorder, the pharmacist, and the setting, and the actual field. So that begins to, I think, address some of your questions. John, do you want to elaborate? You've been involved in this.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

As a member of HITEP, I mean, to your point, it is not only the metric; it's the workflow. So at what point is there a trigger that says, "Yes, I gather this," and who was the recorder? And you might imagine three

different architectures. We were totally architecture neutral in HITEP, but one architecture would be, the EHR or software itself has internally a registry that is capable of reporting on some of these metrics. Two, there is an external registry; that is, there is some nightly extract that takes place. And it may be not an HIE; it may be local to the organization or the integrated delivery network or... And then three, it could be a registry sitting at an HIE level, where, yes, there is this export of selected data elements that goes on an interval basis to a more community-oriented registry. But I don't think we've made any assumptions on which of those three will be used.

**M**

And the answer is "Why not all?"

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

It depends on your circumstance.

**M**

Terrific. Let me thank everyone for a terrific discussion on this. And again, I think many insights that—will be useful to the next iteration of activities. And thank you very much, Janet, for sharing and recognizing what Eisenberg—for all the contributions, and all the members of the Workgroup thank you.

Dixie Baker and Steven Findlay have co-chaired the Privacy and Security Workgroup and will present initial reactions. Let me just begin by thanking them and the members of the Workgroup. It's been instructed to me to follow along, because it is constantly reinforced—the point that Jodi Daniels always makes so effectively—that beyond the obligation to assuring appropriate privacy and security, this is also a fuel to assure the capabilities of everything else that's intended. And I think, in that regard, you just make traditional—or tremendous contributions in the framings. Let me turn to Dixie Baker for your report. Thanks.

**Dixie Baker, SAIC**

Great, thank you. Let me turn [inaudible]. In our first—we've had two meetings, two teleconferences, and in our first teleconference, John Glaser said, "You know, your work is way different from the other two." And I think hearing this today, it's reinforced that fact. It is very different, but in fact, security in particular is absolutely essential to people actually using these systems in a meaningful way as you guys just have—are laying out.

So we've—the—I'm going to give you—thank you—I'm going to give you an update on where we are. We've laid out five steps that we're going through. And the first—the—almost right off bat, we felt that there were—we could see some need for improvements in the policy definition for meaningful—for privacy and security measures for meaningful use. And so, we set forth on reviewing that matrix itself, and I'll present some of our recommendations to you today.

Our second step is to map those 2001 measures into specific features and functions in three categories. And this is really, I think, where the divergence between our workgroup and the other two is—begins to become obvious—is, some of the security features and functions will be implemented in products that will be certified. And those certified products—if I'm going to CMS and asking for reimbursement on meaningful use kind of an argument, I just say, "Oh, I bought this certified product," and that category of features and functions will have been taken care of.

But in addition to the fea—to the security that is inherent in the products themselves, there are also IT infrastructure features and functions that will need to be implemented that that product will assume are in place. So we'll need to specify that category as well—you know, the category of requirements for the product itself, requirements for the IT infrastructure, and then the third is the operational environment in which the system will operate.

So then the third step—once we've set forth those features and functions or requirements, we'll map those to standards and certification criteria that will ultimately be used to determine, you know, whether

the IT's being used meaningfully. And then finally, we'll recommend the standards and certification criteria to the ONC.

The next several slides, as I'm not [inaudible]—oh, okay, good. Thank you, whomever. I'll discuss briefly the recommendations that we're making to the matrix itself. This is the matrix that we've developed by the Policy Committee and handed over to us. On the left-hand column, you see, the goals that are set forth in the matrix as it stands were to ensure privacy and security protections for confidential information through operating procedures—policies, procedures, and technologies in compliance with applicable law. We felt that specifically directing this goal at confidential information is ignoring the enormous contribution that security makes to the quality of care and to patient safety, in fact. Security measures do not just protect confidential information; they also protect the integrity of data and also the availability of essential services and information. And I'll pretty much guarantee that if we put EHR technology out there and the doctors feel that they cannot trust that technology to protect the integrity of their data, and if they can't trust that technology to be available when they need it, it will fail no matter what we do here in the meaningful use activity. And then the second goal that they laid out was transparency of data.

So our workgroup wants to recommend that an additional goal would be to protect individual privacy, care quality and patient safety, and population health. And then we wanted to—we suggest editing the second bullet to delete the—ensure privacy and security protections but make it protect confidential information and essential EHR services through operating procedures.

We also—one of our members brought up the fact that transparency of data sharing is important to providers as well. You know, entities—insurance companies, for example, that they provide information to—they need to know what they do with that information. So our recommendation is to change it to just provide transparency of data sharing.

The next slide sets forth the objective. And the Policy Committee came up with two objectives: compliance with HIPAA Privacy and Security rules and State laws, and compliance with the fair data sharing practices set forth in the nationwide privacy and security framework. We wanted to add to compliance with HIPAA privacy and security rules the AARA privacy and security provisions. And we feel that this is essential in order to meet one of the objectives of the pop—personal health—I can't remember what it was called—the consumer access to information objective; it's earlier in the matrix.

#### **M**

And it's disclosures.

#### **Dixie Baker, SAIC**

And its disclosures, yes, yes. And so, we wanted to make sure that the AARA provision that electronic health record be made available to consumers be incorporated. And we would do that by just adding AARA privacy and security provisions. And we also wanted to add, for the availability concern—patient safety concern, that—assure that EHR services and information are available when needed at the point of care.

The next slide is a continuation of the objectives. And we recommended two more bullets; one is to enable EHR data to be used for population health purposes while minimizing privacy risk. You'll remember that the overall goal of the Policy Committee was to protect the population's health through the implementation of electronic health records. So it's essential that the population health element be in there.

And then finally, to assure that measures are attainable by small practices as well as large hospitals and integrated delivery networks. This will ultimately translate into the standards that we prescribed, because some of them can be implemented by small practices, and others really by definition are for—are really more appropriate for large integrated delivery networks or large hospitals.

Okay, the next slide is the third—the measures for—and all of these are for 2011. The Policy Committee recommended full compliance as the measures—full compliance with HIPAA; secondly, that an entity

under investigation for HIPAA Privacy and Security violation can't achieve meaningful use until they are cleared by the investigating authority; and third is to conduct and update a security risk assessment.

First of all, it wasn't clear—as you know, with AARA, you know, States can bring action for a violation of HIPAA now. And so, we wanted to make it really clear who was investigate—was the investigation under, and so we wanted to insert “by the HHS Office of Civil Rights.” And secondly, we felt that, you know, really to keep it on hold until they're cleared by the investigating authority—we all know that can take forever, and so our recommendation is to put that—“until a plan has been put in place to correct the fault and address the harm.”

Okay, the next page, which is the security risk assessment—we simply wanted to make it clear that this would be a risk assessment appropriate to the size of the organization, and it will vary. We wanted to add several measures—two measures. One is provide measures to assure the timely availability of services and information required for safe care, again, you know, addressing the idea that the care—unless the services and information are available and you can trust the data—trust the information system, this whole undertaking won't be successful.

And then finally, on the next slide is provide anonymized and pseudonymized health data to public health agencies. HIPAA enables the sharing of protected health information with public health, but public health—it's limited to a limited dataset, and it has to be audited. But health—public health organizations generally try to at least anonymize it. In the anonymizing case, they take the names out and just the essential descriptors out. And in—when they pseudonymize it, they put a link so that if they determine that a particular identifier is connected with an outbreak of a disease that they need to go back to, the hospital is able to relink it. So these two capabilities—there are HITSP standards for both of them, and we felt that they should be included in there, in the 2011 time frame. So those are our recommendations.

The next slide—our next step is to segment the—is to specify features and functions required and to segment them into the three categories. I wanted to give you a couple of examples. The first one, I think, is familiar to you: products that can be purchased. This is where the—you know, the organization—the provider that's requesting reimbursement says, “I bought a certified EHR, so I am entitled to the reimbursement.”

The second is the IT infrastructure. For example, they have to provide identity management to provide the identity to the EHR so that it can control access within it and do the auditing, etc. Secure e-mail might be something else that we would want to include in that. These are just examples that the environment provides outside the product.

And then finally, we all know that HIPAA requires an enormous number of administrative—has an enormous number of administrative safeguards as well as physical security safeguards that—in order to show their HIPAA compliance, there will need to be standards and best practices and criteria in that category.

Okay, and in the last slide, I just provide an example of where you might have, you know, the full compliance with HIPAA privacy and security rules as the measure. And we break it out into features and functions in these three areas. We specify standards starting with the HIPAA—the HITSP standards as well as the HIPAA Technical Note 900, which is a very good document, comprehensive on security. But also we'll draw from NIST—has a lot of standards in the area of security—as well as ISO and OASIS and then translate those into certification criteria.

Are there questions? Comments?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Well, let me propose that we have three activities to accomplish, and this will serve as a trans—good transition between this section and the next section. So the first is—and I want to outline them; then we'll go on to putting them in context and discussion. And first, thank you for just terrific work. First is that you

proposed a number of amended objectives, and—forget [inaudible] group. Are there any objections to proceeding with those objectives as amended—as recommended by the workgroup?

**Marc Overhage, Regenstrief Institute**

Marc Overhage. It's not an objection but a question related to the public health one, and in particular, since the sort of very explicit anonymization/de-identification statement when, in fact, public health has an exception and, in particular, where their new FDA commissioners push for the FDA as a public health entity. How does that...?

**Dixie Baker, SAIC**

How do we what? How do we—

**Marc Overhage, Regenstrief Institute**

How do you reconcile—I guess I think that's an overly strong—strikes me as an overly strong recommendation, given the exemptions that are provided within HIPAA for public health organizations.

**Dixie Baker, SAIC**

Yeah, we were recommending that we also include the anonymization and pseudonymization.

**Marc Overhage, Regenstrief Institute**

Yes.

**Dixie Baker, SAIC**

We're not recommending that they use those as operational approaches. We're recommending that the environment be capable of doing that—of doing those—of doing anonymization and pseudonymization.

**Marc Overhage, Regenstrief Institute**

But if you're not going to deliver data anonymized or pseudonymized, why require somebody to have the capability to do it?

**Dixie Baker, SAIC**

Oh, you're saying it should say "if you're required to deliver it in that way" or...?

**Marc Overhage, Regenstrief Institute**

Let me put that in the form of a question. If that were caveat-ed as required, then it would—

**Dixie Baker, SAIC**

Yeah. Yeah.

**M**

In previous use cases that we have been given, we have been asked to include these capabilities, because specific entities may want less than the full demographic identifier—may not need them. In the interest of data being at risk and not having your social security number and these sorts of things, it seemed like a good practice. But I think your comment is fair, and that is, depending on the nature of the organization—

**Dixie Baker, SAIC**

Of the organization, right, a large—

**M**

We may not require pseudonymization or anonymization.

**M**

Okay, let's hit Jodi Daniel, because I—this particular [inaudible] expertise in this area.

**Jodi Daniel, ONC**

Yeah, so two questions on this, one on the same topic. I'll start with that first, since we're having this conversation. The matrix—meaningful use matrix that the Policy Committee discussed last week has something similar for measures—objectives and measures in 2013. Are you suggesting that that be moved up to 2011, or are you suggesting that this is a different standard than was put forth in that matrix for 2013?

**Dixie Baker, SAIC**

Well, I don't know what was brought up last week.

**Jodi Daniel, ONC**

It's—well, in the materials we have here, it says “provide summarized or de-identified data when sufficient to satisfy data request for population health purposes,” which seems very similar—

**Dixie Baker, SAIC**

Oh, in the—yeah. Right. No, that addresses the limited dataset or minimal use, but it doesn't address the capability to pseudonymize data to link it back. But I would agree that—I mean, this really points out an example of how the same objective is not equally applicable to small providers, for example, and a small provider shouldn't be expected to pseudonymize data, but large hospitals and integrated delivery networks probably will.

**Jodi Daniel, ONC**

So then, I'm wondering if perhaps the—hearing what Marc is saying about the—when necessary, if some of the similar language that, when sufficient to satisfying a data request—if that could be mimicked in your recommendation to address that issue.

**Dixie Baker, SAIC**

Yeah. Yeah, that's good.

**Jodi Daniel, ONC**

And while I have the floor, can I just—one other comment that I wanted to make on this—and this is purely from a legal standpoint: On the 2011 measures, where it says “[inaudible] under investigation by HHS Office for Civil Rights for HIPAA privacy or security violation”—and I understand you were saying that your point was to not bring in all of the State—potential State enforcement action. My one comment is, you may want to consider striking Office for Civil Rights, because the Centers for Medicare & Medicaid Services actually have the authority to enforce HIPAA security rule violation.

**Dixie Baker, SAIC**

Oh, security, yeah.

**Jodi Daniel, ONC**

So you might want to just leave it to HHS.

**Dixie Baker, SAIC**

Civil rights is—yeah, that's right. Civil rights is privacy only.

**Jodi Daniel, ONC**

Right, it just—legally, they don't have the authority.

**Dixie Baker, SAIC**

Yeah. Good point. Yes.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Okay. So our purview is to take the recommendations for meaningful use. And the workgroup has recommended some clarification of, at first, the goals at the very outset and then the objectives stated so they can be operationalized. So it's not in our purview to reform, but really to configure so that they can be operationalized and ultimately measured—a specification.

So the second part of our conversation and, I think, a good way to transition into the work of the second half of the day is to come back and—actually, the Privacy and Security Group is a little further ahead in terms of actually putting some more specific measures on the table and to have interchange about that.

That leaves Part 3. So if—one, if we can accept general concurrence with—and task Jodi Daniel's working with the workgroup to make sure that it conforms to law regulation and appropriate taxonomy of all governmental parts, then I think we—can we assume consensus around those modifications to make up—make them operable? Second, we'll come back after the break, and we'll talk about the measures as we segue into the work—the granularity and specificity we need to do. And then let's close this section with general comments, then, that lay the stage or clarify for that discussion after probably a much needed bio-break.

Okay, let's start with—Kevin, you're first up. Then we'll come to Wes, and we'll work around the room.

**Kevin Hutchinson, Prematics Inc.**

This is just in reference to the desire to make these operable. So I just—I know we've added some different language in here—things like small practice versus large hospital. And to make it operable, we need to define—we're going to need to define what's the definition of small practice: four physicians, six physicians—and where's the cutoff for small?

And then, in the section about the—and under Investigation, we stroke “The entity is cleared by the investigating authority,” but we added “A plan has been put in place to correct the fall of the [inaudible]—the harm caused.” Who approves that's an adequate plan to basically allow them to be now meaningful use? So I'm just trying to work through, from an operable standpoint—if these are our objectives, we've got to be careful in how we implement those and measure them and enforce them.

**Dixie Baker, SAIC**

Let me speak to your first comment. I meant to mention this when I brought it up, because one of our work members mentioned it just yesterday—is that that—you know, making these objectives and measures appropriate for the size of the organization is really not specific to security and privacy. It really is one that we should consider across the board, because we don't want to overburden these small practices. The second comment was—let me see [laugh].

**M**

The plan [inaudible].

**Dixie Baker, SAIC**

I live on the West Coast; the time—oh, the plan, yeah. I think the—either the Office of Civil Rights or CMS would be the organization to say, “Yes, it's in place.”

**Kevin Hutchinson, Prematics Inc.**

It's adequate—that the plan's adequate.

**Dixie Baker, SAIC**

Yes. I don't think that it would be the meaningful use people, you know. I think it would be the same entities that are responsible for—same entities responsible—is responsible for enforcing security—the security rule. The Office of Civil Rights is privacy ruling, and it would still belong to them to make that determination.

**Kevin Hutchinson, Prematics Inc.**

Okay.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So the point is very well-taken—is that the terms that imply a specification of size or process need to be defined in operational terms down to all of the “who,” “how,” “why,” “when,” “where,” etc. And I think that’s come back to the workgroup. Great points, Kevin. Wes?

**Wes Rishel, Gartner**

This is along the same lines; it’s more of a question. HIPAA not only doesn’t say what’s a big group versus a small practice; it doesn’t say what’s an appropriate level of diligence for the different size of organizations. All it really does is say that an auditor or someone who’s finding has the ability to take the size into account. Do we expect to actually create—I mean, I’m envisioning that a one-doctor or two-doctor practice probably buys a form at the medical supply store and checks off things. Do we envision an entity that’s responsible for creating that form? I mean, how do we get from the general notion of scalability in HIPAA to something that’s precise enough to say this qualifies as meaningful use?

**Dixie Baker, SAIC**

Well, that is one of my—that’s one of my big topics I would like to discuss, not only with respect—but especially with respect to HIPAA. In many cases, they will have been HIPAA compliant, and they go, “Okay, here’s our documentation; we’re HIPAA compliant.” But suppose we have an organization that had this—the first electronic record system they have—I mean, do we want to really take on the whole of HIPAA compliance under this umbrella of meaningful use? I think that that’s worthy of discussion.

**M**

Well, again, that may not be something we engineer, particularly before the break, but it’s something we’re going to have to comment on in terms of the coverage. I don’t know if—Jodi Daniel, if you want to offer any guidance in terms of, philosophically, how the workgroup best address that in a way that is constructive.

**Jodi Daniel, ONC**

Yeah. We’ve had a couple of these conversations, but I don’t know that I can answer the question. I think it’ll be something we’ll have to discuss a little bit more as we get into the specifics. But I agree with the point that trying to take—outline all the requirements for HIPAA compliance in a meaningful use context would be challenging and would—perhaps repetitive from our other enforcement activities and abilities.

The—from my standpoint, if I can take one step back and I—I said this when we were talking about the Co-chairs, and I think it was helpful: There are sort of two steps for the incentive payment. First is that we have certified products that meet particular standards and criteria, and then second is that adopter is a meaningful user of that product. So, you know, I see this group focusing primarily—although, you know, they can obviously have some influence—but focusing primarily on the standards and certification criteria that we need to make sure are built into the product so that the certified products have the capabilities that are—that folks believe are necessary for these products.

In privacy and security, it’s a little bit muddier, because then, you know, as Dixie has articulated, having a standard in place in the product doesn’t mean that somebody’s actually implementing that and that, in fact, the system is secure. You can have the technical capability, but if you’re not—you know, if you’re giving everybody the same user name and password in the organization, you have no access controls; you don’t have appropriate security in place. When we had spoken, it seems to me that in this area, there may be some standards for the environment and operation, as Dixie had laid them out, that need to also be identified to make sure that, in fact, we have meaningful users of secure products.

**Dixie Baker, SAIC**

[Inaudible] to do that. There are new standards. There are ISO standards [inaudible].

**Jodi Daniel, ONC**

Right.

**Dixie Baker, SAIC**

There are plenty of them out there. But when my three-physician practice walks in the door and says, “I bought an HER, and I’m using it meaningfully,” what are we going to require them to provide to show that not only did they buy this product but they are using it meaningfully in a secure environment? And how much are we going to demand of them, you know?

**Jodi Daniel, ONC**

Right, and I think that’s where we could use your input. You know, clearly, it’s not going to be—walk through every single part of the HIPAA security rule and, you know—and document that for purposes of meaningful use. Obviously, we still have HIPAA enforcement and that approach. What would be helpful is to know what are the key areas that, you know, if—that a health care provider who adopts a certified product should be doing to demonstrate meaningful use and demonstrate that it’s a secure system that they’re meaningfully using. You know, what are—if there are sort of the—you know, the top, you know, five things that we should be looking at with respect to tying it to the incentive payments, that would be helpful to know. You know, if you see what the Policy Committee did, they struggled with this, I think, and that’s why it says “HIPAA compliance” and it doesn’t break down the details of what that means. So any input and—from your expertise into that would be helpful and welcome at this point, I think. You know, I think it has to be something short of all of the specific elements in the HIPAA security rule; we have a regulation that does that. But what are the things that a physician in a small practice would need to show that they are using an electronic health record in a secure way? That would be helpful for you to provide your advice to us on.

**M**

Okay. This is a particularly useful dialog as a segue to the discussion of the measures themselves, because we have to embrace the practicality to drive the intended purpose, at the same time not to be so encumbered by replicating every other aspect of policy and law that exists. And then let’s—we’ll come back that. Steve Findlay, you’ve been co-chairing this, and—

**Steve Findlay, Consumers Union**

Yeah, just—I know you want to take a break, but just very briefly, I mean, I think this is such a critical issue that—I take your challenge that we have to do some thinking around it very concretely and also work with you in an interim process—I mean, you’re delegated to this committee—and get a better sense of best practices and worst practices out there so that we’re fully informed in the workgroup and then can bring that to the committee, because I think it’s probably a very variable environment out there with what’s actually going on now. I mean, Kaiser and others probably do it incredibly well, and there’s probably a lot of docs who bought some things off the shelf—EHRs or whatever. They’re not interoperable, but they bought them, and it’s just terrible practices. So we really need to have a sense of that now—work with you on it. Thanks.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Great. Great comments. Well, terrific first half, and I can see this’ll be a very interesting second half of the meeting. Now to meaningful information: There are two ladies’ rooms to the left on this floor. A men’s room is up the stairs, and—go up by the elevator, then it’s to your right. And it’s 10—I’m sorry—11:40—35 right now. Let’s come back at 11:45 precisely, and we’ll start then. Thanks, all. Thanks to the panel. Thanks, Dixie and Steve, for terrific work. [Break]

Okay, as—before we get on to the discussion, we’ve got a very practical order. I hope everyone has had an opportunity to review the minutes. And I want to thank, again, the National Coordinator’s Office, Judy Sparrow in particular—terrific—I thought, a terrific capturing of the discussion last time in the minutes, and just to ask if anyone has any corrections, amendments, or amplifications for the minutes. [Pause] Carrying on, we’ll declare consensus on that and assume those approved. Thank you very much for the hard work on that.

Okay. Well, John Halamka will be coming back momentarily and will lead through this next part of the discussion, but I think this morning’s discussion was really terrific. The work done by the workgroups—absolutely incredible. And we have greater clarity with the delivery of the documents on meaningful use. And I think this morning’s discussion has been very helpful in terms of creating some new synergies

between the different workgroups. It reminds me of another aphorism from Yogi Berra, and it's really, I think, pretty instructive: "In theory, theory and practice are the same; in practice, they're not." And I think Kevin Hutchinson's point about clarity and specification is really the difference between what's theoretically adequate and what really is adequate practically for creating the tractability that I think all of us are passionate about in terms of the meaningful use and the intended consequences of meaningful use about our health care.

So that really is the segue to this next section, where we'll extend from this morning's conversation to identify gaps and further works and comment on some measures in a general sense. And certainly, I feel incredibly privileged to sit with a subject matter expert with few peers, John Halamka, and ask him to lead us through that discussion.

I do want to offer one note on the agenda. At the—we're scheduled to go to 1:00, and at 12:45, I want to make sure there's adequate time, and we will stop there for public comment. On the agenda, we have a work plan for milestones and deliverables that's actually scheduled for 30 minutes; I think we're going to reduce that to 10 minutes, because truly, I think it's pretty evident to every member of this group that our next meeting is July 21. And in the interim, the workgroups will get together to work on the consequences of this discussion and continuing activities in light of meaningful use, so much will be predicated on that timetable with calls with Halamka and [inaudible] in the interim. So I don't think we need to, you know, protract on that part of the discussion. So just doing a time check, that takes us, then, to about 12:35. And right now, let's begin with the discussion. John?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Great. Well, to tee up to the discussion I want to make sure that the workgroups are on the right trajectory. So what you heard this morning was work plans from each of the three workgroups. So if we begin with Clinical Operations, you saw some of the threads of work, which—our task is to identify those standards from HITSP, from standards development organizations, from implementation guide writers that are going to support meaningful use, and we're going to need to identify some of the gaps. And so, I'll open it up for a moment for discussion of some of those gaps. And at the same time, we're going to grade deployability—I mean, to the extent that we've all discussed what readiness, deployability, and all—try to capture some of those thoughts and that, hopefully, we'll also, within the next couple of days, have a matrix which identifies the work that Clinical Operations and Clinical Quality will do so their marching orders are clear.

So if that's the nature of the trajectory of the work—picking the individual standards, making sure there's some sense of deployability and implementability, and making sure the work is divided between the two groups so it all gets done by July 21—I mean, did folks, after hearing Jamie's presentation, feel like that was a comfortable trajectory? Were there comments on that? I'm seeing some shaking heads—positive shaking heads, so that's good. Okay.

So Jamie, as you have begun work—and it's involved many, many people, not just Jamie—to take a look at the meaningful use 2011 criteria and try to pick those standards that have been accepted, recognized, harmonized, or generally in use, what has been your impression? Where have you seen there are some serious issues and gaps that we, as a committee, should think through?

**Jamie Ferguson, Kaiser Permanente**

Well, I mean, for my own part and in the Clinical Operations Workgroup, we've really just started looking at that—the list of available standards from HITSP, primarily, from the clinical operations perspective. And certainly, where there are measures for computerized physician order entry, there are a lot of order standards that HITSP has not specified, clinical labs and radiology among them. So those are obviously some key gaps that we're going to have to deal with. And then I think also, looking at some of the measures around patient-specific education, also, HITSP hasn't necessarily dealt with those, but there are some SE standards in that area that we're aware of and we've started discussing that we may wish to consider. So there are potentially other sources of standards that, you know, haven't been in HITSP, but those are some of the key areas where we've seen gaps so far.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Well, so, a couple of comments on that—and let's open it up to your comments: What HITSP has generally been charged with is transactions between organizations. It's really not been transactions with—inside an organization. So to the point of "Well, what are the standards that you would use for CPOE?" now are—is CPOE really a set of standards, or is it a set of functions? And therefore, actually, might that be a certification criteria question more than a standards question? You point out on the patient education a patient-family engagement. I mean, there are a lot of activities stated, both on objectives and measures, that actually are a little challenging to standardize. So if the notion is, every patient should be given an electronic copy of their record, does that imply—is it a PDF? Is it a thumb drive? Is it available on a PHR? What exactly—in fact, is it up to us, or is it a Policy Committee question to define what that means, or is—the answer is "Any of the above are fine"?

And I think there may be some other gaps just to think through. Our charge in your particular workgroup is e-prescribing, clinical summaries, labs, radiology reports... lab ordering as a standard—you know, is that well-harmonized, maybe not by HITSP but by others? Is that a gap that you see?

**Jamie Ferguson, Kaiser Permanente**

That was in—so I put that in the orders—the category of orders. There are several. Certainly, clinical lab orders is one of the key areas that we're going to have to look at as a potential gap.

**M**

Great. And just one final comment, and that is, some of the—if you look at the meaningful use metrics—would be such things as "What was the percentage of orders that were entered electronically?" Well, how does one know the denominator of orders that weren't entered electronically [laugh]? And the answer, of course, may be, as John and David have both said, that in 2011, this may be self-report as opposed to some sort of electronic measure of nonelectronic performance. Any comments you would make, John?

**John**

Well, I think a couple of potential thoughts on guidance here. One is, I wouldn't feel the need to take each objective and map it to a standard or—you know, particularly in this case. I think if we say that the standards are fundamentally oriented to the exchange of data between organizations and fundamentally ordered to capture any reporting quality measures, you can look at objectives and say, "It's important," but it's not fundamentally oriented that way, so there's—the fact that there's no standard link to it—there you go. And that may—so that's sort of one orientation. I think the major conceptual trap to not get in is, every objective has to have a standard, so "What in the world can we possibly find on this, on that, or the other?" when in fact that may be not really core to the intent of the legislation or the sort of health care agenda overall.

The other is, in those cases, well, it really is involving an exchange of some form here, but we don't have a standard if we go back to Category 1. And we're not so sure about our ability to accelerate Category 2, where the judgment call gets in. If the industry goes without, so to speak, between now and 2013, how consequential is that? I mean, how prob—it is a problem, but how problematic is that? And that may not give you a standard, because it's problematic, but we might then be in a position to think, "Well, how—what's a compensating strategy or compensating set of approaches here?"

So I think the—it's focused on not necessarily all bullets, but those bullets where there is exchange or reporting of quality data here, once in the subset of that, those are consequential and to the degree there are still gaps and without force-fitting something in there which is unnatural—just wouldn't be done anyway, even if you declared it—is, we'll have to sort of think through what some of the sort of approaches might be for the initiatives. I know, but I—what should I do? You know, "What are some of the options, and what should I do?" is to come up with that.

I think there are—and regarding the measures, there's a variety where the sort of numerator and denominator is a challenge. What is the denominator of all prescriptions and orders that go in? You know, I know, for example, at Partners HealthCare, just identifying a diabetic as a denominator is a problem.

And so, there can be lots of denominator issues which we don't have solved yet and may not be solved in 2013.

Nonetheless, one can say to the—I realize there are issues with numerators and denominators here, but one of the core points, particularly in 2011, is that the organization itself begin to capture and report to itself this kind of data, even because one of the challenges for CMS will be—kind of receive all of this, and it may not be able to. And so, while there are issues associated with numerators, the fact that you are looking at them and engaging in discussions whether—about “How do we improve that?” while resolving measure issues may make this a material step forward.

So there'll be lots of imperfections, and I think it is—rather than try to fix all the imperfections between now and 2011, let's identify that which we can and that which we can't. I think part of the conversation, John, might be of some guidance we can give to the industry while we sort through greater clarity on some of these. [Inaudible]

**M**

One other comment in relation to those gaps that I've mentioned: We are starting from the selection of those standards that have already been recognized by the Secretary and then looking for the gaps of standards that are perhaps related to that. And so, in talking about the lab order standard, as an example, there is a lab result standard that's been recognized by the Secretary, but there isn't a complimentary order standard to go with that particular result standard. There are plenty of lab order standards that are out there, but not one that exactly matches the recognized result standard.

**M**

And Marc, you had a comment?

**Marc Overhage, Regenstrief Institute**

Unfortunately, I do. And I wish David were here for this part of the discussion, because I think this is the really meaty part of things. And the first thing is just a precision issue. Being a scientist, I can't resist, but of course, HITSP does not write standards, and we—I hear lots of “HITSP standards” statements, and we know that's not correct. They do lots of other good work, but they don't develop standards.

I'm surprised a little bit about the observation that HITSP standards are deployed. I think I heard you suggest that the HITSP-recommended standards and implementation guides are deployable. I don't think I agree with that. I think they are at best Category 2 and many of them Category 3. There are some things that could be Category 1 things buried in there, but they're frankly not fleshed out and very well-developed. And if you look at whatever you want to pick—pick the transport mechanisms that are discussed; somebody talked about SAML earlier today. The—for better or worse, the NHIN prototype work that's been done in collabor—has demonstrated that to be very difficult, at best, to deploy between organizations. And probably not—you know, through the criteria that we talked about before, these things being actually used and in deployments and so on—that, to me, doesn't meet those criteria to be a Category 1. So I'm not sure I would agree that there are really very many. I think there are few [inaudible] not terribly well-developed Category 1 things.

The second sort of observation related to this—and I'm having, frankly, trouble getting my head around our overall process in some ways. And I shared some of my personal challenges with the Johns yesterday. But as I'm sitting here listening today, I think part of my challenge—and maybe all of you can help me with this as we go forward, and this is on the principle of “There are no dumb questions,” because somebody else has probably got it, but maybe it's just a dumb question and I don't get it. And that is, it seems to me that—it's easier for me to think about, anyway, if we think about the focus being on the data and the patient that that data represents. We kind of get caught—and I heard Jodi talk about, for example, standards for the EHR. Well, I get balled up, and I have trouble thinking through it when I start thinking about that, because this is a system, an environment of care, and in fact—and some of the things that Jim talked about—labs, radiology centers, pharmacies—are not subject—don't benefit from AARA incentives, for example. And yet we're counting on them, with Farzad's example, to deliver information in a structured, usable format using some of this—well, you know, I'm not sure that I can—that David's

argument that “Well, this is a new world; we have incentives and so”—well, *they* don’t. Maybe they’re incented because their customers will demand it, and that’ll be a helpful thing when that’s uniformly done.

So I think there’s some—but I think, at least for me, if we think about some of these discussions in the form of what has to happen to the data—the Clinical Workflow Group, for example—data capture is obviously a key part. Another key part—and frankly, to me, this is a lot more important—if you look at that bending the curve kind of diagram that Paul Tang presented to the Policy Group that John shared with us before, we talked about the first step being capturing data. Well, to do that, you’ve got a bunch of stuff to do, and it’s not just about picking the standards; it’s about implementing those standards. So you’ve got to do the data normalization; you’ve got to do some of that heavy lifting. And frankly, it doesn’t matter what standards are on the right-hand side of that process so much, whether it’s a CDA or an HL7 B2 or something else. That work of saying, “Take us from where we are today”—and this is some of Kevin’s comments about pharmacy—you know, from where we are today, where we’ve got—so now we can do an NCPDP SCRIPT standard—receive it, but frankly—and I think this is some of the stuff Jim was talking about; we ran into this, too—you know, the pharmacy system that receives that, the vendors have implemented and so on, but it’s not in the workflow of the pharmacy. And so, that electronic prescription gets stuck somewhere. And so, the goals, the things that David talked about us trying to achieve, of improving care and efficiency simply don’t happen.

And the last thing—and this is a long-winded comment, but I have to leave early, so I figured I’d get it all in—is that this partly, you know, manifests—and I think one of the things we’ve got to be really exclusively sensitive to is the inelasticity of our system. We can sort of—you know, we can poke at it in various ways, but there are tremendous forces pulling it back to the way it works today, whether it’s electronic prescriptions or whatever it is. And I think we’ve got to be careful not to fool ourselves as we’re having these discussions that just because there’s something that could work and has been demonstrated to work and, in some leading organizations, has been made to work—so I think something that brings me back, anyway, is to say, “I’d rather be a little bit narrower.” And I don’t want to set the bar too low; I—John used the phrase earlier, I think, of “making the industry sweat a little bit,” and I’m all for sweating, but it’s like a personal trainer sweating, right? We’ve got to make sure something happens and not just everybody gets frustrated and a lot of—and I’m really worried that we’ve got such a broad agenda. And we can dream all we want, but this is not easy stuff to move forward. Even with the incentives in AARA and things, it’s not easy stuff to move forward.

And like any other good leader, I think—I hope that our Secretary and National Coordinator will focus our efforts in the next year or 2 on these very fundamental things. And I think the Policy Group had it right: you know, capturing the data, normalizing the data, getting it freed—that will actually help move us down the road. But I think we’re way beyond that in what we have on the table right now. So other than, that I have nothing to say.

**M**

Hey, great comment [laugh]. Jonathan, you wanted to respond?

**Dr. Jon Perlin, HCA Inc.**

Well, Marc, thanks for those comments and then leaving. We’ll have them fixed by the time you’re back [laugh]. You know, truthfully, I’ve seen, as you’re speaking, a number of cards—a forest of cards blossom on the tables. And let’s just say for the record—let’s agree that there is a sense of the magnitude of this challenge that is extraordinary, and it’s resonant from the vendor community, from the provider community, from the physicians, for patients, for privacy and security. But—so here’s what I’m going to ask: Let’s agree—let’s stipulate that general concept. So with the forest of cards that just went up, let’s refrain, Marc, and let’s stipulate to your point. This is challenging. It has to be practicable. It’s going to involve incredible change. There may be elements who are not incentivized in the health community—that there is a certain degree of inelasticity or resistance to change and the state of deployability is not perfect.

Let’s stipulate to all of that, but in terms of what I’d—is that we frame this next tranche of questions into “What can we do within the purview of this committee?” Remember, David Blumenthal told us, “Don’t try

to boil the ocean.” That’s bigger. But within the construct of what we have in front of us, as to ways to make this practical, what can we do that attaches reasonable standards to objectives that are appropriate for the time and, in a general sense, match with effort? I mean, it’s not going to be easy, but with appropriate effort to achieving certain markers of supporting improved value of health care 2011, 2013, 2015—so if I could just ask the indulgence of the committee, we’ll agree. We stipulate these things are absolutely real, but let’s channel it into how we surmount those challenges in the context of the comments. John?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

Yeah, I think it’s—all of Marc’s comments are very well-taken. The question is “What are we going to stipulate when?” And that is, we know in a perfect world, with any standard and enough money and enough time, we can get it done, but what can we really get done by 2011, and what is the parsimony of standards? You know, it’s “Here’s the lab. Here’s the e-prescribing; here’s the radiology result; here’s the clinical summary and those that would be sufficient for quality measurement based on lab, RAD, e-Rx, and clinical summary.” You know, some—I’m just throwing that out as a straw man, but I mean, this is the kind of thinking to your point of “What can we achieve given the state of our industry as we know it today?”

**M**

Well, let me start with the forest.

**M**

Yes, go ahead.

**M**

So I wanted—this question was really for David, but I’ll ask it to the group that remains. And it really gets back to the point that he was trying to make in sort of stretching the goal. When—I think the grading and the taxonomy that present—that was presented earlier around standards is a very good way to do it, but clearly, he was leaning forward trying to get us to stretch out. And I think that we need to be very clear about what we’re doing at the base, getting to this point of specificity and being clear about what we can accomplish. If we start stretching Grade 1 or whatever taxonomy you use into something that is a little more theoretical or not achievable, clearly, in 2011, I would be concerned that we’re going to end up with the concerns that Marc had through promoting those kinds of standards.

So my view would be that if we took the grading and took the time off of it for the time being so that we’re not dealing with David’s question about how fast we can do it, but just clearly what is the grade first, then have a second step that focuses in on time, it would at least make that an explicit process that we are pushing ahead, I mean, rather than just bearing it in, but we just pushed it into Grade 1 and really didn’t have that second conversation. So that’s one.

The second one then gets to Marc’s other point. And again, I don’t want to focus on the sort of gross challenges, but I do want to come back to what’s not coming explicitly out of the standards process. So I believe we will get something that says, “You should be looking for a CCHIT standard system to implement if you’re going to meet meaningful use.” I think we’re going to get clear descriptions of what “clinical operations” really means. But these comments about what’s not on the list, I think, should also be captured. So just the experience of having implemented laboratory interoperability in the State of Florida, Ohio, and Nevada—that’s three totally different experiences, and the vendor on the other side was exactly the same.

So as we start to think about what deployable versus deployed means, that’s an important part of achieving whatever goal we want in terms of interoperability and true meaningful use adoption. So although we can’t certify those vendors, getting those issues on a sheet of paper somewhere where people can see them, I think, is going to be important, because small practitioners—two- or three-physician office practices don’t have the technical wherewithal to sort of understand those issues. And if we don’t help guide them, I’m concerned that they might make—or they should be making a different decision than the one they might make if they are totally unaware of those things.

**M**

Very good comments. So the idea of actually separating our grade and the taxonomy from a date and then bringing it to the committee to say, “Here’s a Grade 1, a Grade 2, a Grade 3; what do you think?” is that—hey, you may want to advance a Grade 2 to a 2011 deadline if we all think it’s a reasonable stretch goal. And hey, there may be some Grade 1s where, as you described, because of the complexity of the various ecosystem players, even that might be a stretch. Well-said. Kevin.

**Kevin Hutchinson, Prematics Inc.**

Well, my comment’s going to be really short. That’s usually the first clue that means you’re going to talk a very long time [laugh]. It really is going to be short. One of the major standards gaps, going back into this—we keep talking about e-prescribing. I think we, as an industry now, in SureScripts and RxHub and the combination of the two, are on, like, version 10 of the implementation guide for the NCPDP standards which have been deployed so far. And I think as we consider—think through where the major gaps in standards—it’s one thing to identify the standards, but if we don’t, as an industry or as an organization, if this is what this group is designed to do, come up with a way to create that implementation guide of how to implement that standard, there’s going to—that major gap of actually making these standards deployable is rather large.

**M**

So don’t worry; my comments won’t be that long, but you’re exactly correct. And that is, take HIPAA, again, for example. Back in 1998, we were all told, “Go implement HIPAA. Here’s XP—or here’s X12 4010.” That’s great; it actually works really well. But unfortunately, if every single training partner implements it differently, you’re not going to get interoperability. So what Massachusetts did was create one implementation guide for the whole State and got us actually to connectivity quite rapidly. I think it is very true that we need the constraints that are in implementation guides to achieve as much plug-and-play interoperability as you can, because if you start with just a base standard, there’s just too much variability. So sure, when there—and it’s an enormous task in the next month, but when we can point to implementation guidance as opposed to a base standard, that would be better.

**M**

I’m cognizant of Jonathan’s guidance to focus on the plus, so I’ll try to minimize my piling on on the negative here, but—and I do think we should note that Marc dropped his bomb and left, but [laugh]—

**M**

[Laugh] if I might, it’s not focusing on the positive so much as really taking the recognized challenges and thinking how to work through them into something that’s practicable for our task.

**M**

So as a comment, I thought—I think Jamie is one of the most brilliant and hard-working people in standards, so it’s not about him. But I thought Category 1 really was two categories, and that was—the fact that that wasn’t recognized, I thought, was a difficulty with that presentation. If you look at that category—that portion of Category 1, which is broadly implemented, I think you’ll find it’s limited to what SureScripts and RxHub does. And the reason is that there has been a multiyear effort that provided enough value that people went to the trouble to get certified by a certifying operator of the interoperability mechanism.

I think you can look at pockets in the United States. I mean, generally, anything that’s being done in Massachusetts is a good example of what you might be able to do in California 10 years later. I think you can look at Indianapolis; it’s a wonderful town for interoperability. But when we look at meaningful use criteria, we’re being asked to say what we’ll either get a physician in every county in the country paid or not paid this incentive money or a hospital for meaningful use. And pockets of implementation then are, in my mind, sort of the second of the categories in—second subparts of Category 1. It’s not a very hopeful statement.

And I think that we very much need to consider this issue that I raised earlier of “Are we just incenting people to get EMRs? Are we using interoperability as a way to measure indirectly a proxy for actually going in and counting how many times they produce orders or something like that? Or are we really trying to create an incentive that incents people to beat up their vendors, to get interoperability to beat up their labs, to get interoperability to do all the things it takes in the ecosystem to actually get interoperability?” And how we come down on that issue will be a strong point.

I suspect that even if we take a very proactive effort, if we’re using the incentive as an incentive to work through the ecosystem problems around interoperability, we will still find that a very good strategy would be self—what’s the right term? It’s self-certification, essentially. Yes, I’m doing—I’m getting structuring lab results from somebody in 2011; maybe in 2013, I’m doing it by this standard or something like that. But I mean, I really don’t care. I really think that if we just focus on the level of “It’s working somewhere” for 2011 and then raise the bar to “It’s working in a standard way,” we do a better job of attacking those ecosystem issues up front.

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So this is exactly the deliberation of the committee. And that is that—how, based on your experience, are you going to evaluate if something is ready for prime time? And just because it’s implemented in one State, well, doesn’t imply it can roll out more generally. I think that’s fair. Jim.

**Jim Walker, Geisinger Health System**

Thank you, John. Jim Walker. I think that we have a mental model where this is a linear process in 2011 and 2013—2015—will be kind of a linear progression. And it occurred to me there’s probably a lot of people in this who’ve never actually seen an implementation go. And the fact is that what you see is, at the beginning, it’s very hard. And having tried it a number of ways, we found that if we give people very, very simple things to learn that fit their existing mental models—that fit their existing work patterns and their sense of who they are and what they do—just providing people, back when this mattered, e-mail and just providing them labs that they can look at—and that’s all; they don’t have to do anything with them; they’re just available to look at, and so it’s much faster than when you had to go find them somewhere in some pile of paper—that it starts slow, but once people start to get the first sense of the benefits that they can achieve—getting lab results and knowing you’ve seen all of them and seen them fast; getting radiology images, which before were always lost, and you’d spend an hour every day in the hospital that you rounded on patients just trying to find films to look at—that when people get those small wins, then what happens fairly rapidly is, they start to say, “Well, you know, you could be giving me this in a better format. And why can’t we communicate with those other people across town? And why can’t I send a message to my patient and they tell me what their blood pressure is and we don’t have to drag them back in here every time we’ve got to check their blood pressure?” And a pressure grows to increase what’s available and to change processes and to really transform health care. And so, I think, as we’re thinking about this—and I love Martin’s idea: Let’s just categorize it first and then talk about dates. But I think we want to remember that if we can get people hooked and give them a positive and productive experience at the get-go, the sky really is the limit, and we’ll be able to move faster and faster with more and more functionality, more and more quality, more and more interoperability, partly because they will be driving it.

**M**

A very good point. And some have said, for example, that if you create a simple standard for exchange of data—that is, “How do I get data from place to place securely with authorization and authentication?” then transporting the stuff—that’s the easy part. You know, it’ll accelerate so rapidly. Today it’s prescriptions; tomorrow it’s x-rays; and beyond that, we won’t have what feels like a linear process. So good point. Dixie, a comment?

**Dixie Baker, SAIC**

It occurred to me that the easiest way to get individual provider and small provider groups to adopt EHR quickly would be to get them to sign up for service, and I was wondering—you know, software as a service kind of a solution instead of going out and buying a computer and putting it in a...right? And I just had Doug bring up the AARA, and, you know, it talks about reimbursing for the adoption of EHR; it doesn’t say reimbursing for the purchase of EHR. So I was wondering whether, you know, maybe we—

our entry is to really try to target a lot of the software as a service solution instead of strictly buying—purchasing EHRs.

**M**

I think our challenge is that, at least the way David defines—many of you are thinking about meaningful use—is that we have to be agnostic to the kind of software you implement, whether it's software as a service, a package, module, home built, etc. I mean, I certainly agree with you: Software as a service is good; it's what I do. But it's going to be highly heterogeneous throughout the country.

**Dixie Baker, SAIC**

Highly what?

**M**

Heterogeneous throughout the country. I mean, some people may have iPhones with five apps that do labs, e-prescribing, clinical quality reporting, and data exchange. And some people may have \$50 million, full-blown EHRs locally. Some others may use [inaudible] Web-based applications.

**Dixie Baker, SAIC**

Can't you certify the service?

**M**

Yep, sure.

**M**

You know, notwithstanding my admonition not to pile on, I think one of the things in standards is that we want to—I mean, theoretically, we want to support not only the adoption—that's an obvious—but we don't want to suppress innovation. And I'm very hopeful that there are things that we can conceive of today that may simplify that we're, frankly, agnostic to. Does it provide the service? And it may be, you know, an application service provider model or things that we've not yet envisioned but that support the concept. And so, I think that's really where the Policy Committee, you know, has given us guidance in terms of what the intent is. And our standards have to support what's doable using, frankly, the frame of reference of what's known, but to the degree that can be anticipated and not suppressing innovation for what may become possible. So—and your point's very well-taken and [inaudible].

**Dixie Baker, SAIC**

Huh. I—

**M**

Did you want the—Jon?

**Dr. Jon Perlin, Partners HealthCare**

Yeah, I think one is, we ought to be agnostic on how, realizing that there are models which might be, you know, much more effective for the small provider, because they're hassle—they're less—and a variety of other things that go on here. I just want to go back to sort of a core sort of series of comments here to make sure I'm listening correctly. And I have my own form of dealing with this stuff back up in Boston here.

So I think if you were to say 2011 industry—let's take the lab transactions that said everybody ought to be on the—using these kinds of standards regarding lab, receiving lab results, etc. And if you were to say, "Well, geez, you know, you could take a whole bunch of providers into—expect large numbers to be at 100 percent of all lab results"—just isn't real. And whether it's—Martin, you're sort of [inaudible] to this, that, or the other or the Farzad numbers—that isn't real because of the lack of implementation guides and all kinds of stuff that is out there.

On the other hand, what isn't acceptable either is that we're kind of where we are today, 2—you know, 2 years from now. If you had to phrase the standards in light of a sort of "a.k.a." or equivalent of a 38

percent or some—I mean, how would you phrase, you know, or sort of express the need to get to a standard, realizing 100 percent may not be real, but there's some intermediate ground that would cause the sweat to occur, but also not sort of force people into untenable situations? Is there a way to express across all workgroups? Because you could have the same on the—you know, Jamie's terrain as you could on the other two terrains that we were talking about—is the—focusing on those things but having some sort of sense of movement that isn't complete in 2011. Jamie?

**Jamie Ferguson, Kaiser Permanente**

Yeah. Actually—so I want to say two things. One is, I want to come back to Wes's comment and some of the other comments that were made about the taxonomy and what's deployed versus what's deployable. If—I just wanted to clarify: The taxonomy that's been proposed does not mention what has been deployed. It's completely deliberate. It only talks about what is deployable. And that's really following the direction that Dr. Blumenthal gave us earlier in the first part of the meeting about setting stretch goals and moving things forward. And so, it actually explicitly does not include what has been deployed, although that certainly could be categorized as what's deployable. And if we wanted to add a Category 0 to the taxonomy of what's already widely in use, that certainly could be done, and, you know—so it would be the slam dunk “gimmes,” essentially. And we could certainly add that kind of a category.

But then, switching gears now—and John, to your point just now about, you know, what percentage should the threshold be set at for declaration of success, one of the concepts that I've heard about is one whereby there wouldn't necessarily be a single definition of success on an individual measure basis, but rather aggregated across multiple measures of different kinds so that if you happened to implement—you know, whether it was prescription orders—if you have a limited capability to implement things in a particular time frame, you might implement one kind of capability first and then another one sequentially so that, aggregated over multiple different kinds of measures, you achieved an average score of 50 percent or 70 percent or whatever it is, but you might be 0 in something that you hadn't done yet.

**M**

And another way that we've been doing standards harmonization—have tried to think about your point—is, sometimes you can't get to a single standard, but instead of 20, you get to 2. And you say, “Ideally, we'll get to 1.” So it is acceptable to do it this way or that way; hey, but 3 years from now, it's one way. And that way you get people sweating and on the trajectory. That's certainly another acceptable approach.

Well, we have only a couple of minutes left for this part of the discussion. Did you have another comment on this?

**M**

Just quick: If you think about Farzad's 38 percent, what we need is a performance standard that says, “Labs shall provide lab results in this standard and according to this implementation guide.” And then we'd be in business.

**M**

Right on that?

**Group**

[Inaudible]

**M**

Okay. Perfect. Well, I wanted to just make sure we covered clinical quality as well as a couple of comments on privacy and security. So on the clinical quality side, we established a trajectory where the group, of course, is going to first make sure that we divide the work between clinical operations and clinical quality. And Chris and I were chatting at the break about—I can tell you, having worked on HITEP, it is not the notion of the NQF or the HITEP work to invent standards, code sets, etc. They're going to point to other clinical operational activities. And that is absolutely the intent. So that's the body of work we're going to do.

And then there's going to be the "How do we take all those measures that are specified in meaningful use and put a nomenclature so that the quality metrics are defined in terms of EHR data types, which then point back to other existent standards?" So if that's a trajectory, I mean, did that seem reasonable to folks? Comments on that? [Pause] Okay, no comments. But Janet, from your work thus far, did you see major gaps? I mean, I know that you and Floyd together have worked to identify where you feel there may be some gaps in data types.

**Janet Corrigan, National Quality Forum**

I know some of the ones that Floyd identified were the structural measures and the ones that will probably have to be personal attestations, so that's where we don't actually have measures that are currently developed. I will say one of the concerns that I am a little worried about that I'll start to look into more deeply after this meeting is the pace at which the measures that we select can actually be retooled—that those measures can be re-specified using the high tap data type so that we have those ready as well, because that really needs to be moving in parallel with this other effort. They need to be ready for implementation in 2011, then, too. And I think that that's a sizable piece of work, frankly, that has to be done.

**M**

Right. So clearly, there are some of those metrics that are stated in non-EHR terms, so they have to be recast.

**Janet Corrigan, National Quality Forum**

They are non-EHR terms.

**M**

Yes [laugh], as you've said. So clearly, what will be done by that workgroup is identify, whether it's on objectives or measures themselves, where there are gaps to be filled. And—but there has been a lot of work done over the last 2 years, as we talked about earlier, on capturing what data, when, by whom, and so that kind of detail could also be leveraged.

On privacy and security, we outline the idea that we're going to look at three different layers. We're going to look at product privacy and security. We're going to look at IT infrastructure, best practices—the privacy and security elements that are necessary to support the product—and then operational best practices. Now, based on those three constructs, was there any comment? Do those seem like three reasonable constructs to approach? [Pause] Okay. Well, since—Dixie, based on your work thus far, major gaps and issues that you have seen?

**Dixie Baker, SAIC**

Well, the workgroup hasn't really gotten into discussing the standards that are available. But in terms of security standards, the HIPAA requirements for security are what most companies that cared about security at all did 15 years ago. So there are plenty of standards in security.

There—in terms of the certification—CCHIT certification, my personal opinion is that there are some shortfalls in assurances but not in functionality. In my experience, the most—furthest out on the three categories, I think, is consent management—to include both privacy authorization as well as informed consent. And consent management is starting to get some standards.

**John**

And this is to the point of the deployability. And when you look at—sure, are there good encryption standards? Absolutely. NIST is filled with, you know, a whole set of guidance, and ONC has actually pointed to those. Are there reasonable authentication standards? Now, are there some standards with regard to role-based access control? Oh, there are some, but with patient consent, recording granular consent, mapping that to role-based access control, they're just emerging. So that may be something that is a 20—

**Dixie Baker, SAIC**

Even the policy is just emerging.

**John**

Right. So we could have a unified national policy for the way consent is done much easier. And—

**M**

[Inaudible]

**John**

Okay, that's good. [Laugh, inaudible] is still supportive today. This is great. I—

**Dixie Baker, SAIC**

[Inaudible] interest. So it's an interesting problem, so—and a lot of, you know, the research community is interested in it and—as well as the provider community—public health. So it's a good topic.

**John**

Well, so, have brought agreement, then, on the three workgroups' charge, and we'll turn in a moment to the actual getting to the deliverable by August, but I just want to comment: ONC, AARA have—and this administration has provided us with an interesting forcing function. I mean, I think we really do have to take Marc's comments seriously. And that is, it is a challenging industry, the standards aren't perfect, we know there's tough work ahead, we don't have enough resources to get everything done, the ecosystem is complicated, but yet we are being forced to say something by August 1.

Now, you guys could say, "Eh, it's just too complicated. Let's just send faxes for another 5 years. Meaningful use, good luck." But I don't think that's our charge. I think our charge is to really take this careful look and look at the fact that, yes, e-prescribing is ubiquitous. Lab? Well, it may not be perfect—Farzad has had a struggle—but there's a pretty clear trajectory on how we actually can get beyond where we are today. And other issues, like clinical summaries—yes, very much a work in process. But I think, as you—maybe folks have heard me say before, even if it is not semantically interoperable but it was a piece of text from a provider to a specialist so they would understand why the patient was there, that would be better than we have today.

And so, what I would encourage us and our workgroups over the next month is, take all of Marc's comments seriously; take your experience and implementation, as Jim and Marty have highlighted; and then just ask what really can we achieve. But let's be a little aggressive; let's cause a little sweat; and let's just do the best job we can for the small provider, the large provider, recognizing it's going to be a journey.

So now the work ahead. Let me turn it back to you for the next month.

**M**

Thank you, John. You know, I think there is the risk of— I mean, of sounding very Pollyannaish to say, "We're going to, you know, charge ahead, and these huge problems are ultimately surmountable." But you know, the irony is that what I observe is that the cautions are coming, myself included, from individuals who are parts of large systems that have implemented a lot of these technologies. And I think that understanding some of the pratfalls and complexity actually, you know, lends a philosophy that's necessary. You know, in a sense, I think in our work today, we try to be very value neutral in doing this and, somewhat scientifically and reductionistically, map standards to objectives. And now we realize that—I think that's really the value of today's discussion, because, you know, frankly, we cannot, in the context of this large a group, go through all the standards that each of the workgroups have independently identified that—and in a sense, you can telegraph what the next section of that calendaring is going to be—is that each of those groups will have to triangulate with each other, based largely on the sort of the most granular items in the clinical operations.

Can they be aggregated, or can the quality concepts be framed in a technically reductionistic-enough manner to create a viable measure? And oh, by the way, the value judgment on top of that is valuable to change a measure specification over time as measure evolves or different evidence emerges. And then—so really, in the privacy community—and I think the discussion was extraordinarily helpful and robust—that we have to drive the intended consequence, which is secure and authentic and private communication of information, but not constrain it by trying to replicate everything that other—as I mentioned earlier, statutes and regulations and practice—good practice, as already specified.

I see, Aneesh, you have a comment you want to—so we certainly welcome your comment at this juncture.

**Aneesh Chopra**

Yes, [inaudible]. I just wanted to say briefly—to applaud the work of the committee Co-chairs in getting pretty far along the path here. But I also wanted to affirm that the White House wants to be as supportive as possible in areas that are active and practical. You have Linda and Nancy here representing the VA and the DoD, literally, as we speak, undergoing clinical transformation and developing a new methodology. So as these committees work to think about life on the ground with these standards, I would imagine that neither Nancy or Linda would be objectionable to the idea of being as active as possible to say, “How would these ideas that we work on over the next X weeks start to gel with life on the ground with folks that are actively engaged and to the extent could be helpful?” So we have ONC resources, AARA efforts, and now we have other aspects of the Federal Government all available and willing to be as supportive to this group as possible to achieve the goals in a very short period of time.

**M**

[Inaudible] appreciate that, and certainly I do appreciate that they’ve already proven to be great resources and—from their realm of experience of some of those institutions, but—outreach, HL7, etc. And that will definitely be taken note of during the accelerated work of the next month before we reconvene for a meeting.

So having established, then, that our goal is—I’m sorry; go ahead.

**Aneesh Chopra**

I just want to add that the National Institute of Standards and Technology is certainly in line with the others, and—willing to help where we can.

**M**

Absolutely. And Anish, I did introduce three new members of the group just shortly before you were able to join us and—really are terrific resources that frankly—and are pretty well-known to the group, but—okay.

Well, we’ve established—let’s go back to the first principles. Someone phrased at the beginning that they feel like we’re on the—to use a bit of a metaphor, on the verge of a climate change. And the climate change is from a world that has been paper based to a world that’ll ultimately be electronic. And I think Jim Walker’s points were well-taken: that it’s not entirely a perfectly linear march with the same cadence. It may start more slowly and then accelerate. And the hardest work is at the outset. And so, we’re now trying to come up with the framing that is, you know, rational.

And let’s—now let’s think about our colleagues over here at ONC. So they’re there, and there’s a very clear governmental intent to drive an improvement in health care. If we operate too slowly, we’ll never make the mandate. We won’t get to things that, frankly, I’m growing tired of as a consumer of health care who wants that health information that ultimately is transportable. On the other hand, if we’re too ambitious and aspirational, then however right the vision is, it’s not achievable, because you’ve lost traction with all the elements that have to be specified. And I think tremendous work has been done introducing a taxonomy that’s been shared. And then today, there have been some terrific discussion that said that there are some supervening characteristics about the standards, their deployability, their actual use, their achievability, and the implications for the ecosystem. There are elements that are directly

incented. There are others that are not incented. There may be a business rationale that makes it, or there may be a business rationale that simply emerges from the incentives that are applied on—in certain quarters.

So we have to now go back to our workgroups and triangulate them amongst the three. I think in the clinical operations, John and Jamie, I'm going to ask a series of three questions. Do you feel from today's discussion that you've got a sense of the group in operational terms to provide another cut into the taxonomy that helps really to define a trajectory that starts in a manner that is realistic yet, you know, ambitious, not demoralizing but appropriately ambitious, and begins to map to 2011 in much more concrete or practical terms?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So we'll have two workgroup calls and, I'm sure, thousands of e-mails along the next 30 days. And I feel comfortable that we can take the meaningful use matrix and fill that out with capabilities, standards, and this mea—this notion of deployability and then have that for this entire committee to review by the 21<sup>st</sup> of July.

**M**

Great. Okay. And let's go now to Janet. We had terrific discussion—again, appreciate all the terrific work. And you showed us the concept of the matrix. And there was the concept that we have two different sets of standards. We have the standards for the measures, which are much more emergent and akin to natural language; and we have more reductionistic data elements that we have to marry up ultimately to support; and a superimposition of different communities, be they providers or physicians specifically, as well as other providers; and ambitions that aren't just a measure of how much something got done but how well something was communicated. Do you—and speaking for Floyd as well—feel that you have the connectivity to the clinical operations to provide that next iteration working with Paul and HITEP, etc. [inaudible]?

**Janet Corrigan, National Quality Forum**

The—we certainly, in the next week, can go back in and take a look at the available measures to address the issues around whether we have adequate measures for specialty areas, ones that cross all different types of providers and settings, and also think about whether we can have a common classification and definition of the levels of—the units of analysis. And I know the issue came up earlier in the context of the—Dixie's presentation about the definition of a hospital versus a clinician versus small practice setting—all of those issues. That should be the same set of definitions, probably, for the measures where the quality measures apply at those different levels.

So we'll go back in and take a look at the available measures to address different types of providers, settings, and levels and units of analysis. I think what, then, we have to do very quickly, though, is to meet jointly with Jamie's group, because there's clearly—once we get the measures laid out, we bleed right over into the area of the operational standards.

**M**

Well, terrific. And you know, I'd also—I think this is a perfect time to take note of Anish's offer that there is a great deal of technical expertise among the members of the committee. And certainly, I'm sure that would be welcome in terms of mapping.

Okay. So let's go to Dixie next and—appreciate you and Steve Ruthford's risk report. And I mean, we're very fortunate to have Jodi Daniel's expertise. And do you feel that you've got sufficient clarity from discussions today to come back and actually map to the objectives to measures, again with that sort of ascending slope 2011 and on, that encourages adoption but also assures all of the responsibilities that facilitate the adoption?

**Dixie Baker, SAIC**

Yeah. I think getting some clarity on how we really interpret this requirement of "Comply with HIPAA" and our freedom to really constrain the applicability to meaningful use, I think, is a—that's—in my mind, that's

the next thing we really need to do—is how we want to break that out. What really are—should be part of our certification criteria and standards? Steve?

**Steve Findlay, Consumers Union**

Yeah, I'm going to rewrite HIPAA and give you a new version. I think you'll all be thrilled with that.

**M**

To this point, I mean, do we get to the level of authorization and authentication, role-based access, control, consent, auditing, and disclosure and then show the standards that are necessary for those and best practices? And so, I think this is going to be some of the work of the group. And we'll have two phone calls for each of the groups. I believe we have most of those phone calls scheduled. There's probably still some additional scheduling to do and then probably some cross-workgroup calls that will be held as well. And then, you know, to the extent that we can have early deliverables that we can circulate to people for comments and then get all those deliverables back here by the 21<sup>st</sup>, then we will make you guys—at least by July 21, give you a set of deliverables that are reasonably grounded.

**M**

[Laugh] That adjective “reasonably”—I look forward to that. That was good.

**M**

Oh, I could say [inaudible, laugh].

**M**

Clearly grounded.

**M**

See, we're not allowed to use the word “meaningfully” anymore. So yeah.

**M**

The tasks ahead, I know, feel very overwhelming. But think about what's going to come. I want to take us back to our last meeting, when meaningful use had not yet been specified to us. We had to anticipate some likely trajectory space, and I think the approximations are pretty good. We've triangulated; there's some refinement on meaningful use with this, some refinement as well in terms of our philosophy and matrix, but I think we can come out at a good place that serves the ultimate intent—support of the AARA 8, but also meaningful use and accelerating the adoption.

Let me invite John Glaser for any comments before we move to public comments. John?

**John Glaser, Partners HealthCare**

Yeah. First of all, thank you all, you and your teams, for the work you've done. I think the fact that it's—you've had a week at this. And so, given what was done in the last 7 days, I have great expectations of the next 28 days in terms of what you can accomplish. And it's just really remarkable that we've made this much traction, this much progress, in an exceptionally short period of time. And that's due to a lot of hard work and a lot of focus and a lot of expertise. So nicely done.

My guidance to you would be—is that I think one ought to focus for the 2011 on standards and criteria which one ought to reasonably expect—I'll use that word again—to be broadly implemented or the industry well on its way. And so it is, you know—and I think we can get stuck on the “How far does it actually have to be in 2011? Does it have to be 100 percent?” Well, it probably won't be at 100 percent, both in aggregate or in specifics—that'll be that far along—but separate the threshold from where the broad statement, “We have reason to believe the standards are well-defined HER” or whatever it might happen to be—that we should expect broad adoption or substantive adoption or meaningful use by the year 2011. There's obviously work of—whether their implementation guides or further product development, etc.—but I think if we hold out that it's got to be 100 percent across all this, we'll back away, and we'll back into some stuff that we know is safe to do and, you know—and too likely to be done, and we won't cause this sweating that we do.

There will need to be, obviously—and it's just—not only in this area, but it's also in the feedback we're getting from meaningful use—is a calibration of what will cause the sweat—at the same time won't cause the industry—because this is a voluntary program at the end of the day; nobody has to take this money. They can decide it isn't worth it and to walk away, and that is not the reaction we want.

So let's put off to the side the sort of measurement process and the percentages and this, that, or the other and focus on you—we are—you know, there's—pushing it. We ought to be able to get this stuff done in an aspirational setting. But it's also mindful to reality that it's hard to push forward, initiate, or be at a broad place if the standards haven't been agreed upon, if the products really aren't there, and a variety of other things. There are real limits to what the industry can get done.

So anyway, I just wanted to set off to the side the threshold conversation so it doesn't cause us to inappropriately back down from this kind of stuff, because I suspect there are ways to grade accomplishment, both in aggregate and in the specifics, and still accomplish this stuff we're doing. But again, really nice work, and I look forward to the next set of conversations.

**M**

John H.?

**John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center**

So I think the next 28 days will be a marathon, but I'd just emphasize good communication among all of us, and I am convinced that we can achieve the goals that have been outlined today. It feels like the process we've put in place is really quite sound. And I think that's the most important thing for today.

**M**

Great, and as we go to—thank you both for those comments. As we go to the public comments, let me just add my thanks to each of you. The amount of work and the effectiveness is as extraordinary as I've ever seen from any group. And I think it's—the work ahead is ambitious, but I also am optimistic on the basis of what you have already done and the members of your workgroups that we can come back with that. And I think John Glaser gives us good counsel in terms of thinking about what's deployable and leaves the conversation about, you know, percentages of achievement to someone else, because that will divert our focus from really envisioning a way to map standards in support of the concepts that drive—that “meaningful use” implies.

So with that, let us close this portion of the meeting, and let's come to our public comment. And then we will ask each individual to please state your name. Please limit your comments to 2 minutes. [Inaudible] Judy, I turn to your...

**Judy Gallagher**

A short comment, yeah.

**W**

Well, we have a microphone in the room if anybody in the audience cares to make a comment. And we also have a dial number on the screen that you can dial—that telephone number. Press star-1 to speak.

**M**

Thanks. We'll try to cut back and forth between anyone who calls in and people in the room. So we'll start in the room.

**Richard Eaton, Medical Imaging and Technology Alliance**

The work the committee is doing—I prob—I wanted to make a comment about something that's probably pretty obvious to you: that if you're talking about a standard that's not only deployable but it has been deployed worldwide as the DICOM standard that is accepted by thousands of hospitals, nearly 100 percent of the big hospitals in this country have adopted it, and the adoption rate among smaller hospitals is increasing all of the time.

**Judy Gallagher**

Your name and organization?

**Richard Eaton, Medical Imaging and Technology Alliance**

Oh, okay.

**Judy Gallagher**

Thank you.

**Richard Eaton, Medical Imaging and Technology Alliance**

Richard Eaton from the Medical Imaging and Technology Alliance. So I would urge you to give that very strong consideration as one of the deployable deployed standards. Our members can certainly be of great aid to you as—in the next month as you talk about implementation guidances. I think we can be of a lot of help to you there if you need our input.

One observation I wanted to make I'm a little confused about—hopefully I can get a clarification—is that, in looking at materials today, those from the Clinical Operations Workgroup seem to state that radiology functionality reports are fairly much pushed into the foreground, as far as when they will be implemented. I may have that wrong, so I—anybody can clarify that for me, I would appreciate. But there seems to be a disconnect between that and the first draft recommendations of the HIT Policy Committee, in which it appears that implementation of radiology information is pushed back to 2015. So there seems to be a conflict between those two. And given that DICOM is a deployable standard, is deployed, is adopted, and that medical imaging is a key part of the medical record, it would seem to me not logical to push this off until 2015. Meaningful use certainly is not a complete concept without imaging information. So if anybody can clarify that for me, I would appreciate it. Thank you.

**M**

Just one response, and that is that looking at the meaningful use matrix as issued from the Policy Committee in first revision, multimedia—i.e., x-rays—are listed as a 2015 exchange criteria. And you know, certainly, we'll take guidance from the Policy Committee if that's revised.

**M**

Yeah. I think the best way to do that—and whether it's move stuff forward or move stuff later [inaudible]—is to make sure that the comment process for meaningful use—it's really not in the purview of this group here to move stuff around; it's the Policy Committee. And so, there's a comment process, which, if you need—and Judy can help you know what that is if you're not aware of that, but that's the best way to get in comments about moving stuff between the years that they've laid out. Okay.

**M**

[Inaudible] Okay, so you'll interrupt us if we have any comments to go with [inaudible].

**Dan Rode, American Health Information Management Association**

Good afternoon. Dan Rode. I'm with the American Health Information Management Association. Your conversation this morning is extremely exciting. And those of you who know—our members and my colleagues know how excited we are to see where the standards are going and the quality measurement and privacy and security.

The one thing I would ask you to keep in mind that came up in your last meeting is, we also have the implementation of the HIPAA standards upgrade and the ICD-10 changes coming in 2011 and 2013. And if those can be integrated as you look at the changes and suggestions we're going to be making, it would be greatly appreciated. I think, too often, we look at one set like AARA and say, "Well, I've got to do this," and we forget the other pieces. And I think it's going to be extremely important as we look at the value of data and the collection of data and how we're going to use this data by 2015—that we make sure that all of these changes are incorporated in what we try to put forward so that our users and providers and

payers can recognize that all these things are moving forward at the same time and not in isolated silos. Thank you.

**M**

I mean, to the point that Jim has made and Marty has made and, I think, John and I live every day, life as a CIO is fraught with far more demand than supply. And so, to say, “We are going to implement ICD-10 and 5010 and lab and e-prescribing and DICOM and clinical summary exchange, and it all has to be simultaneously,” would be a challenge. So your point is well-taken. We should certainly think about that as we think about these deployability questions.

**M**

Thanks.

**M**

Gary.

**Gary Dickenson**

Gary Dickenson. I’m a consultant representing [Inaudible] Health. In terms of your standards gaps, it seems like the biggest gap that I perceive is the whole issue of electronic health records. The standards that are coming forth and the majority of standards, and certainly in the interchange standards space, are focused on point-to-point interface or interchange with transient messages or transient documents, as it may be. And if we’re talking about electronic health records, we need to be talking about end-to-end persistence, indelibility, authentication, auditability, etc. And that doesn’t seem to be a topic that’s coming forward in [inaudible] significant three. But if we expect that people are going to trust what we produce and use it in a trusted way so that patients and providers, those who are subject to the records, those who are recipients of the records, are going to be able to trust what they get so that they can use it beneficially to their practice, beneficially to their patients, we have to have this end-to-end trust—end-to-end record flow that is traceable from this point of origination to its ultimate point of use. And if we don’t get on top of this soon, we’re going to have done a lot of work that will ultimately collapse simply because we can’t trust it.

**M**

Certainly a comment that Dixie has made multiple times in her workgroups is this idea of “Not only are we looking at the security, but we’re also looking at the data integrity.” How do we ensure, to Gary’s point, that actually the data that is incorporated is not only legitimate from a known source but isn’t lost or modified along the way? And so, you know, Gary has been a very valuable contributor to HITSP, and he and I have engaged in a lot of dialogue on thinking through how do we get to, as a whole industry, this idea of making sure more that there’s good data integrity. So good point.

**Dr. Robert Zantz**

Hello, my name is Dr. Robert Zantz, and I’m a practicing primary care physician in Florida and in Texas. I’m interested in a lot of these issues you’re talking about today. I’ve been to Europe several times, especially Germany and Austria, and seen some of my colleagues happen to address the same types of issues that you are talking about today—for example, having to amalgamate medical data from disparate database systems, having to maintain privacy and security in the health care systems, and dealing with challenges with respect to portability of health care data. I was wondering if—has the committee studied these systems and extracted guidance by dealing with solutions for the problems you are addressing here? So I know that at least in those two countries I’ve visited, they’ve faced, you know, again, a lot of these same issues, and they’ve been overcome to some great degree.

**M**

Well, certainly, in the standards harmonization activities that we’ve done through HITSP, we’ve had a whole committee devoted to looking at the international landscape, and we asked questions: Where can we learn lessons from Europe, from Canada, from the U.K., from folks who have done this? And certainly, if you look internationally, there’s been a lot of work on semantic interoperability—the adoption of common vocabularies and code sets. And so, we have tried through our committees to take those

lessons learned and to drive to common semantically interoperable code sets that we can then publish. And I think what you'll see coming up as part of the next round of the HITSP deliverables supporting AARA is that we do, in the USHIC tool in AHRQ, publish a lot more of these kinds of code sets, as have been used in Europe, to ensure that registries are more interoperable.

**M**

Any other questions? I just acknowledged that the Office of the National Coordinator has looked across the European Union experience in terms of some of what their challenges are and experiences have been and brings that knowledge. And I know a number of our colleagues also have served as racehorses and brought ideas back.

I appreciate all of the comments, and I appreciate everyone's participation and your stamina to sit through 4 hours of discussion and deliberations. My thanks to the Office of the National Coordinator staff for all of the work that's going on in the background—from the hours of the e-mails I've seen of the ONC staff working 24/7/365. Please know, as we have the privilege of participating in this, how much we appreciate that support. And to all members of the committees and the workgroups, thank you for not only what you've done but for the formidable task work that lies ahead. I think we'll all be getting together on the phone. Talk to you soon.

**M**

[Inaudible] adjourned for today. Thank you.

**Public Comment:**

1. Why does Janet Corrigan's presentation list ICD-9 CM as the coding system for diagnoses when the HITSP C80 document would lead me to believe that this should be encoded in SNOMED?
2. What about coexistence of standards? Some use HL7 V2 while others use HL 7 V3?
3. Where does the migration of a standard fit in i.e. HL& V2 and HL7 V3
4. Is the charge really to recommend "requirements for" standards/implementation specs/certification, or is it really to recommend the standards themselves? "Requirements for" sounds very high-level and not specific.
5. Too much of the discussion so far is properly the domain for the Policy Committee.
6. What provisions will be put in place to enable patients to correct their data?
7. The HITECH Act states Federal agencies shall utilize HIT systems and products that meet standards and implementation specifications. How will this be monitored for Federal agencies that do not participate in CMS?
8. Is a standard being considered, defining EHR itself? I mean, its structure and contents (mandatory and optional components)?
9. Initial standards selection has more to do with tools and less to do with architecture
10. The HITEP II approach to quality measures makes intuitive sense, and might represent a giant leap forward from the current state of measures. However, no one really knows how it will work in the real world.
11. What is the plan for real-world implementation and evaluation of HITEP II driven measures prior to its use in this or any other program?

12. I made the following comment at the HIT Policy meeting on June 16, 2009 and will add a question and reiterate that comment here as well. My question is, who, when, where and how do the two committee's envision EHR vendors becoming coming certified?

This has massive implications to the financial health of EHR vendors. The committees are addressing the question of 'what' the certification and meaningful use criteria will be very adequately and should be applauded for their work in this very complex area. My comment goes to the potential certification bottleneck of EHR vendors obtaining their certification. There are perhaps thousands of EHR vendors, in our vertical (optometry) alone there are likely over 20 EHR vendors.

I can envision there certainly being a rush to get in front of the certification queue if that is the process. As a corollary, if CCHIT certified vendors are grandfathered into 'certification', this certainly could provide a crippling blow to EHR vendors who do meet criteria established by the ONC but who are unable to obtain certification in a timely manner.

A suggested alternative, at least for providers in private practices might involve providers/practices completing annual attestation forms in a similar manner to the methods personal and corporate tax returns (1040's 1120's) are completed attesting to the extent their deployed EHR system meets certification standards and is utilized to meet the definition of meaningful use. The completed attestation form could be subject to audit by the certifying organization/organizations.

The consequences to having one certifying body or even a handful for that matter are numerous.

13. What are the mismatches between HITSPC80 and the HITEP sponsored data types?
14. Regarding the Overhage comments, the HITSP recommended standards are indeed implementable but they may be hard to implement in certain large systems that are now in place. We cannot simply plan on the expansion of existing systems. even ones as prominent as the one developed by Regenstrief and deployed as part of the NHIN prototypes
15. I just heard the speaker say "write standards". Would it not be wiser to speak about "selecting standards"?