

**HIT Standard Committee
Final Transcript
December 17, 2010**

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good afternoon, everybody, and welcome to the 20th meeting of the Health Information Technology Standards Committee. This is a virtual meeting, so just a couple of reminders. Please don't put your phone line on hold, or we'll all enjoy your phone hold music, and please use the mute button when you're not speaking. It's also a Federal Advisory Committee, which means there will be opportunity at the end of the call for the public to make comment, and the summary of the meeting will be posted on the ONC Web site.

Let me do a quick roll call, please. Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dixie Baker?

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

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Anne Castro?

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Steve Ondra, you're on for Aneesh Chopra. Is that correct?

Stephen Ondra – NeHC – Senior Policy Advisor

That's correct.

Judy Sparrow – Office of the National Coordinator – Executive Director

Chris Chute cannot make the call. Janet Corrigan?

Janet Corrigan – National Quality Forum – President & CEO

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Jamie Ferguson?

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

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Steve Findlay? Linda Fischetti?

Linda Fischetti – VHA – Chief Health Informatics Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Kamie Roberts for Cita Furlani?

Kamie Roberts – NIST – IT Lab Grant Program Manager

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Martin Harris?

Martin Harris – Cleveland Clinic – Chief Information Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Liz Johnson? I know she's trying to dial in. John Klimek?

John Klimek – NCPDP – VP Industry Information Technology

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Judy Murphy?

Judy Murphy – Aurora Healthcare – Vice President of Applications

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Nancy Orvis? Marc Overhage?

Marc Overhage – Regenstrief – Director

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Wes Rishel?

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

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Cris Ross?

Cris Ross – LabHub – CIO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Rick Stephens? Walter Suarez?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Yes, I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Sharon Terry? She might dial in late. Lorraine Doo for Karen Trudel?

Lorraine Doo – CMS – Sr. Policy Advisory Office eHealth Standards & Services

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Jim Walker? Also on the line, we have Doug Fridsma.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Did I leave anyone off?

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

Nancy Orvis.

Judy Sparrow – Office of the National Coordinator – Executive Director

I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Good morning, everybody, and thank you for your participation today, especially this close to the holidays. It's hard to believe that it is the 20th meeting, but it's also quite remarkable to watch the progress and to know that each of you have been a member of this committee and all of those, especially in the Office of the National Coordinator, have supported nothing less than a transformation. It's quite

remarkable to reflect on this past week's news, the most recent survey from the CDC that shows that over 50% of physician offices now have at least modest electronic health records, and that trajectory is increasing rapidly. Certainly, those of us in the hospital space see a similar trend toward adoption, and kudos to all involved with moving this forward. It is a very exciting time.

Today's meeting sort of represents the complexity of the fabric of all of the activity that is occurring. We've got Doug Fridsma bringing us up to date on some of the standards and interoperability activities, and John Halamka, in particular, will be bringing us some additional detail and discussion from the Policy Committee charge to us to really provide some depth of support in the standards realm for digital certificating. Dixie Baker will provide insights from her team's view and the NHIN activities. Of course, we have some of our own work to share with each other, as it relates to the Implementation Workgroup's activities in preparation for the upcoming hearing. Something that certainly, as someone who is in the healthcare delivery side, but recently has also been advocating the issue of device interface and medical standards for devices. An area that really can help to connect those devices, which in many instances literally touch patients with the information systems and allow the integrity of message and information flow, the ability to support error checking, and the ability to intervene with decision support.

It is also a meeting that occurs in the context of the recent Presidential Committee of Advisors in Science and Technology or PCAST report. Certainly, that receives a great deal of press, having spent a better part of a decade in Washington and worked with many of these reports. They're really terrific documents. They help to inspire a lot of activity, and the individuals who come together are typically leaders in their field. Sometimes they have domain expertise. But they, in a sense, set up a challenge that needs to be addressed, and so these sorts of reports tend to be very inspirational, oftentimes very high level and, in that regard, predominantly directional.

There is an established, legislated, public process for assigning the standards to the meaningful use requirements that our colleagues at the Policy Committee offered to the Office of the National Coordinator. That process really completes the thread of the fabric that takes us from the aspiration to achieve meaningful use, the aspirations of the PCAST report, to really come to or bring to fruition the continuation of the activities that have really accelerated and, in many instances, even accomplished during the time period of the last 20 months. I hope everyone feels very connected, very integrated, and realizes that we have a great deal of work to do in terms of providing another level of detail, of public vetting. As is the expectation or requirement of a Federal Advisory Committee in terms of helping the Office of the National Coordinator really bring together the standards and interoperability framework and meet the aspiration that are so eloquently put forward by the PCAST report.

That is to say that ONC has many different meanings. Those who have joked, "It's the Office of No Christmas," are absolutely correct because, as this would hopefully be for many a time of quiet reflection at year's end, it's also a period where we in fact are recharged. A lot of work is required to really ... the support that the very literal and detailed level for standards, implementation guidance, and additional specifications to really realize all of the aspirations, both those of meaningful use HITECH, those that are articulated in the PCAST report, and those that most fundamentally bring everyone involved in this activity to this activity. That is the hope for higher performance healthcare, healthcare that's safe, effective, efficient, and compassionate.

With that, let me actually turn it over to John Halamka, who has been working with some level of detail with the PCAST report. I appreciate your introduction. In fact, in David Blumenthal's ... this morning, as ... Washington weather, etc. have given David one of those frequent colds that occur, and he can't be with us today. So, John, appreciate your insights on PCAST, etc.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks so much. As you've said, today is an important meeting. We do want to thank everybody for all the 19 meetings before this one. PCAST, I'll start in a moment, but I also want to reflect on the important work we'll have today reviewing the standards and interoperability framework priorities. I think all of us are in the throes of dealing with a certified electronic health record technology implementation and planning for meaningful use. We're starting to see, as we do these data exchanges, where the gaps

really are. I think we're going to, over the next couple of months, really know where the work needs to be done to achieve some of the goals that we're outlined in our Implementation Workgroup of reducing the cost of implementation and making sure more data flows.

I think my issue, as sometimes I read in the press, and it says, the real problem with interoperability is that we don't have the standards. I'm not sure that's really true. I mean, there are gaps certainly that we'll be working on together, but a lot of this may have to do with adoption of existent standards. So I think, as we look through Doug's priorities, a question we should ask and I think will be likely assigned to our Clinical Operations Workgroup, is of the priorities that Doug has outlined and we'll discuss today, what are those things that all of us who have experienced this in the real world feel are necessary to accelerate adoption, so we get more data flows in support of interoperability, stage one? What is planned for stage two and three?

Also, I think it's going to be very important to hear what Dixie Baker's group has concluded on their review of the Direct Project and how, with some subtle polishing, that can be, I think, very much aligned with its goals, so lots of great discussion today. Look forward to your input. As John has said, our work is never going to be done. There's going to be exciting work ahead, so with PCAST....

Judy Sparrow – Office of the National Coordinator – Executive Director

Dr. Halamka, Dr. Blumenthal is dialing in now, so I don't know whether you want to just wait for a moment.

John Halamka – Harvard Medical School – Chief Information Officer

Absolutely. Since he had planned to introduce the PCAST report, this will be a perfect timing. I'll just state that on my blog, I did do two things. There is a PCAST review, which we'll talk about today, but I also reflected on Monday on some of the work that the HIT Standards Committee has ahead of itself. I would say that the blog I wrote on Monday is really looking at some of our short-term work, and what are those things that we need to make sure, for example, in today's agenda, we're addressing. But also, we need to keep in mind that long-term work, and I think that Doug's discussion will reinvigorate a lot of the activities of our Clinical Operations Workgroup, as this committee really serves ONC in helping set those priorities that really should be its work. We should not be a committee simply reviewing the outputs of the Policy Committee and ONC. We need to be a committee that is very forward-looking in helping guide through our advisory capacity the priorities of the work ahead. Has David joined?

David Blumenthal – Department of HHS – National Coordinator for Health IT

Yes, I'm here.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. David, perfect timing. We all hope you are feeling better.

David Blumenthal – Department of HHS – National Coordinator for Health IT

I'm feeling much better. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Good. We were just about to commence the PCAST discussion, and so would welcome any introductory remarks you have.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Thank you. Thanks for your blog, John, which was a terrific review of it. Thanks, as always, to all members of the committee for taking time for this work. As we approach the holidays, I want to again express the deep appreciation of the Office of the National Coordinator to all of you for the incredible amount of effort you expend every day, it seems, to help us move forward, and it's had an enormous impact already. We're going to be asking you, as the year comes along, and as we move into the next phases of meaningful use, and the next phases of standards, to continue that critical assistance that you provide.

The PCAST report, which John will talk about at some greater length in just a moment is, as you all know, a report of the President's Council of Advisors on Science and Technology. The importance that the President attaches to the HIT agenda, the HITECH work, the prospect or the vision of an interoperable, private and secure, nationwide, electronic, health information system, I think, is clearly apparent in the PCAST report. There are many, many aspects to that report, and we are very much looking forward to your detailed review of it, and we're going to make sure that you get a chance to look at it in detail. We want your views on it, but I think the overlying message is that the administration is absolutely committed to achieving interoperability and to achieving the benefits of interoperability, and that it's not a minor issue for them. It's a core issue for the future of the HITECH legislation, for the future of this office, for the future of the Administration.

PCAST obviously felt that medi-tagging and universal exchange language and privacy and security protections were core attributes. There are many specific recommendations. But the most important message is that we are going to move forward with a great deal of aggressiveness on health information exchange and interoperability and probably even faster than we had expected, based on the President's, on this council report. So it's going to be up to us to try to make sure that we pick a path that is technically as refined and as open to innovation, but as reliable as we can make it.

I was encouraged that the Administration, the White House, care as much as they do about this, and I think that in some ways the commitment is as important as any particular recommendation in the report itself. So I think we should feel empowered to move forward with knowing that we have a great deal of support within the administration. I think we have a great deal of support in the Congress as well. I think that's what everyone is really hoping for that we will create this kind of opportunity for a data exchange. Now the question is what's the best path forward. PCAST has outlined one path. I think, in the end, we'll find it to be a path that we can all not only embrace, but feel is a very important and useful one. But that's, in some ways, the message I think we should take away from the report, an endorsement of the work that we've already started and a commitment to continue it.

John, I'm going to stop there and let you lead a discussion of the report itself.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks very much. David, did you want to say anything about the notion of ONC establishing a review committee of multi-stakeholders from multiple workgroups and committees to take a deeper dive on this?

David Blumenthal – Department of HHS – National Coordinator for Health IT

Yes. As you know, the pattern that we've followed when we have a technical issue that requires some more intensive work is that we've created working groups to manage them. We're going to create a working group on the PCAST report, combining members of the Policy Committee and the Standards Committee, as well as some outside members. They're going to bring back recommendations to the full committees, and we're also, I think, going to arrange for members of PCAST to come and talk to both the Policy Committee and the Standards Committee at a future time. We haven't exactly pinpointed a date for that.

We're also going to be processing this report with other technical groups and privacy and security advocates, so there'll be a whole series of activities. But ultimately, when it comes to setting new standards for the second stage of meaningful use, we are going to be relying on this committee, advised by whomever the committee feels the need for advice on. What we simply do often is provide a kind of subcommittee framework to do a really more intensive look than we can do in the relatively infrequent meetings that the Standards Committee has.

John Halamka – Harvard Medical School – Chief Information Officer

Good. The history of the PCAST report: One year ago, in Washington, at the Keck Center, Christine Cassel, the president and CEO of the American Board of Internal Medicine, and Craig Mundie, the chief research and strategy officer of Microsoft, as co-chairs of a working group, convened members—Peter Bach from Sloan-Kettering, Basit Chaudhry, Molly Coye, myself, Eric Lander who does serve on the PCAST larger committee, John Levin from Stanford, Louise Liang from Kaiser, Bill Press, a computer

scientist from the University of Texas at Austin, Stephanie Reel from Hopkins, and Harold Varmus who was president of Memorial Sloan-Kettering at the time—to have a one-day discussion of some of the great challenges in healthcare information exchange and standards facing the country.

Then a month later, in January, there was a two-day meeting in Irvine, California, where the working group met additionally. Several experts testified along the way, so there were multiple members from ONC and from vendors and from standards organizations that offered input. Initial work was done to create a few early chapters with early ideas. Then the materials of the working group were turned back to the PCAST subcommittee on health where then internal work was done. Ultimately, there was a presentation of a report to the full PCAST membership. So if you think about the tiering of this, you gathered expert testimony in December and January of last year. Then the members of a subcommittee within PCAST and PCAST itself produced this report. So it is PCAST's essentially independent synthesis of all of this information that they gathered from multiple sources. So you'll see a disclaimer at the beginning of the report that notes that working group members participated in preparation of an initial draft, but are not responsible for, nor necessarily endorsed the final version, as modified and approved by PCAST.

What you have is really a report that represents synthesis by PCAST membership in answering the question, how can we use healthcare IT to enhance quality, safety, and efficiency of healthcare in the United States? So now, we have received this report. As a committee, I think it's very important that we do what both John Perlin and David Blumenthal have suggested, which is embrace the commitment to interoperability, as where are there major themes and major directions that should influence our work going forward. As one reads the report, I think, from a standards perspective, and we have significant domain experts on the phone, there are many aspects of the report you might consider not precisely accurate statements, so the state of standards or their implementation in an electronic health record and healthcare information exchanges. But as both John and David has said, I think rather than focus on individual paragraphs that may have statements that we may not agree with it, it is better to say, directionally, how do the themes suggest where we might go in the future and broader concepts we may want to embrace.

As I read the report—and again we'll turn it over to you guys for your reading in a moment—I saw the theme of it is a good idea to have a universal exchange language, as defined as an XML construct. Or constructs with good vocabulary controls that enable the representation of healthcare data as a middleware layer to exchange information between EHRs, PHRs, repositories, and other consumers of data. Again, I think, directionally, saying that XML standards, as are today used in the CDA, CCD, and CCR and other standards with good vocabulary controls that can be sent through a transmission mechanism such as Direct, no one is probably going to argue with that as a direction. It's, of course, the details of what it means. Does that imply modular CDA, that is components of XML that can be put together to perform a construction of any set of data elements? Is it something else? I would certainly hope that it is not the notion that we should start from scratch and develop a new XML construct for healthcare that is simply unrelated to the work of....

Data atomic was another idea. The concept that if we are going to have a universal mechanism of exchanging data through middleware, instead of saying here is an unstructured, text based document that requires natural language processing to discover smoking status. That you should be able to, in this XML construct, represent individual problems, medications, laboratory results, and items that might be used for quality indicators like smoking status and then be able to separate those out from the document or collection of data elements or modules as a whole. Again, the notion there is probably pretty reasonable. As I've indicated in my blog, I think you do have to be a little bit careful about what you mean by data atomic because you could imagine that a problem list is comprised of a problem name, a problem identifier, a date, and an active or inactive indicator. To simply say we have a data atomic value of a problem inactive without any context of which problem or how a problem is structured is probably not a great value. So probably, some debate and discussion on what that topic means.

But metadata is important. This is, if it is the case that we wish to, in the future, aggregate information across multiple information sources so that we can have an accountable care organization or a

community of care coordination and population health analysis, being able to discern how an individual data element relates back to a patient, a gender, a zip code. Something that would indicate characteristics of how the data was gathered, by whom, for what purpose, and what patient or class of patients it refers to inherently seems reasonable. It also provides a structure where it may be desirable in the future to provide more granular privacy control, although the Privacy and Security Tiger Team has rightfully suggested a granular data element level control is certainly challenging to implement, but it certainly provides an infrastructure for which additional privacy control is possible.

Search engine technology is highlighted as a mechanism of being able to order this data. That rather than using a giant, central repository to document registry kind of exchange, the notion that data elements and their metadata might be appropriately searched and organized through search engine technology is highlighted. And, of course, that does raise several issues of how might data in an index of a healthcare search engine be protected because even hosting metadata and pointers to data can be itself a privacy risk. Then, finally, highlighting data reuse that, with patient consent, appropriate use for clinical trials, clinical research, population health, biosurveillance, if we did have a mechanism where data could be pulled out of a XML construct with privacy controls and repurposed that it would conceivably lead to very interesting, innovative uses in EHRs, PHRs, research, and population health.

That is the gist of where I saw some big themes, but would sort of like to open it up to the group now for your discussion of how you read it and what elements of the report you think should be incorporated into our work going forward and how we might do that. Let us open it up, and raise your virtual hands.

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

Wes raising his hand.

John Halamka – Harvard Medical School – Chief Information Officer

Go right ahead, Wes.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This is Stan raising his hand too.

John Halamka – Harvard Medical School – Chief Information Officer

Okay. We'll start with Wes, then Stan.

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

A couple points: one, the vision that we attack health information exchange more at a national level rather than as a hierarchy of state components interconnected, I think, is a strong point that needs to be carried forward, not that we don't believe that the states and their HIEs have a role. Just that it's hard to comprehend them as being the entire picture for health information exchange in the United States. An approach that allows coverage to develop at its own pace, driven by the needs for coverage rather than sort of having the priorities structured up to the state level has some advantages.

The second comment would be that there are a number of reasons for health information exchange in the United States, several of which involve retrieving data as required. Some of the other use cases that we've described involve really signaling an event from one entity in the healthcare system to another. An event could be as simple as we're done analyzing the lab data, or as complex as we're about to discharge this patient and need to schedule homecare and rehab for the patient at the same time.

My sense is that less attention was paid to that issue. There are comments about using published and subscribed as an alternative for forwarding events. I am not convinced that publish and subscribe is an alternative to an event-based model. Therefore, I think that one of the ways to deal with the PCAST report would be to go to its strength, which is the use cases that involve being able to access patient data either for research or at the demonological reasons or for unanticipated or unsigned interactions with the patient and treated as that part of the overall HIE picture.

The notion of atomic or elemental data is an important one. It is one that has to be recognized as an important point of view, but not necessarily the entire picture. You raised the notion of a problem list gets separating – a problem from the problem list being separated from the information that you need in order to take the problem into account. We might assume that the definition of what is an element can be raised to a limit where it is essentially a concept and all of the necessary related concepts to make it useful.

If you look at the treatment of documents today, as we envision it for HIEs, certainly as it's being done now in Microsoft HealthVault, there's a notion of shredding a document, and that doesn't mean that the document ceases to exist. It means that that data, which is amenable to being structured elementally, is stored redundantly in a database for access easily. For example if a dozen documents have come in with different capillary blood sugar values, and the desire is to plot the blood sugar values, it's not necessary to open and decode a dozen documents. That data, you just access those objects serially and post the data.

I think it's an important point to mention. It's nothing new for the way we've been dealing with documents, and it would be possible, if we weren't careful, to lose information in the sense that often a document represents not everything we know about a patient, but everything a physician wanted to say about an encounter. For physicians, the art of knowing what to leave out is as important as the art of knowing what to put in. It's been my observation that the physicians pride themselves on generating a concise, well organized summary of an encounter, and value that in receiving input about patients as opposed to a dump of data, and we would like to preserve those uses where the context comes from the document, including what's in and what's not in.

It strikes me that the notion of demographically based patient linking across the population of the United States, particularly with a limited number of data elements, is not consistent with the testimony we received in the privacy tiger team last week where we learned that there is no way of achieving ultimate accuracy. There is simply a way of tuning an algorithm to emphasize false negatives or false positives, and that each strategy is appropriate for different use cases. At a minimum, I think, as we analyze the approach in PCAST for its utility in various—I hesitate to use the term use cases because it sounds a little specific, but—various categories of use cases, we need to understand whether there are alternative methods to patient linking. Whether the notion of a richer set of data elements for patient linking is appropriate, and that all of the retrievals done using demographic based patient linking will have an error rate, as does almost everything in medicine, and the job is to understand how to deal with that error rate. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

I think what you have said quite eloquently is the PCAST report describes some use cases that data atomic notion may be perfectly reasonable and very helpful, in fact, but there may be other use cases where maintaining the context of the encounter is also important, so use PCAST where it makes sense, but other alternatives where it does not. Stan, please make your comments.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

The points that I want to make, I think, you could describe as sort of more detailed sort of looks at areas you've mentioned, and Wes had mentioned. It strikes me that as they were talking about this universal language, they were talking about what I would call detailed clinical models without necessarily knowing that word or that definition. As I look at the kind of exchanges going on now and what we have from the existing standards organization from HL-7 and NCPDP, there are some well-described medical documents and structure. At the one end, we have detailed structures for orders and for medication orders. At the other end of the spectrum, very less complex, essentially just a single code associated with the value, we have standard lab data that says things like hematocrit and hemoglobin, and serum sodium, etc.

But there's this vast, I hate to go to the donut hole analogy, but there's this huge area of things that are not.... If you talk about things as simple as blood pressures, most people would represent blood pressures as a single coded element in the record. But as you get more sophisticated, you have the

opportunity and, in fact, it becomes important to note along with the blood pressure what was the patient's position when this was taken so that you can take orthostatic blood pressures. It may become important to know whether the blood pressure was taken with a blood pressure cuff, or whether it was an end dwelling arterial catheter that allowed me to obtain the blood pressure.

Likewise, with weights, to do what you want with weights and actually have the data be understood and exchangeable. They want to know whether the patient was dressed, whether they had their shoes on, whether they were naked at the time of the weight, whether it was done with a sling from bed or whether they were standing on a scale. As you get into it, you realize that there are literally thousands of models that you need to understand for those kinds of data.

It has to do with the prime finding that you're looking at and associated data to go back to the example that has been mentioned a couple of times already with the problem list. It's easy to conceive that the problem list is sort of a single code that describes the problem, but if you look at implementations of actual problem lists in working systems, people have chosen to qualify that information with other fields that might express the severity of something. Or if you're talking about rashes, they would express, as a separate field in that model, what body part the rash is on. They would express other things about the fact that I'm trying to rule something out rather than the fact that this thing is actually present.

So there's a need that I see to get to the level of information exchange that the committee is talking about that really has directly to do, and in the spirit of open disclosure, this is something that it's a thing that I've been working on for ten years, and so it's a particular interest of mine. I don't have any financial interest in it, but I have huge interest in what it enables in systems. I'm doing work in this area. It's the essence of a lot of work that's going on in the open EHR activity out of Australia. It's at the heart of what is going on with the logical record architecture work out of the United Kingdom. Those kinds of models have been promoted and described by many of the modeling activities within the VA and within the DoD. So I see an opportunity here.

In fact, this is a complicated enough thing that it might be useful to have a one-hour tutorial just to make sure that people are starting from a common playing field, but I see that's an area. It's an area that we're not covering today on a national scale, and not coordinating on a national scale. Again, at the heart of it, it's saying we have some complex things at one end of the scale like orders that are fairly well described and, at the other end of the spectrum, we have simple things where just the name value pair of a code and a value get us quite a bit of benefit. But then there's vast middle part of that spectrum that is completely unspecified, and we can't get to interoperability around things as simple as weight, blood pressures, and heart rates unless we do more than what we've already done. This is also exemplified in the term info work of HL-7, and I'm sure I'd forgotten some other areas within there as well. That's the first point is that there's a whole level of modeling at a detailed level that we haven't broached as a country that's going to be necessary to create the kind of exchange that I think the PCAST report was talking about.

The other thing that I would mention is that, as we've – there's been a workgroup within HL-7 looking at sort of what we could do as a next generation of HL-7 stewards, and we've been reviewing people's use of the standards today, especially version 2.0, version 3.0 messaging, and CDA documents. One of the things that's been repeatedly made clear is that CDA documents, by intent and by design, are snapshot in time. It's difficult to use CDA documents if what you're trying to do is to maintain a consistent and single, non-duplicate copy of what data exists for the patient because you receive one snapshot last week, and maybe a month or two from now you get another snapshot. CDA by intent and by design does not include the information that would tell you, this thing that I'm sending you today is actually a correction on an object that I sent you earlier. So the transactional semantics around maintaining a consistent, electronic, medical record or a consistent view is not in place. In fact, you start imaging multiple participants in the exchange of the information.

I'll use my own local facility to make the example, but you have, for instance, Intermountain Healthcare and the University of Utah, and the Salt Lake VA exchanging information. The University of Utah requests information from the VA. The VA sends that information to the University of Utah. They

incorporate all or parts of those elements in their electronic medical record. Intermountain then asks the VA and the University of Utah what information they have. They send the information, and now I'm getting primary data from the VA that was sourced at the VA, and I'm getting echoes of the data that were sent to the University of Utah, also now sent again. If I'm trying to reconcile that and make a coherent record that a person can understand and use within Intermountain Healthcare, I have to recognize data that's coming, that originated from the VA, but may now be coming as part of a report of information from the University of Utah.

There are some fundamental things that we could put in place that would say things like the original source system has to assign a unique ... UID sort of identifier to data so that anybody receiving the data later can both recognize updates, as well as recognize redundancy in that data. The CDA, as it exists today, is not set up with all of the semantics that you need to do that. So I think this isn't to say what we're already doing is bad because that's not true. There's huge value in what we've already described in the use of CDA and CCD, CCR. It's hugely useful, but recognize that there are limitations. Then I would just go back to my first point that this huge ... clinical data exchange that will not be possible at an interoperable level until we talk about models at a more detailed level for that set of activities and objects. I'll stop there.

Marc Overhage – Regenstrief – Director

Marc Overhage raises his hand.

John Halamka – Harvard Medical School – Chief Information Officer

Just a quick comment then, Stan. I think you've really also highlighted a very important point on the difference between transactions and summaries in time. The issue that we need additional metadata to prevent data duplication, as we have more and more data being sent from place-to-place, because otherwise it will grow exponentially, as we simply replicate one institution's data multiple, multiple times that goes from place-to-place. The notion that you probably do need some sort of whether it's a RIM, clinical model, a dictionary, so that one understands what are the potential, not set of data elements alone, but the modules or the context in which they need to sit. As you've mentioned, a blood pressure by itself isn't so useful unless you know a bit about the how, the what, and the why it being taken. You need a model to tell you what those fields might be. Marc, please, comments.

Marc Overhage – Regenstrief – Director

I'd like to both build a little bit on what Stan said, and tie in with what John Halamka opened up with. That is, I think the PCAST report, the work that, as a country, we're trying to get done right now is obviously important work. That's why all of us are investing so much time and energy in this. Therefore, it's very important that we do it as well as possible in getting sets of eyeballs on that process from every avenue possible is helpful and important.

I think the risk though that we have to be cognizant of is this is not a new set of questions, nor are the concerns and ideas novel. In other words, at least in my read of the PCAST report in talking to others, I think there are things to take away from it and to scrutinize. I didn't find novel things that haven't been discussed, thought about, and worked through previously, which is okay. I think it's important for us to look at that report and ask ourselves the question, is there something that has been missed? Is there a stone that is not turned over?

At the same time, and this is my major concern or point, we cannot and should not allow ourselves to divert our attentions from the task at hand and moving the country down the road. In other words, I guess this is a plea to use the thoughts and care that went into developing the PCAST report to make us better, to challenge ourselves on all those fronts. At the same time though, not put a comma on our activities or semicolon on our activities, whatever the proper grammatical thing to do is, because I think that that entails risk as well. So unless there is something there that we think we fundamentally have it wrong, we should keep forging ahead as rapidly and as direct a fashion as we can while, at the same time, examining the feedback and using it to strengthen what we're doing.

John Halamka – Harvard Medical School – Chief Information Officer

Marc, I think that's very well said because, as I introduced, we are all in the throes of implementing certified EHR technology and trying to achieve meaningful use, and running into issues like, oh, my God. How do we exchange certificates? And how do we deal with provider directories? So there are some very real, short-term challenges, and I think what you will see in Doug Fridsma's presentation that there are some of these, what we'll call low hanging fruit. Probably we all can agree without a lot of debate. We better charge forward with getting them done. In parallel to that, there are the more longitudinal projects that Doug's S&I framework will be able to deal with over time, as it may be more forward-looking.

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

I just want to comment that prioritization is important, but a lot of times the forward-looking projects take more time and should have more work done in a corner, bringing back interim results to the community. So that prioritization might not, should not be considered a reason not to start on an effort such as detailed information models, knowing full well that it's going to take some time to aggregate the ideas that have been done in a longer time for system developers to be able to incorporate the logic into their system to deal with it.

John Halamka – Harvard Medical School – Chief Information Officer

Right. Good comments.

Linda Fischetti – VHA – Chief Health Informatics Officer

First of all, Stan, you very eloquently detailed the fact that there are many of us who have been working in this direction for a long time. Thanks for the gratuitous call out. That knocked off half of what I was going to say.

To go with what Wes said, we need to go to the strength of this document, and that is, and what this gives to us is the opportunity to create a roadmap of how we move forward. The first thing, of course, that we should spend a great deal of time on, and it would probably be more of a policy decision, as well as a technical decision, is to make sure that we fully understand the privacy issues of discoverability. That's something that we need to spend time on. While going to this model can help us with attributes-based access control that's very fine grain, there continue to be concerns there, and we need to fully understand that, internalize that, and know what we're going to do about it.

We also, Marc, thank you so much for saying that this report does not do anything to help to cause us to slow down on our current activities. We need to continue to move forward as much as we can. Those of us who are working in this space already have that glide path in our minds, working on small components of this, and looking for small scope opportunities to then just bring that into the mainstream and continue to move forward.

Hopefully the number one thing that this will bring to us is, continue to emphasize the need for resources on the common language. I think I've heard all of the speakers talk to that before. Many of us have been working on the common language issue for a long time, and it feels like the time is up on that conversation, we need to bring resources to bear. We need to do the hard work. We won't be able to deal with information as a nation until that barrier is removed. I think we have the skills and ability to do it. We just need to get it done.

John Halamka – Harvard Medical School – Chief Information Officer

I think, just to emphasize to everybody on the call, the PCAST report does support everything that has been done by ONC and our committee as foundational to moving forward, and I think what has been said, both by Wes and by Linda and Marc, is don't derail what we are currently doing. It is extraordinarily important work, and we can, with additional resources, build on some of the strengths of the report in parallel to the work that is already being done.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I want to be clear, John, I feel that same way. I don't want the new work that needs to be done ... clinical models to derail any of the current work that's essential for us to make current progress.

John Halamka – Harvard Medical School – Chief Information Officer

Other comments from folks?

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

First of all, I think they make a lot of good observations about the security and privacy landscape. I think that they make some observations that are absolutely right on target, and they provide real value by making them, such as the point that they make about consumer's hesitancy to have their data sold while, at the same time, they're fine about sharing information for public health purposes. I also agree with them that the HIPAA privacy rules have definitely had a deleterious effect on research, and I would further observe that this fact has resulted in the research community having to develop some convoluted ways to get adequate, high quality data at the sacrifice of transparency to the patient, and that's not good.

I disagree with ... well, further, I think that there are some concepts in there that they clearly don't understand like confusing identity with authentication, which are two entirely separate things. At the same time, they failed to address the two principle barriers, in my mind that, moving forward, need to be addressed. Number one is the whole identity issue. As we know, the HIPAA call for a universal identifier has been tabled forever. In fact, research can't even be done, is not even allowed to be done in this country on potential universal identifiers. I think that problem needs to be addressed head on because our lack of a single patient identifier and our lack to really do predictable patient matching has detrimental effects on our healthcare, on the quality of care, and the safety of care as well.

The second point that they didn't mention at all is the fact that our privacy and security policies across the country differs between states and the federal government. The federal government does not have the final say on health, privacy, and security. It also differs from state-to-state. I think that that's another issue that is a meta-issue that needs to be addressed over and above all the rest.

Their idea of tagging individual data elements with persistent tags that reflect privacy ... I think, is unworkable, unrealistic, and potentially harmful to the patient. The fact is that our privacy preferences are context specific and the context changes over time. Secondly, they're even linked to time. As medical advances are made, our sensitivity to certain types of information being exposed lessons. As diseases become curable, then the fact that you have the genetic markers for those diseases will become less sensitive to you. So I think that reflecting what others have said, I think the basic concept of metadata tagging at a very fine-grained data element level is unrealistic. But, in particular, it's certainly unrealistic with respect to privacy rules. I think privacy rules need to be attached to data at the time the data are exchanged and not persisted with the data over time. I think those are the principle points I wanted to make.

John Halamka – Harvard Medical School – Chief Information Officer

Very good comments, and so when I was a resident, HIV testing was considered very controversial. The notion you had an HIV test had an implication.

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

Good....

John Halamka – Harvard Medical School – Chief Information Officer

Today, one-third of Americans have had an HIV test because it is often a prerequisite for obtaining insurance. And so hence you're right that maybe, over time, the value of an HIV value might continue to have significant privacy implications, but the presence of a test being done may have less and less implications, so very interesting points. Other comments?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The excellent comments by Wes and Stan and Dixie and Linda don't leave a whole lot of ground to cover that we haven't already discussed, but I do want to point out a couple of things that I thought were very positive. I thought, to some degree, novel or at least novelly attended to, details in the PCAST report that I think warrant further attention. One of those is the notion of building national scoped indexing service that understands where the content in a patient's record might be available in a way analogous to what

Google or Bing or other Web indexing tools do. We're building a system similar to that at Cerner, and our initial response from our clients has been very positive. It seems to deliver some value with a relatively modest amount of effort, so I commend that approach.

I also was interested in essentially what they're proposing as a digital rights management approach to the patient confidentiality where the data has to be unlocked dynamically with a key that's available from some kind of a service that would represent the patient's existing preferences around what should be shared and what should not be shared. Whereas I think there are a number of thorny issues with making something like that work at scale, it's an approach that has a lot to commend it. I think that would deserve more research and more attention, along with the kinds of things that Wes and Stan and Dixie and others have already raised. That's just my two bits to throw in.

John Halamka – Harvard Medical School – Chief Information Officer

Carol Diamond, I'm curious. If you read the report, you'll look at this data entity access service or DEAS. It sounded to me a whole lot like the Markle record locator service. I agree, Wes, the notion of having an index that points to where records might exist for a patient is generally helpful to a pull type strategy, the emergency department type strategy, but it did seem to be restating some things that had been in the past. Carol, any comments you have? We may have lost Carol.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

In Carol's absence, or while she's unmuting, I think the difference is in the degree of detail of the information that is indexed, and that's a really important difference. I think the concept is very similar though.

John Halamka – Harvard Medical School – Chief Information Officer

I see, so the notion with a record locator service being a, here is an identity, and they have records that they have consented to release at XYZ location, but there really isn't a set of metadata that would describe the data elements that might be found at that location.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. Correct, so that the use case they detail is a pretty good one. Find me all of the mammograms. You could even say, find me all of the positive mammograms. Or you could even say, find me all of the mammograms that have a particular, specific, codified finding, and the DEAS service would know where those records exist. If you possess the right permissions, you could unlock and read those records. That goes beyond the traditional interpretation of a record locator service, certainly not necessarily beyond what some people have done to extend the model, but I think PCAST calls out kind of the ultimate extension, which is that you index all of the information.

John Halamka – Harvard Medical School – Chief Information Officer

Right.

Marc Overhage – Regenstrief – Director

One of the things that....

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

John?

John Halamka – Harvard Medical School – Chief Information Officer

Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Sorry. I just wanted to let you know, I heard you say my name, and when I tried to unmute, I disconnected myself.

John Halamka – Harvard Medical School – Chief Information Officer

In your absence, we answered for you, which was the record locator service that Markle had presented as part of a common framework, and the data element access service (DEAS) are related. But David McCallie pointed out that the record locator service really never was intended to have a rich set of metadata describing the data elements that were actually to be found at that location.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I would say that more strongly than that. It was intentionally not to have metadata for the very reason of disclosure.

John Halamka – Harvard Medical School – Chief Information Officer

Yes. The question, of course, is....

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

By the way, it was also never intended to be centralized in this way, from what I take away from the report, at such a national level.

John Halamka – Harvard Medical School – Chief Information Officer

Right, and as we've talked about, as we think about protecting privacy, there are benefits, and there are costs to the two different approaches.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, and sorry, Marc, if I interrupted you.

Marc Overhage – Regenstrief – Director

No. I was just building on the other thing that I feel like I'm being negative today, which is not my usual mode, but I do think we've got to be thoughtful about some of these ideas that are being discussed in advanced. We can't even get, in most of the country, two hospitals across the street from each other to share data for a whole variety of reasons. Then we have a conversation about, we're going to worldwide Google search, match everybody today. It's one of the usual challenges, and Carol probably will chime in on this as well.

These are not technologic problems that we have to solve. People know how to do those things. We have, as Dixie highlighted, trust and security issues. We have patient preference issues. Sometimes we see these beautiful pictures painted, and we can't even get the watercolors on the page, must less construct a work of art. I just think we ought to be careful not to get caught up thinking about too many of the pretty pictures we could paint before we can even get a simple outline on the page.

John Halamka – Harvard Medical School – Chief Information Officer

Well said. We have to be practical, as well as visionary. That's right. Other comments people would make on this report? As we said, I think there's going to be this multidisciplinary committee that ONC will put together to take a deep, deep dive and then, of course, report back to us on what they find. But are there themes that we've missed or concerns that you had?

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

Yes. At the risk of being a bit repetitious, but thinking in terms of Marc's comments, being careful, which was so true, I think that it wasn't important to pick on individual issues in the report today because it's more of a visionary thing than a detailed roadmap. But one of the concepts in the report that has been a pragmatic problem for interoperability all along is that most operational systems, which are viewed as the correct source for these documents, even after they've been found through the index, are not able to be good network citizens in terms of dealing with an unpredictable amount of demand. Particularly as you go to queries that might pull multiple amounts of patient data at the same time, all patients with this kind of positive radiology finding or something. And the notion that's implicit that the system should, that ONC or the federal government, through one of its levers, should require all systems to operate that way is a limitation. I really think that it's important though that some of the issues that came up in this call be pursued. Not on the basis of it's going to be a meaningful use requirement in 2015, but on the basis of, in

2015, we're going to know whether what parts of this recommendation should be introduced into EHRs going forward from there.

John Halamka – Harvard Medical School – Chief Information Officer

And so, of course, what will we need for accountable care nirvana is something that is on all of our minds.

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

Yes, we've done so well on EHR nirvana already. Yes, I would say that nirvana carries an implication of impracticality. My view of standards work is that the easy stuff is what we've already done, what we're already doing, and we just need to create a common format to do it in or common transport to do it with or something like that. The more visionary work that people would like to find is a ten-year process. But it's on a ten-year process from when you start, and we ought to be starting.

John Halamka – Harvard Medical School – Chief Information Officer

Right. Well said.

Jonathan Perlin – Hospital Corporation of America – CMO & President

John, I think that's a terrific segue from the aspirational vision to the more immediate work. We certainly have a lot of work to do. I know that we want to hear our updates from our Implementation Committee and clinical operations vocabulary taskforce. We also need to be sure that we get Doug's update on the terrific work that the S&I framework team is doing because that really lays some of the molecular foundation to realize this vision. I know that his team is really chomping at the bit to make sure that they're as active and productive as they can be.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. Turning it back to you, John, and let us go forward with the Implementation Workgroup.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Why don't we go right to that? Judy or Liz, who is updating us on that today?

Judy Murphy – Aurora Healthcare – Vice President of Applications

I'll start out by saying as far as the Implementation Committee, we're making great headway for the January 10th and 11th Implementation Workgroup hearing. Judy Sparrow, you could probably tell me the exact percent, but we probably have about 75% of the names confirmed and probably about 50% of those have already gotten back and confirmed participation.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Yes, that's about right, Judy. We've got 23 we've already set, and we've already heard back in the last 12 hours of the first 8, so we're rocking and rolling, as I would say, right?

Judy Murphy – Aurora Healthcare – Vice President of Applications

Absolutely. I think I'd like to reiterate an invitation. It is just prior to our next committee meeting in January, and so if any of the folks from the Standards Committee would like to attend, we certainly would encourage you to do so. We think it's going to be a very interesting hearing. Again, the panels are organized mostly. The majority of the content is about implementation experience with the early adopters in meaningful use, measuring it, and attesting to it. Then we do have a flavor of people responding about the regional extension centers, about the health information exchange, and about the— What am I missing, Liz? There are three of them at the beginning, and I'm doing this from memory.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Sorry. I'm sorry.

Judy Murphy – Aurora Healthcare – Vice President of Applications

That's all right. There is a little bit of flavor of the support infrastructure as well. That's going to be helping the people who are achieving meaningful use. So again, regional extension centers and health information exchange are being....

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Yes, and the certifiers.

Judy Murphy – Aurora Healthcare – Vice President of Applications

And the certification process. Thank you.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Right.

Judy Murphy – Aurora Healthcare – Vice President of Applications

Are there any questions?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Yes, the only other comment I would make, we've worked closely with the ... group out of the Policy Committee. They've had some very insightful recommendations that we've put into this planning process, and I think you'll see that reflected. The actual agenda and speakers will be out to you very soon.

Judy Murphy – Aurora Healthcare – Vice President of Applications

I'll call again. Are there any questions? Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Judy and Liz, many thanks for your work. I hope that those members of the committee might find it possible to attend will be able to do so. If you have further input or recommendations for that hearing, provide that to Judy Sparrow, Judy Murphy, Liz Johnson, John Halamka, or myself. Again, many thanks to the Implementation Workgroup for your efforts.

Let's turn now to John Halamka and Jamie Ferguson for your update on Clinical Operations, particularly as it relates to medical device.

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

Sure. First of all, Dr. Perlin, I want to thank you for your introductory comments about the device work in terms of the need to focus on data integrity and clinical decision support and patient safety aspects of both the clinical devices, as well as consumer devices. What I'd like to do is I'll just give a little history and background on what we plan to do, essentially as an advertisement, and members of the committee seeking your participation in this activity as we go forward after the New Year.

Where this really came from is we heard from EHR implementers about difficulties, several different areas where they had difficulty. First and perhaps foremost is difficulty integrating data from devices into their electronic health record systems. That includes both difficulty from the interfaces, difficulties in storing and finding places to put the data in the EHR systems, and also difficulty retrieving the data from wherever they had stored it for using it in the clinical decision support capabilities that they had deployed. So those are things that are sort of all about the data.

But then there are also some aspects that we want to focus on about the devices themselves. One is really uniquely identifying the devices, and this is something that certainly there's work going on in the FDA around this for the regulated device space, but we've also talked about that in the vocabulary taskforce for both the consumer devices and clinical devices in terms of unique identification challenges. But there are also interesting issues in terms of monitoring the integrity of the remote devices as a data source, especially outside the realm of the FDA regulated devices.

Then, of course, there are issues maintaining the security of the devices and patch levels, things that we've also discussed. We really would like to get input on that broad array of areas, so the next step is actually planning. We'll have a planning meeting of the Clinical Operations Workgroup in January. I'll be working with Judy Sparrow to set that up. So if anyone is interested in that, please join the planning

meeting and help us to set up this activity where we want to hear information about some of these devices, device challenges, and paths forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Any comments, questions, input for Jamie? John, anything you'd like to add?

John Halamka – Harvard Medical School – Chief Information Officer

Just recognize this is such a timely issue because, as you look at healthcare reform, there's going to be many homecare demonstration projects, and there's certainly going to be more monitoring and care delivery in the home. The FDA has been very hard at work on a whole variety of new standard activities, including the universal device identifier, so I think this perfectly aligned with the work that needs to be done.

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

I have a question. This is the same question that Nancy Orvis brought up at the last meeting. Will you be covering implanted devices?

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

That is a great question. I don't have an answer for that, but I would urge you to join the group working on this hearing. How about that?

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

Okay. I'll help you out. Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let me just – editorial observation. This is also a very timely conversation. I don't think that the dialog has ever been more intense about the value of healthcare in terms of how far the health dollar goes from businesses, employers, payers, government, and patients as consumers. The response to providers or the environment in which they're operating is a pressure on margin, and that plays out on the hospital side with the updates, for example, from both federal payers in the commercial space and in physician offices, the SDR discussion, etc.

Everyone is looking for efficiency. I'll just give you a classic example that is incredibly complicated. Not only is it inefficient, but it introduces inaccuracy and a lack of timeliness. Think about the last time you had your blood pressure taken. Those data were probably born digitally because you were quite likely to have an electronic blood pressure cuff. What happens is someone transcribed and some point, possibly much later, that data either lived on or may have died on a paper format, or maybe it was transcribed into an electronic format. This would seem to be just so easy, but it's extraordinarily difficult.

Linda Fischetti could relate to the VA experience where there's really a documentation of labor saving by simply allowing the electronic data created from a digital instrument, blood pressure, a Sigma nometer, to automatically go into the electronic health record. It also means, for example, for hospital care, that those data are not entered at change of shift, end of shift, frankly, after decisions have been made, but accrue in real time so that decisions that are made about medication also accrue more thoughtfully.

Amplify that out, as John Halamka suggested, to the consumer space. Think about the diabetes and essentially epidemic and the glucometers with the ability to upload, but the lack of consistency in terms of being able to integrate those data for patient benefit and for provider use for making informed decisions. And that goes on. I think Dixie's point and the point that was made previously about Nancy about implantable devices, the querying of pace makers and ICDs, etc., are tremendously important. Then, additionally, in terms of the ability to think about the security of the information flow, it's really much more sort of coherent project when there is the world in which some standards exist.

So I am extremely enthusiastic about the work, and this is really an important component of the interoperability, as this information becomes useful for informed and efficient healthcare. Many thanks for the work on that, and I hope that there'll be some good engagement of the entire committee because I'm

sure that you will, just as Dixie and Nancy did, suggest additional use cases that help to provide the basis for thoughtful recommendations to ONC on this.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

I just wanted to say, I do a lot of work on the rural and on telemedicine. I just wanted to make sure that that's one of the other areas we look at because a lot of these rural cities and towns do a lot of work with the major hospitals and that, and telemedicine, I think, will be very important in the future, and make sure we have standards on that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

That's a great point, particularly in terms of the interoperability. I think David was so eloquent in the comments about the interoperability and need for that interoperability. If one wants to take sort of an acronymic viewpoint, one looks at technology and says this is telemedicine. These are devices. That's an electronic health record.

One wants to take a forward-looking perspective, then one sees the convergence of these. So, when you think of telemedicine, maybe one is thinking about essentially video teleconferencing and interaction. But I'm sure John and the great work that you've been engaged with are thinking about all other modes. For example, one might have pathologists at one site actually driving the stage of a microscope half a world away to provide analysis, annotation, and help to that capacity in telemedicine actually become associated with a set of standards that allow those data to interoperate in all the appropriate forms. So much work to be done in this area, and really we'll look forward to the discussion. Other comments, other thoughts, other use cases?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Jamie, in the kind of vast array that we've already attributed ... can come in from biomedical devices and also, I think, have very explicit interactions with those and the lack of ability to get the data. Have you set a charter? Is that what your plan, your meeting is for, so that we can really begin to understand sort of the piece of the world you're going to take on? Are you taking on the whole world?

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

I think that scoping is exactly what we plan to discuss in this planning meeting in January.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Again, I think, with these sorts of use cases, one can sort of frame that stuff. Let me give you another use case that's certainly one that's been in the press a lot lately is that in addition to some of the equipment malfunction that's resulted in radiation injury, both for diagnostic and therapeutic uses of radiation, how does one actually manage cumulative radiation exposure? Some of you may have seen the reports, *New England Journal* among others, that Americans are heading toward up to ten or more CTs during their lifetime, and the cumulative radiation exposure is on par of that for Hiroshima or Nagasaki suburbanites. That's a pretty astounding amount and different evaluations of the risk/benefit of the diagnostic study may occur when one has an understanding of the cumulative radiation dosing.

What is the standard sort of context that will allow not only the receipt of that information from the diagnostic or therapeutic equipment into the repository, but also the interoperability of those repositories so that, across provide settings, that cumulative exposure would be known. I just suggest that as a sort of use case, one with respect to acquisition of blood pressure that is both labor saving and supports more effective informed decision-making. Again, great comments about the implantable devices, great comments about scope, and then another that out and out is an absolutely defined and present patient safety issue. Other comments? Thank you very much for that.

Jamie, anything else that you'd like to update, or John Halamka, from the Clinical Operations Workgroup?

John Halamka – Harvard Medical School – Chief Information Officer

The only thing to add is, as we go through Doug's discussion today, I think we should be attentive to how we can be most useful to Doug as an advisory group. That Clinical Operations is probably going to be

joined at the hip with Doug, as he marches ahead and begins some of the low hanging fruit work we all know needs to be done right now to get us implemented, but also plan those things that we would like to have in the future. So our Clinical Operations Group just seems like a natural home for Doug to be in partnership, working through those priorities, starting now, but advising him in the future.

Jonathan Perlin – Hospital Corporation of America – CMO & President

John, I think that's a terrific framing because we need to really help with the recommendations for Doug, but we need to also, as a group, provide our best advice for his success and the Office of the National Coordinator's success. But really, in this regard, want to make sure that there's full understanding that, as an Advisory Committee, our role is advisory, and so we need to make sure that he and the Office of the National Coordinator can proceed a pace during what for everybody is a very compressed timeline. So I think your introductory comments and focus on those low hanging fruits is really a great place, again. Let me turn back, John Halamka, to you for any additional comments, and then we'll go to Doug.

John Halamka – Harvard Medical School – Chief Information Officer

Yes. I think we are ready to proceed with Doug. The bulk of the rest of the meeting will be Doug's presentation and where we go with that standards and interoperability framework priority set, and then hearing from Dixie and her committee on the review of Direct, which I think everybody will be quite interested in.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Thanks, John. I'm really delighted to be able to spend some time. We've been working heads down with our various participants in the standards and interoperability framework. I know there's a tremendous amount of pent up demand to just start doing the things that we need to get done because the activities are moving very, very quickly. I'm just really delighted to be able to sort include this group and get the advice and recommendations about how best to proceed.

Before I start, I just wanted to have one comment about the PCAST report. I think it's important to note for the record that it is not ONC's CDA, but in fact HL-7's CDA, and that the Standards Committee and HL-7 are an important part of that sort of ecosystem that we've got. I just wanted to make it clear that that was the case.

Now I have a couple of slides that I've put together, and you've been given a number of different documents and information. In a sense, there's sort of three different things that have been included, and maybe four if you include the information that was recently posted on the FACA blog. The first is a set of prioritization framework. We've been working hard to try to make sure that we have transparency in how we come up with the priorities to work on and to make sure that those priorities link back into the priorities that the HIT Standards Committee believes is important. The priorities that we see, not only for stage one meaningful use and the maintenance activities that we have for the current standards that have been adopted, but also looking forward to those things that we anticipate for stage two and stage three.

That spreadsheet was sent out just so that people could begin to comment on whether we've got our priorities for our priorities framework correct. So I welcome people to spend some time. We probably don't have time to solve that problem today, but to spend some time taking a look at that. For those who have had a chance, we can, at the end, have a little bit of time for comments.

The second was a list of 11 initiative summaries. In some sense, I'm trying to figure out a way to best convey, both to the HIT Standards Committee and to others, what are the problems, the scope, the targeted outcomes, how it aligns with other initiatives, and what would be use cases that would be related to these various initiatives? So those have a tremendous amount of detail in them, and that was also included in the information.

The slides, however, that I'd like to step through, at least as an overview and introduction, are slides that you've seen before and that I wanted to sort of step you through what we've been doing over the course of the last year and kind of where we are now, giving you that context. Then hopefully begin a discussion about how best for us to proceed and to be able to include the HIT Standards Committee in the process

by which we set up our framework that we establish our priorities and help us monitor that we're achieving the successes that we'd like.

In reality, the standards and interoperability framework began as an idea almost a year ago in October of 2009. We've been actively working on that, both in terms of organizing some of the contract moneys that we've had, trying to figure out how to set up our structures to help support the work of managing the standards and the interoperability specifications that we need to help support meaningful use. In September of this year, we had the kickoff with really the last of the contracts being awarded, and we had close to 100 contractors and participants, I guess. There weren't 100 contractors, but there were 100 folks that were there to kind of get a sense for what we're trying to accomplish, what the different parts of the framework are supposed to do. Since that time, we'd been very, very active in trying to organize how we're going to coordinate all of the activities that are going on.

As you know, in parallel to all of these activities, we also have the Direct Project, which was an exercise in trying to run the development process in a way that is open and transparent. That tries to be as inclusive as possible, and that uses the technology, the wikis, and discussion to really get consensus in the community and among all of the private sector and the government participants and the like in rallying around solving particular problems. So we have just tried to, as best we can, take that work and figure out how we can use those kinds of initiatives, like Direct, and the way in which that was organized, and meld that together with the work of the standards and interoperability framework.

The slide that we have about taking targeted problems and connecting them through with the interoperability framework to help us go not with 1,000 flowers blooming and not with command and control, but to really help to have that focused collaboration that we'd like to see. I think that's a critical part of what we're trying to get to. I think, over the course of the last couple of weeks and months, I think we've gotten increasing refinement on how those initiatives would work with the standards and interoperability framework.

I go to slide three that talks about the approach to the standards and interoperability framework, we realize that all of this has to fit into the national goals that we have for quality, cost, access, and public health. We want to make sure that those priorities are all working together with the standards and interoperability framework that we have. On the fourth slide, this was one that we presented just a month or so ago. We sort of talking about using the standards and interoperability framework as a platform for all of these different initiatives that we would have going on. That we would use the resources of these contractors, not so much to determine what those implementation specifications should be, but to help us standardize and have high quality artifacts that are consistent across initiatives so that it provides some coordinating mechanism across the different activities that we have.

Another view is represented on the fifth slide in which what we do is really kind of a matrixed organization. We have stakeholders that can participate, people that may be interested in defining use cases or people that are really driven towards doing the reference implementation. Those would be crosscutting across all of the various initiatives that we have, and so that we could use the resources of, say, our use case team to help get consistent use cases across all of the different initiatives. Then, within the initiatives, they would just leverage all of those resources. In large part, I've sort of told the folks that are participating in the standards and interoperability framework that the initiatives will help us focus our attention. They will help us identify what goals that we want to try to achieve. It will be a way of coordinating across all of these activities. But that the people that are participating in the standards and interoperability framework are actually going to be staffing or organized through the initiatives that we would set up.

That's what leads to this particular discussion, and if we go to the next slide, when we want to talk about if we've got a series of initiatives, and even if we had unlimited dollars, we don't have unlimited time. We need to have some mechanism that allows us to understand how best to prioritize things and how to be able to support the work that we do. As we go through this, to reprioritize as necessary. I think one of the ways to view this, and this is a conversation that Arien Malec has been contributing to with the Direct Project. Sort of how to put these initiatives together is that while we need to manage each of the

initiatives in sort of a project management approach, when it comes to each of the initiatives, we really need to think about those as an investment portfolio and that we have a series of investments that we're making. That will, I think, give us the biggest return towards interoperability, towards improving the quality and efficiency of our healthcare system.

So we have to be able to evaluate our investments. We need to make sure that our investments are getting the appropriate return. We have to make sure that we've got all of the pieces in place so that we can evaluate how best to both invest and diversify our portfolio. So some of the early work that we'd done is to take a look at how we can set up our priorities. Clearly, when we take a look at something, we have to think about it in terms of things like if we've got meaningful use. We have to make sure that when we're looking at an initiative to make sure that it conforms to the U.S. healthcare reform legislation, that it supports existing standards. That it perhaps provides tools that will help bridge gaps in achieving stage one measures for meaningful use or provide foundation, as Wes has sort of articulated that may need a little bit more work and is more foundational, but will support stage two and three and maybe beyond that in terms of our interoperability.

Things like the Nationwide Health Information Network, we need to be able to have initiatives that build on the existing framework that include not only the Connect and Exchange portions of the Nationwide Health Information Network, but also Direct. Then we also address other critical interoperability initiatives that are coming from the President such as the virtual lifetime electronic record project, and most recently, the PCAST report. Certainly when we were putting these things together, we knew of the PCAST report, but we certainly had not put that into our prioritization framework.

We've identified internally a number of different priorities that may be potential work for us to be working on. I put these out there as proposed, not as things that are set in stone and that in fact this is probably an incomplete list. There are probably additional things that we have just simply not thought of and that may need to come to the table. So on this slide number 4, there are essentially, it looks like, 12 different sorts of initiatives that are listed there. We have things like the clinical summary. We know from some of our experiences with the Nationwide Health Information Network and the work that's gone on with the C32 is that it's an important step towards interoperability. But there still is a fair degree of optionality, and that we need to probably take a look at that as part of maintaining our standards and refining them to help support meaningful use.

That feeds into more broadly other activities such as templated clinical documents or the idea of how do we make sure that as we think towards stage two and stage three meaningful use. We have the correct metadata around the information that we exchange be it a single laboratory test, be it an entire laboratory order or if it's a clinical summary document, making sure that we have the right metadata for that as well. There's a discussion that we have with the regional extension centers and with the state HIEs about trying to decrease the cost of laboratory interfaces. That includes getting value sets identified for common laboratory tests or common LOINC codes, as well as making sure that we have standards that are simple and easy to implement, and can lower the cost of electronic health records connecting into laboratories.

There are issues around medication reconciliation. We know that we've had some discussion, and we in fact probably will have some additional discussion about what to do with provider directories and certificates, and how do we manage certificates for authentication that doesn't create 50 or 60 or more different sort of certificates that are not able to be exchanged or interoperable across different environments?

Provider directories become just sort of a certificate discovery mechanism, and there's, I know, been a lot of discussion, both in terms of white paper and yellow pages representations of that. Syndromic surveillance is a priority that shows up in stage one meaningful use, and that our initial implementation specification that was posted in the federal register had to be taken back because we noted that there were some errors in it. So clearly we want to get as much specificity in the standards that have been adopted in stage one and help drive that forward.

Throughout the work in stage one, and we know that stage two and stage three, we're going to have to have quality measures developed. It isn't as if people aren't working on quality measures or that there aren't activities there, but we need to see how that fits with some of the other data collection mechanisms and make sure that there's consistency. I enjoyed the discussion with Stan Huff about getting these detailed clinical models and making sure that we know, as data gets collected and used for other purposes, the relationships between that data, so we know how to best utilize that.

Population health query, the ability to sort of create a mechanism to get a sense for how are we doing from a population health perspective, and being able to query data that may be federated across lots of different organizations. Be able to get a sense for how we're doing on things like hemoglobin A1c or cardiovascular disease and blood pressure control. We know that clinical decision support is something that there has been tremendous amount of work being done on. That as we think about going from collecting data in standardized ways to exchanging data in a standardized way, to using that data in a standardized way to help improve the quality of care, clinical decision support is a critical element in that and needs to have additional work to get us to a set of specifications or standards that will help us promulgate that.

There's been a lot of talk about the blue button, which is a way for patients to access their data. Currently that is a tremendously powerful mechanism that provides a very simple download, usually in a ... limited field that allows patients to have access to the information that the government has. That, I think, becomes tremendously empowering to patients to be able to have access to that information and to be able to use it.

The green button is sort of a variation on that. If I have a blue button option in an electronic health record that allows a patient to download their record, the question would be is if it's possible to have a green button that allows us to do this over all the patients in a provider's practice. Therefore, give some degree of portability, not maybe perfect, but have the ability to say move a patient database for a practice from one electronic record in a standardized way to another one, and thereby create a marketplace for innovation and for change and for value added services within that.

Then, finally, across, I think, all of these initiatives, there's the need to have value sets. What I mean by value sets is really if we've got a whole series of ICD-9 codes, and we're moving to ICD-10. We need to be able to have a way of having a simple or constrained list that says here are the top 200 diagnoses or here are the top 600 labs or here are the top 1,000 medications and providing the regional extension centers, the states, the HIEs, the providers who are using electronic health records, all the tools that they need to be successful in moving forward.

If we go to the next slide, we also have a series of other kind of criteria that we are thinking about in terms of long-term challenges or broader requirements. So categories such as importance and relevance, and does it address some of the important criteria that we have at a broad level for stage two and stage three meaningful use requirements. Is it helping us support accountable care organizations? Does it support patient centered medical care homes? How do these things potentially drive sustainability of the standards and interoperability framework? If we need to, for example, leverage some of the work that's been done within the federal health information modeling effort or some of the work that's been done in HL-7 around the EHR models, are those things that we need to have as resources and available to folks that are going to be developing implementation specifications and standards? On the next slide after that, there are a couple of additional categories, feasibility, usability, evidence-based medicine and research support to make sure that we're thinking ahead towards the learning healthcare system and some of the other activities that I think are going to be important for us, as we think about interoperability.

So the last slide here or, I guess, it's the second to the last slide is to talk a little bit about some of our perspectives, ONC's perspective on some of the near-term priorities. We have been spending the last couple of months really trying to organize, and we have a bunch of things that are underway or that we're beginning to work on, but there's nothing that we haven't started that we can't stop. But it is important for us to kind of understand where we're initially beginning to sort of develop initiatives around the standards

and interoperability framework. I think one we've alluded to already is that it's important that the work of HITSP and some of the other standards that have been developed in the past continue. That certainly it was the intention to have a lot of the HITSP standards, particularly those that have been adopted to support stage one meaningful use, and that we anticipate may be relevant for stage two and three. We need to make sure that as we determine that there are things that we can improve and things that we can fix about those specifications, we need to keep working on that.

I think, when it comes to things like the clinical care summary, the C32, the CCR, we need to continue to work towards making sure that those are easy to implement, that we have the right specifications there, if we identify that there are things that we need to improve, that we have a mechanism to do that. We also need to make sure that we respond to some of the key HIT Policy Committee recommendations. I think it's been increasingly recognized over the course of the last couple of weeks to months, and certainly through the Direct Project, we've seen this, is that the notion of having a certificate that assures that the information has, the people have, been authenticated. That they are coming from the person you think they're coming from, that message, and it's going to the person that you want it to is an important aspect of the exchange. There are lots of different kinds certificates out there. There are some certificates that people can simply attest that they own a Web site and get an SSL certificate that allows them to use that certificate to secure their site. There are other kinds of certificates that require in person authentication and a lot of additional work.

What we need to do is we need to think about how do we make sure that, as people get certificates, and we have certificates for people or for organizations, that there's a certain degree of consistency across what we do. So that we don't have tens or hundreds of different kinds of certificates that are out there, or that we have thought through what it would look like in terms of managing those things. Another one that we have heard about from the states and the regional extension centers is really getting low cost interfaces into the laboratory systems. That includes all aspects of laboratory exchange, not only the standard, but it requires looking at the value sets, the vocabularies, and the terminologies, making sure that the technology and the implementation specifications are easy to implement and serve the needs that we have.

I think, finally, the other thing is that we do our best work when we learn from actually doing. So for us to get the standards and interoperability framework right, and for us to make sure that we've got the appropriate coordination processes and that we've got the appropriate degree of transparency and inclusion, we just have to get started at some point. As we learn things, then we need to fold that back in, and we need to improve the process. But I think there is a real sense that we've got some ideas about how to move forward. We want to include this committee and the work that we do, and that we want to continue to keep you abreast of the activities that we're doing. What's working? What's not? Helping us to manage sort of this portfolio, and then to kind of get your feedback.

So one of the things that we've already done is, working with the chairs of this committee, we've posted all of this information to be available on the Federal Advisory Committee blog. We've only had about seven comments so far. Obviously we've had suggestions for potentially new initiatives that we haven't included, some feedback on the current proposal, proposed initiatives that we've got, other comments about sort of timing and interdependencies and things like that. We're hoping that we can get sort of the broadest input and get the best minds to help us do this in the best way that we know how. Then provide the feedback and the coordination with this particular committee to make sure that the things that we're working on, the things that we're doing, we can leverage your expertise to help do that better.

With that, I'm going to sort of stop and then turn it over to John, and if there are questions or other things that you want to talk about.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much, Doug. That was really a tour de force, and I think it really does represent how much activity is occurring in the Office of the National Coordinator. Let me turn to my co-chair, John Halamka, and perhaps some introductory comments, and then let's have some discussion in terms of helping to offer some insights on priorities, but ultimately would like to culminate with an endorsement of

Doug's general direction and then articulation of our thoughts in terms of priorities. With that, let me turn to John.

John Halamka – Harvard Medical School – Chief Information Officer

One of the things we want to make sure of, since we have a rich array of implementers and clinical experts in the committee, is that as Doug marches forward and ONC begins to execute on these activities with contractors, that we have the opportunity to offer very helpful advice and guidance. For example, many of us have worked with laboratory implementations. I think it's fair to say that the HL-7 2.5.1 implementation guide that is included in the standards and certification final rule is quite good. And, in fact, for many, many purposes, does exactly what is necessary.

A challenge or a gap, which is something that Jamie and the National Library of Medicine, vocabulary workgroups are thinking through, is how if you want to reduce the cost of a laboratory interface, could you accelerate by removing barriers to implementation? If you had a universal compendium of LOINC codes for ordering the 98% most common labs, then that would be actually a real accelerator. It would reduce the cost. It would bring that \$10,000 cost for each lab interface down to \$1,000 or something like that. It would seem to me, and this is where I want to open up for discussion, that we can be very, very helpful by bringing to Doug what are the real world challenges where the contractors should focus their efforts in these various domains. But certainly welcome the group's input on how we could be most helpful in this process and what you think of the priorities, as Doug has articulated them.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Every time I see this presentation on the S&I framework, I'm left with the same question, and I'm going to ask it again today because every one of the areas that's proposed here on its own has its merits and is extremely important, and we know we have to sort of advance the technical work. But the question that I have to ask again is where is the policy direction in the S&I framework, both on the front end in terms of the expectations for how the technical decisions get made, how standards get selected, what the implications are for those standards, and where is it sort of all the way through the process? For every one of these areas that I look at and look at sort of the proposed work that needs to be done, and even in our experience so far with NHIN Direct and other NHIN work, every one of these steps forward from a technological standpoint involves, in many cases, decisions that make policy decisions because they are technical in nature. But they make determinations about how the information is shared, how it's stored, what metadata is used, where that's kept. But that they also raise all of these questions in a way that I think is best understood and thought about on the front end because it's very hard to have this whole lifecycle happen and then, at the end, do some sort of review. I appreciate provider directories is a topic of conversation now with the Policy Committee, but every one of these areas benefits from having policy direction, both at the front end, and then throughout the lifecycle so that that can be integrated and factored into the decisions that get made. I've got to ask this question again. How is that going to happen?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Thanks, Carol. I think one of the things that I'm hopeful is that if we launch a particular initiative, that the team members that come onboard to help organize and facilitate and comment and participate includes all of the various stakeholders that would need to be involved. So, we need to have vendors. We need to have providers. We need to have SDO, standards development organizations. We need to have PDOs, policy development organizations. We need to have all of the folks at the table because I think you're absolutely right that each one of these raise technology and policy that is linked at the hip, as we go forward. There is....

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But every aspect of development here that's mapped out in the S&I framework seems pretty carefully thought through, and I guess I just want to understand how we can reflect what you're saying in this process so that it's part of the life cycle.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think it needs to be perhaps not called out as a separate initiative, but completely integrated across the entire spectrum because, as we identify the use cases, there are policy implications there. As we think about harmonizing things and how we decide to kind of construct information models and what information is related to others has an implicit policy implication. Certainly when we put together implementation specifications and how we make the decisions about architecture or the value sets or whatever, I think there are policy implications there.

It would be, as you said, we could put a box in that said something about policy, but I'm not sure exactly where it goes because this shouldn't be a waterfall type development. In fact, there should be lots of iterative and incremental development that includes not only the technology, but the policy pieces as well. I think that's something that we need to be sure when we launch an initiative that we include. I think we've learned a lot from the experience that we had with Direct about how we can engage the policy development organizations and the community there that are interested in policy activities in these initiatives. I think we need to continue to do that and to refine it, as we go forward.

Arien Malec – RelayHealth – VP, Product Management

Just one more thought here, and I certainly don't claim that Direct got this right. I know that Direct did not get this right in the beginning, but during the course of the Direct Project, we came up with at least a reasonable solution here where I have weekly meetings with the ONC key people for policy. Try to be incredibly transparent about the areas of work that we're doing that have profound policy implications, and then make sure that we've got the appropriate touch points and handoffs to the Policy Committee and to the workgroups of the Policy Committee. For example, there was often a lot of good discussion prior to and during tiger team and Provider Directory Taskforce and other areas of Policy Committee work that touched on areas that had ... for Direct. Again, I'm not claiming that we got this right, and I'm not claiming that we did this well, particularly in the beginning, but I think some organized process for having policy issues surfaced early and vetted to the right place in the Policy Committee has some merit.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, I'd love to see that be a part of a process that is standardized, if you will, for the work that's planned and that's moving ahead. And if there's any interest in pulling a small group together to think about what that process might look like and what the sequence might look like and how to incorporate it, I'd be very interested in doing that. I really worry that this can't be ad hoc. It can't be an afterthought. It really has to become an integral part of the way you approach all of the technical issues in terms of standards and interoperability, and standardizing it into something that is replicable, I think, is a good discipline.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Are there other comments that—? Again, we want to make sure that at the end of our call today that we have given Doug enough latitude to move forward so that the contractors can do some of the work that they would like to begin. But also establish a process by which the experts that we have, especially on our Clinical Operations Group, are informing and continually offering advice and assistance....

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Doug, I've seen the presentation on the interoperability framework, and I'm trying to understand more what your vision is of how sort of the practical work gets done. Based on your priorities, the assumption is that we potentially need enhancements to existing standards, or we may need entirely new standards. The crux of my question is around how the day-to-day work is organized and how, in particular, the existing standards organizations are involved. In a sense, it seems to me, and please correct me, that what's happening is that the contractors essentially would become the standard creators in the future, and that you're inviting everyone to participate. But it changes substantially the role of HL-7, NCPDP, DICOM, and others from the paradigm that we've had of open consensus development groups to sort of contracted development of standards. Am I perceiving that right, or could you say more directly about how you see the sort of day-to-day activity working and how people get involved, and how especially the existing standards group will be able to lend their expertise and knowledge to that process?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think there are a variety of activities that are ongoing, and we can drill down as deeply as you'd like to. But I think, in general, if we've identified something like the clinical care summary, what we really need to do there is we need to kind of help refine that HITSP C32 standard. We need to make it open and transparent to all. So I think I characterize the S&I framework as being supported by the contractors, but it's certainly not the contractors who will be setting the priorities or who will be determining what those standards should be.

When it comes to those things, we're having a lot of conversations with HIE and HL-7 about how best to engage them in some of these activities. We are going to follow a process that is consistent with the W3C and the ANSI requirements for having openness and transparency. It may be that for some initiatives the way that we get the work done is that the contractors are used to help staff and to help provide publishing support or to provide work within some of the standards development organizations. There is sort of that.

But at the end, you've mentioned a number of different standards development organizations. If there is some consistency across those different organizations in terms of how the requirements for the standards, the use cases, perhaps some of the harmonization efforts occur, that provides a lot of value in terms of how we make work that goes on with the NCPDP and the work that goes on with HL-7 and the work that goes on with ASTM or with DICOM consistent. We could have a number of kind of meetings and coordination, but it seemed that given our timeframes and kind of the clear directions that we can get around meaningful use, if what we do is we say we want to have a particular goal or objective, it provides the mechanisms for all the standards development organizations to participate in some way.

It may be that as we move forward that we engage more directly with one of the standards development organizations to help refine the standards and to sort of move things through. But at the end of the day then we have artifacts in consistency across all of our initiatives that allow us to sort of begin understanding how different standards relate to one another, as they help support meaningful use. I know you're a techy guy, so I can dive a little bit deeper, but we're working very closely with open health tools and some of the model driven health tools, a lot of that work that's been done by Dave Carlson in work with HL-7. But to be able to take and read UML models and to be able to generate implementation specifications from that becomes a valuable way of helping us to coordinate the technical expertise.

We're certainly not there yet. There's a lot of work that still needs to be done on some of those tools. But I think that's sort of the vision is that if we pick a goal that we want to try to achieve, it helps us focus our attention to understand which of the standards development organizations need to kind of work collectively on that. It will require coordination with IHTSDO and some of the vocabulary and terminology groups, the National Library of Medicine, HL-7, all of those things to help us deliver on what that initiative proposes to accomplish.

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

Wes raising my hand.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Let me just do a follow-up question, and then I'll cede the floor. You know I love the intent and the goals absolutely, but to drill in and even just a more specific question, for instance, you mentioned following ANSI open consensus process. Would that include basically ONC then conducting their own ballots on new standards or revisions of standards as opposed to the balloting process that happens within HL-7 or ASTM or any of the others?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

No. ONC is not an ANSI recognized standards development organization, and I don't think it ever will be. I only mention that because our goal is not, and it was more in response to your comments about contractor developed standards that in fact what we're trying to do in all of this is to make sure that we have transparency. The reason we're having these conversations in this particular committee. We want to follow the kinds of things that we did with the Direct Project. In some circumstances, it may be that that initiative says we already have a standard that will serve our use case and all we need is the following

other pieces. In which case, there isn't going to need to be a lot of validating, but we will use that to help us develop implementation specifications and the tools for people to be successful in using those standards.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I think, Doug, your summary is, this is not, in any way, meant to replace the ANSI approved processes. It is meant as a mechanism of coordinating existing standards development organizations and bringing more resources to the process. So, as you've described it in the past, you get an end-to-end factory that can move this thing along by leveraging the work that all other organizations are already doing, but putting it together into a coherent framework. Others...?

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

Wes.

Kevin Hutchinson – Prematics, Inc. – CEO

Yes. John, it's Kevin. I'm raising my hand.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Wes, and then Kevin.

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

Doug, I know you've read my paper on profiler enforcer organizations. I believe I sent it out to the Standards Committee. If anyone wants a copy, I'd be happy to send it. I can't make it available for public distribution though because it's copyright material.

The issues, there are a couple of issues going on. One is that most organizations that actually take responsibility for seeing interoperability through work on deadlines. The deadlines are set by laws, in our case, in different countries by when the administration is likely to change, by all kinds of things. But it boils down to the right reason for doing interoperability, not for its own sake, but for some other goals for the healthcare system that needs to be met.

Generally, the timeframes don't permit a fully open consensus process, and the organizational scope of the consensus organization often is not the same as the organization that's taking the responsibility for seeing implementation through. For example, it may be an international standards organization, and it may be setting its agenda based on priorities that come from a number of sources. The requirement that any given entity that's really profiling and enforcing has to either find a way to engage with an SDO to assure that its work products are responsive in time and content to the needs of that country, or do it themselves. In addition, they have to engage with multiple SDOs to coordinate, for example, I think, a lot of the reasons why we've struggled with the detailed clinical models has to do with affectively coordination with....

Finally, if you're going to use the standards, you have to use them in a way that allows you to take intellectual property from multiple standards groups and create a cohesive and coherent and single sourced set of specifications for what people have to do. Right now, if you put one finger or thumb in every place in the specs document where you need to read to implement a profile, you need four hands. There are just too many cross-references rather than creation of an integrated document. However, the standards development organizations have developed on a model where their work is funded by the sale of the standards and, therefore, it's a suicide mission for them to make the standards available for free. This is nothing new. It's been talked about before. I am concerned that we have not heard more in the S&I framework about how to use at least some of this money to solve the barriers to use the work of the standards development organization. I fear that by not doing that, we will default to the contractors being the standards developers, and we will redo an awful lot of work.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Doug, any comments or thoughts?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I look to this astute group of participants that help us sort through some of those issues. I think, Wes, you raise a tremendous amount of valid points. Carol talked earlier about policy. This to me is an important issue that we, I don't think, have yet struggled with within the Standards Committee, which is how do we manage the intellectual property issues. How do we foster innovation? It's around the holiday season, so I'm just going to paraphrase one of my favorite sayings about Christmas cookies, and that is, good standards aren't cheap, but cheap standards aren't good. We need to be able to have mechanisms that we can continue to sort of foster high quality standards that takes resources to do that, and what are the right business models to do that.

Part of the challenge that we have had and, John, you could even speak to this, is with organizations like HITSP and others. There is a challenge to be able to create integrated standards across the lifecycle and to do that in a way that is still able to have the intellectual property and things like that be taken care of. If all standards are free, then we aren't going to be developing a lot of standards because it takes resources to do that. I'd welcome additional discussion about how to do this part better.

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

I'd certainly like to. You can't really see people around the table here nod, but Wes' point was an excellent point, and I would like to further connect it with the earlier discussion of the PCAST. This is an issue, I think, that needs to be addressed at that PCAST level.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let me just make a quick comment. That is, I think Wes' point, Doug, is very well taken that if you, for example, see it as an ONC priority to develop a set of laboratory artifacts that are going to accelerate and reduce barriers to laboratory connectivity. One would of course create an implementation guide that would of course create an implementation guide that would be widely available for all stakeholders that would contain in one single document the content and vocabulary, code sets, and transmission information. One would need to make this as close to plug and play, but to do that would require a licensure of content of intellectual property from various sources. So it is maybe one aspect of our advice to you as to what models might exist that the federal government could contribute to the simplification of laboratory information system interoperability by acquiring certain intellectual property. Dixie, your relationship with this to PCAST?

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

Yes, even at that level, when you start doing the standards at the national level for interoperability, across electronic health records, it's the same issue. You run into the intellectual property issues once again.

John Halamka – Harvard Medical School – Chief Information Officer

That is to say that if we said the universal language....

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

Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

...some variance of an existing CDA plus vocabularies, how might you then produce a guide that would make it easy? That would require, again, licensure of intellectual property to reduce the barriers that Wes described or the barriers that Doug described of indirection of having 27 different artifacts hidden behind five different Web sites that one would have to assemble ad hoc.

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

Right, and also Wes' point that, at the PCAST level, that universal language needs to capitalize on the work that's been done by standards development organizations.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Kevin, I know you had a comment as well.

Kevin Hutchinson – Prematics, Inc. – CEO

I did, and it is related to this very item. Mine is more direct on process. Doug, if we were just to pick on one item, say provider directories as an example, which is being highlighted as the green button, if during the implementation of a solution for a provider directory service during this process of this framework we discover deficiencies in the rollout and implementation of those directories. In your mind, what's the process that will be used to correct those deficiencies? Is it to go back to the contractors that the harmonization group, which I think is Deloitte, and have them work on that from a harmonization? Or is it to come back to this committee? I just want to get your thoughts on where you think what happens next when you run into those hurdles.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think it depends in large part what the nature of the error might be or the question. If it's a typographical, the purpose of use versus purpose in use, for example, those are the things that we just need to correct our specifications, and we need to sort of move on. But I think what really is important is that I would much rather have the community come together and be the ones who drive the process. For example, if we take a look at the Direct Project, a tremendous amount of energy and good work at defining the use cases and sort of articulating those, that work all composed in text on a wiki should be translated into a computable representation, maybe a UML mode. Then that conveyed back to the community saying, did we get this right? Have we captured all of the nuance that you had in defining these use cases?

The same would be true, I think, of the harmonization process so that if different standards are overlapping in terms of their ability to support that use case. There is the need to understand the relationships between those different standards, where they overlap, where they're complementary and things like that. One would hope that within the discussion that occurs around that harmonization in support of that particular use case that that discussion can happen on a wiki, and it can happen in those sorts of forums, but then that gets translated into a consistent language, XML or UML, conveyed back and said, did we capture the discussion correctly? Have we generated artifacts that are consistent with the discussion that would occur?

To me, if there is some error that occurs in the way in which we overlooked or that we missed or something, those are the things that would be simple for us to correct in the specifications or in the artifacts that we construct. But I would suspect that a far more of them would benefit from, did we miss a use case? Did we think we had it right, but we needed to fix it, and that's something that really the community needs to be engaged in.

John Halamka – Harvard Medical School – Chief Information Officer

Doug, let me ask the question. If I were to say ONC has a set of contractors who are already beginning work, and there is a burn rate that happens day-to-day, and you want this committee, which in effect serves as a board of advisors, a board of directors to help you out, my sense is, in the short term, what you want to do is begin assembling your contractors to begin cleaning up or enhancing gaps in C32. You want to begin some initial work on certificates. In fact, we will be talking next about a charge from the Policy Committee on working through certificate standards, if you want to call them that. Certificate discovery, certainly we'll also be chatting about provider directories in a bit, although we haven't had the official charge from the Policy Committee yet to begin looking at provider directory standards. To look at where are there gaps in laboratory information systems implementation guidance and adoption that that body of work is something that you would like to begin some work on. Presumably what could happen is the Clinical Operations Workgroup could help by saying here is our experience from the field, and where we think the real gaps and the issues we should focus on might be. Here are some impressions of existing standards and ways that you might be able to reduce barriers.

Then, as you go forward, you have a whole series of other priorities that you've articulated. Conceivably the Clinical Operations Workgroup can offer advice as to once you start these initial three projects, you look at the remaining seven or eight, and here are some things that we see as real work that must be done to get the country to meaningful use stage one and two as rapidly as possible. We think that these

are things that are going to be really important. Is that the kind of thing you would find as a committee helping you to do?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think that'd be tremendously valuable. If I had to pick one, I would really start to work on some of the content specifications around the clinical summary. I think that a couple of weeks ago, I spent a weekend, much to the chagrin of my family, reading through the RFCs for TCP/IP just to get a sense for how all the good things that happened with the Internet, what were those discussions like, and how did they organize and set up? I came across Postel's principle or the Internet robustness principle that says when we send things, we need to send them conservatively. When we receive things, we need to receive them liberally.

What that means is that when we send information, data grams on the Internet and stuff, we want people to conform to the standards, and we want the standards to be very, very explicit, easy to implement, and as simple as possible in terms of how we send information. But when we receive information, if somebody has missed a code, or if they've given us an extra code, we don't want to block that communication. We want to try to provide as much – sort through it and figure out what the right thing to do is so that we can kind of keep the exchange occurring and the information flowing.

So, to me, that means that one of the things we have to do is we have to link the way that we describe our standards to the way in which we describe the services and the technology that uses those standards. To me, one of the things that we've done in looking at the C32 and things like that is we've provided a lot of options. We've wanted to try to take people where they are so that we can sort of start with where they are and move from there. But that's resulted in a lot of optionality in the standards that we've adopted. So what we have is we have a situation, and then our experience with working on the National Health Information Network has been to get to interoperability. We have to be very, very careful about what it is that we can receive, and we've tried to work on some conformance and interoperability testing so that we can get those systems to work together.

We have, in a sense, started at a place in which we send liberally because we have a lot of different options that we have, but we receive conservatively because that's how we get to interoperability. And so that may be the right model for healthcare, but I think we need to make sure that we take a look at that. From my perspective, looking at some of those services that we need, looking at some of the standards that we would be able to support with those services, I think, becomes important. That's why I think the clinical summary is important. I think, getting the metadata, whether it's a full hospital summary or a clinical note from a visit or a single lab test, we want to make sure that that metadata is consistent and is scalable across those different sizes. But I don't want to do it in the abstract, and so the C32 becomes, I think, a very nice way of looking at things, the C32 looking at the clinical summary documents, CCR.

Then I think there are all also some services that we need to take a look at as well. I think when we talk about certificates and provider directories, we want to take a look at those as well. So I think those things are probably the top ones on my list. I think we also have a lot of feedback from the states and the regional extension centers and others that laboratory interfaces are expensive. I think we need to explore why that is. And we need to figure out what are the barriers to that, and some of that may be a standards issue. Maybe it's vocabularies and value sets. Maybe there are other things that we need to think about there. But I think that's another issue that I've been hearing about that people would like us to pay some attention to.

John Halamka – Harvard Medical School – Chief Information Officer

Jamie, let me ask you the question. Do you think, in the new year, that Clinical Operations could assemble a group to look at a clinical summary and template document issues? Then advise the S&I framework folks and Doug as to what you think are some of the central things to clean up to make these things better, to adhere to some of the use cases that they've published? It also sounds like the Clinical Operations Group could probably offer some insight as to what you think the real barriers on laboratory information exchange might be.

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

Thanks, John and Doug for that. I think we can and we will now schedule a meeting of the workgroup to, as you said, talk about the experience from the field how to reduce those barriers to implement the existing standards, and also to talk about what the experience indicates the priorities should be.

John Halamka – Harvard Medical School – Chief Information Officer

I think, Doug, as well, there'll be a lot of discussion that we have on certificates that are necessary for securing the – well, identifying organizations and ensuring that the endpoints are secure, and that we'll be talking about probably in the context of Dixie's work, and we'll be getting a charge on provider directories to come. I know that John Perlin had to run off to a 220-person holiday party. So does it sound like a reasonable next step that Doug will commence some work on organizing around clinical summaries and templated documents and some aspects of laboratory. As well as certificate interoperability and provider directories where we will, in parallel, have our Clinical Operations Workgroup and, presumably our Privacy and Security Workgroup, providing ongoing advice and guidance to those activities. As well as we, as a larger committee, in conjunction with our workgroups, look at the additional future work he wishes to do, and make comment on priorities, especially where it enhances implementation?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I guess I'm wondering if there is a need for a parallel process to what you're proposing on the policy front, at least for the acute needs that Doug may have in some specification work that he wants to have done.

John Halamka – Harvard Medical School – Chief Information Officer

Certainly, there's very good policy coverage at the moment on certificates and provider directories in terms of the policy work that, for example, on laboratory and clinical summaries. Thoughts on what policy issues you want to address, such things as privacy and data integrity, other things that come to mind?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. I think it's important to understand what the requirements are for the specifications that are being written. Obviously, I don't think any of us have really seen that, so if there's a review process or an opportunity for input about whether or not there may be specific policy guidance that needs to be a part of those specifications, I think it would be important to surface that.

John Halamka – Harvard Medical School – Chief Information Officer

Very reasonable, and Arien highlighted how he learned from the Direct Project of making sure that there was this formal, continuous process of integrating policy, as processes go forward on the technology side. Doug, I think you've heard from Carol and from others that if you brainstorm with Arien how you might close that policy gap, there would be a lot of comfort in that.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Yes, I agree. The only amendment, friendly amendment that I would make to Carol's statement is that I don't want a parallel separate process. I think for us to really get to the issues of things is that those policy discussions need to be integrated into the initiative, and not be something separate. If it's something separate, we will probably have this conversation again.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, I agree. I agree, Doug. I don't want it to be separate. I want it to be fully integrated. I guess, for now, I'm settling for something parallel because I think there's a gap to close, and we should try to close it in whatever tactical way makes sense. But I think, strategically, it's really important to think through this as an integrated process.

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

Yes, and this is Jamie. I'd like to....

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

I have my hand up after Jamie.

John Halamka – Harvard Medical School – Chief Information Officer

Jamie, please go ahead.

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

Right now, I'm wearing my hat as a partial report out from the ONC grantees meeting that we had this week. Doug, I'm sorry you weren't able to stay in the room to listen to the experience of the folks who have actually implemented the HIE exchange for treatment purposes. But actually what we heard there was the experiences that the clinical summary is not the issue anymore, that that was sort of last year's issue that was solved, and that's actually was not the priority from the experience of the implementers. Actually, their number one issue was exactly what Dixie said earlier, which is patient identity. And both resolving unique patient identities and correlating or matching those identities across the different entities involved in health information exchange was the number one issue.

I think, as we think about input that this committee can provide in terms of input to Doug on the priorities of what needs to be worked on, we also need to think about what the actual experience and what the evidence says. And I think, actually, that does align then with what we're getting from the tiger team from the Policy Committee, which had its hearing, I think, December 9th, and I think has its next meeting in January where the issues of patient identity are very much on their agenda for passing work over to us.

John Halamka – Harvard Medical School – Chief Information Officer

So, Doug, if the issue is how do we exchange a summary for coordination of care, it may very well be that Jamie's group comes back to you and says, well, actually, is the insuring that we have some mechanism of representing patient identity that is a bigger problem than how we represent the problem list? Other comments?

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

Just as an adjunct and a query – I apologize. I had to step out for the beginning of Dr. Fridsma's presentation on the initiatives. The laboratory piece is very, very important on maturing that between the lab manufacturers, as we've said, and what you're trying to do for helping interoperability of lab information data. But I did want to bring up, what were your considerations regarding a priority or a future priority for the multimedia imaging radiology community?

The only reason I bring that up is that I am aware that the Radiology Society of North America has agreed to partner with the American College of Radiologists this year to work out on linking radiology terminology, ordering terminology, resulting terminology with the actual imaging themselves. One of my questions is, well, that may very well be a good, private, or the organizational, professional organization work together. Is there a venue for them to come and get a sanity check against the S&I framework in this year's plan?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think one of the ways that we can look at that is to take a look at the prioritization parameters and just take a look at the things that we should consider when it comes to prioritizing both existing and new initiatives. That may be a way that we can take a look at those things and see where they should fit in the work that goes on.

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

And I think, maybe in a broader perspective, I think a lot of professional organizations in certain area of clinical data may or may not be starting to do some of their own internal work, and HITSP used to offer them that venue. I'm just putting that out there that there may be queries that come up that say how can we get a national sanity check for what we're trying to do?

John Halamka – Harvard Medical School – Chief Information Officer

Doug, just to relate to the task, if AHIC set priorities one through 10 that we all agreed that was important, but it was number 11 suddenly got huge resources poured in by stakeholders across the country, is there a mechanism by which you can then provide some S&I framework guidance to what is ultimately a private funded initiative? Should additional resources be brought to bear externally?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Yes. I think that's ultimately our goal is to be able to have a variety of different ways that people can engage in developing standards that harmonize across the various use cases. We had talked about one, which is, if we've got initiatives that are high priority from the HIT Standards Committee and the Policy Committee that are supportive of meaningful use or of other presidential initiatives, then what we need to do is we need to put some of our resources in to support that. There may be others in which we provide tools and we provide guidance and advice. We provide sort of modeling and best practices, concepts of operations, if you will, that allows people to have resources. There may be others that are on the list, but for which we don't have a lot of resources to fully fund, but we may be able to provide sort of supporting mechanisms for that as well. I want there to be a variety of ways that people can engage. We will figure out how to do that, as we think about how to manage this portfolio and how we can make sure that we've got the coordination resources that we need.

Arien Malec – RelayHealth – VP, Product Management

One additional....

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

Wes....

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

John, thank you for that. It might be good that we put that there's some paragraph or small paragraph about that, whether it's on the Web site or as you go forward on this, saying that if there are private stakeholders that are starting to do good work this year, that there will be – we certainly want to encourage that. As a large clinical provider, I've had many clinical domains come up to me and ask kind of sort of that question. Are there resources to help us do something in our area? I think it's a great idea to continue to put out the positive word that if you can start to find your interested stakeholders together and that there will be some – we will look at ways that that can be supported, whether it's this year or next year.

John Halamka – Harvard Medical School – Chief Information Officer

...is that you, Wes?

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

Yes, I think there was someone else before me, but I wanted to raise my hand.

John Halamka – Harvard Medical School – Chief Information Officer

Was there another person on the phone?

Arien Malec – RelayHealth – VP, Product Management

I just wanted to make one more point there, which is that to the extent that those resources, those initiatives come in and have all the resources they need to be successful, I think that can be an incredibly important way, using the tools that the S&I framework creates. I'd also like to acknowledge that many of these initiatives rely on a core team of volunteers from across industry and across the policymaking bodies. We end up with volunteer fatigue. So it's important to set appropriate priorities to make sure that we're not outstripping or overrunning the level of knowledge, experience, and expertise that we have across the healthcare system and essentially get volunteer fatigue. That's the only warning sign that I'd like to make sure gets reflected.

John Halamka – Harvard Medical School – Chief Information Officer

Very well said, and when HITSP did take on, for example, clinical trials and clinical research, there were those from the industry who brought in additional volunteers to try to avoid that exact issue. Wes?

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

Actually, the cure to volunteer fatigue is to start another initiative because they all sign up for the new one and get all charged up again, but that was meant to be semi-humorous. A couple points with regards to

this: I'd like to talk about letting 999 flowers bloom because 1,000 flowers seem to be a problem. Two principles that I've come to recognize through my work on the FACAs is that standards are not right for adoption in a regulation and mandates across the industry until they've been used. The possibility that we would create a bottleneck in the group that's trying to get a nomenclature for ordering for radiology by it being prioritized to be reviewed by the personnel handling the S&I framework is troubling.

I think that there will be an appropriate time when the S&I framework when it has gone through a few issues and taken them to resolution that an investment in describing to people how to organization work that they're doing ad hoc. So that it can be more easily adopted into the S&I framework, as time goes on, would be valuable to the point of offering tools, offering education, things like that. But I fear that if we create a priority, if we say the P word there, the prioritization, we're sort of in the worst case in terms of stifling innovation. What we really want is innovators to innovate knowing that they will have a success rate that is small individually, but that the aggregate of their work, that work that succeeds will be important, and have a way to input that into the S&I framework after there's been some experience with it.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. I think the spirit of this, Wes, is to insure that there can be private efforts that do proceed, but it would be certainly great to the extent that we could provide them some tools so that it is, when appropriate, easier to integrate their work into the other activities that are going on in ONC.

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

Exactly. I think, generally, people are looking for those tools when they do these frameworks. If they're available, that's great, and if, as a byproduct it's easier to submit, so much the better. But in addition, I think it's important that the mechanics of using the S&I framework go through a couple of cycles before we really get serious about offering this material. Because I think we need to be able to tune up the S&I process without worrying about impacting 100 outside projects that are also depending now on the tools and so forth.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Well said.

John Halamka – Harvard Medical School – Chief Information Officer

As a next step, Doug, if you are beginning to assemble your resources internally to ONC with your contractors to gear up for clinical summaries, templated documents, laboratory directories, and certificates. Then I think you have volunteers from the Federal Advisory Committee, specifically Jamie for now, and I will be asking Dixie about this when we talk about certificates in a moment, to provide advice and guidance and input from the real world.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

That sounds great. Thanks so much. Wes, thank you for your comments as well. I couldn't have said it better.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you very much for a rich discussion on that. Now Jonathan has e-mailed me that administratively we have not yet approved the minutes, so before we go forward to talk about certificates, if you've had a chance to review the minutes from our last meeting, were there any comments about the minutes? None being heard....

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

I just want to know what kind of guy goes to a holiday party and thinks about the minutes of the last meeting.

John Halamka – Harvard Medical School – Chief Information Officer

He's a serious guy.

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

Good point, Wes.

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

Get him under the mistletoe.

John Halamka – Harvard Medical School – Chief Information Officer

No objections being heard, we have approval of the minutes. Let us now move forward to the HIT Policy Committee request of the HIT Standards Committee in their transmission letter of November 29th to David Blumenthal. Specifically, the Privacy and Security Tiger Team was interested in building public trust by having a framework for information exchange between EHR systems not including authentication of individual users of the EHR, but creating a high level of assurance that an organization is who it says it is. And, that there's a balance of cost and burden of implementation, as we look at getting data securely from one endpoint to another endpoint at an organizational level. There's a series of observations they made as to what provider entities should require certificates and how should they be issued, how is that trust fabric maintained, and the process for evaluation and reevaluation of organizations that join this fabric? Who issues such credentials?

The specific charge to the Standards Committee is the following. The Standards Committee, through ONC, should select or specify standards for digital certificates, including data fields, to promote interoperability among healthcare organizations and EHR certification should include criteria that tests their capabilities to retrieve, validate, use, and revoked digital certificates that comply with standards. And so to begin this discussion, because we received this official transmission and request, which then we need to figure out ourselves how to respond to, Dixie, let me ask you. If you were given the charge of coming up with guidance on the technology around digital certificates for the use of organizational identity verification, what would you suggest?

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

We don't have to reinvent much here. The X509 digital certificates are already specified as the standard we should use. VeriSign earlier on came up with a classification of digital certificates that had been adopted more broadly across the industry, and class one digital certificates are for individuals. Class two are for organizations. Class three are for software servers. So I would certainly look at the X509 standard. It already identifies fields, so we would want to look at which fields we would want to make mandatory. X509 doesn't specify the vocabulary for recording values in those fields, so we would want to agree upon the vocabulary to use in those fields, but that's certainly where I would go.

John Halamka – Harvard Medical School – Chief Information Officer

So it sounds like, I mean, based on e-mail exchanges we've had and your knowledge of the industry that your team, the HIT Standards Committee, Privacy and Security Workgroup, could make the recommendations as to existent technology and gaps to be filled in response to the Policy Committee's request?

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

Yes. Yes, and I would want to include not only the organization, but the servers too so that you could have exchanges between organizations with more than one entry point because there won't be a single gateway into every organization.

John Halamka – Harvard Medical School – Chief Information Officer

Very reasonable, and this dovetails very nicely into the work that we just discussed about the S&I framework because, of course, Doug, one of the things you're going to be working on is the whole notion of certificate management and certificate discovery. If we align the work of the Policy Committee's request to us with the work that is being requested by Doug on the S&I framework, it seems to me that we can get double duty out of this particular effort. So other comments that folks who may have had a chance to read the Policy Committee's request would have as guidance for the committee? What you're telling me is this is about as interesting as reading the TCP/IP documents that Doug read over the weekend.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

And I can give a report on that if people want to know more.

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

Yes.

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

We're voting no right away.

John Halamka – Harvard Medical School – Chief Information Officer

Doug, are RFCs a cure for insomnia?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

They're a cure for something.

John Halamka – Harvard Medical School – Chief Information Officer

Good. Then I think our to-do item is we have acknowledged the receipt of this charge from the ONC as a communication from the HIT Policy Committee. Judy, do we have a timeframe in which you wish a response back to ONC?

Judy Sparrow – Office of the National Coordinator – Executive Director

I don't think there is one, but let me have a discussion here, and I'll let you know or let Dixie know.

John Halamka – Harvard Medical School – Chief Information Officer

That would be great. Obviously then we'll coordinate these activities, Doug, with the S&I framework activities on certificates.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Yes. Just more of a complementary element to an upcoming charge to our Standards Committee, the Policy Committee's information exchange workgroup has finished up a first round of recommendations regarding provider directories. A lot has been said during the meeting on provider directories, and in fact, one of the priorities identified for the S&I work, and so it is expected that very soon the charge to the Standards Committee will come from the Policy Committee regarding the review, analysis, selection, and recommendation on standards for provider directories. I thought it would be helpful to bring this up and sort of give a fair warning to our own Standards Committee on that work, and I expect that the security and privacy workgroup would also be asked to look into this.

John Halamka – Harvard Medical School – Chief Information Officer

For those of you who haven't followed the provider directory work, it's very interesting because they've debated quite a lot as to whether it should be a yellow pages or a white pages, organization-to-organization security or individual-to-individual security. I think you'll see that the conclusion is provider directories should begin with organization yellow pages kind of activities. So this dovetails very well with this certificate question of organization-to-organization or server-to-server certificates. It also dovetails very well with the report that Dixie is about to give on Direct because there is, in the Direct specification, an approach to discovering the certificate information of an organization that might be necessary for transmission of data from point A to point B. Again, this whole constellation of work looking at the S&I framework, certificate and provider directory information, the charge from HIT policy on certificate and provider information, and Direct are all converging.

With that, Dixie, if you could begin that discussion of your evaluation, the team's evaluation of Direct, I think our committee will find it very interesting.

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

I don't have control of the screen, so someone else will need to bring up the slide, whoever is controlling it.

John Halamka – Harvard Medical School – Chief Information Officer

Judy, who is controlling the slides?

Judy Sparrow – Office of the National Coordinator – Executive Director

Hold on. I'll send them an e-mail and let them know, but they do have it.

Coordinator

They're loading up right now. Thank you.

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

And you'll advance it?

Coordinator

Yes, we'll advance. Just let us know, next slide, and we'll advance it on your behalf.

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

Thank you very much. As you'll recall at our last meeting, committee meeting, the Standards Committee was given the action item to do a second technical review. We did one earlier about six months ago actually, a technical review of the NHIN Direct Project, which has been renamed the Direct Project, so that's on the title slide, but to avoid ambiguity in this presentation, I, for the most part, call it the NHIN Direct.

The review team were Carol Diamond, David McCallie, John Moehrke, Cris Ross, and Walter Suarez. I'd certainly like to thank all of this team for working so diligently. All of us took this very seriously, and I think our result is good, but I'll leave it up to you.

The objective of the review was to assess the extent to which the NHIN Direct Project's body of existing documentation represent what the ONC attributed the NHIN Direct as being, and those attributes were that it would be simple, direct, scalable, and secure. During the first technical review, we came up with definitions for simple, direct, scalable, and secure, and those were the definitions that we used in this evaluation as well.

The approach was that we reviewed a number of five key documents that have been generated by the NHIN Direct project. Arien Malec helped point me to the body of key documents that really overall represent the project itself. Those documents are the design principles that they developed early on, the consensus proposal, which is the final agreement of that group of what NHIN Direct would be, the core specifications for NHIN Direct, the specification for using XDR and XDM for direct messaging, and the security and trust consensus proposal. We reviewed all five of these documents, and then I generated a questionnaire that really asked with respect to each of these five documents, does this document basically represent a transport that is simple, direct, scalable, and secure? Then each of our team members did an overall assessment of the whole NHIN Direct. Given this body of knowledge, do you conclude that NHIN Direct is indeed simple, secure, direct, and scalable? Then we held discussions and ultimately came to agreement on the recommendation I'm presenting here.

The first attribute, which was simplicity, we concluded that we really couldn't determine. Don't worry. I don't have this answer for all of them, but in the area of simplicity, we really couldn't figure it, couldn't come to a conclusion. One of the reasons— This is not a surprise to Arien. He's quite aware of it and is working on it right now is that the core specifications document itself is messy. It's messy in several ways. It repeats information. It includes a lot of tutorial information. It's inconsistent in some areas. So if you were to hand that to me and say, go build this, I would have a lot of trouble doing that. So it's hard to call something, the specification itself simple.

It also, the specification has a lot of optionality. There's a lot of, well, not only are there are a number of musts, which are the real requirements, there are also a number of should, and we recommend. There are also a lot of operational descriptions in there. There's the option of either using or not XDR and XDM. The specification suggests, again kind of as an option, suggests the use of the domain name service to

discover and distribute digital certificates. Although the DNS specification itself does allow DNS to be used for that purpose, in practice DNS has never been used for that purpose. To adopt a mechanism that never has been used for that purpose and to call it simple is kind of a misuse of terms. We concluded that something that's never been done, you really can't conclude that it's simple.

Also, there are a number of, in fact, the security and trust document itself calls out existing capabilities to distribute certificates such as the federal ICAM GSA US access capability data and the Cantera open source capability. There are also, we discovered, at the grantee meeting earlier this week, there are states that are developing certificate distribution capabilities as well. And the fourth bullet is that there are a couple requirements that require that the sender know something about the receiver beforehand. One is the suggestion that the transport layer security or TLS establish, be used to establish a secure link between the sender and receiver before the information is sent. And the sender would not necessarily know whether the receiver is capable of supporting TLS because it's not required in the spec.

It also allows a destination to reject content, a content object, but it doesn't really constrain the criteria for rejection. Obviously there are certain reasons why you would want to reject like if the information is garbled and you can't really parse the content package, or if there are security reasons that you think it could be a security risk. There could be reasons for rejection, but the specification says that a destination can reject a content object if it's not what they expect it to be.

Our recommendation is to make it simple. Make NHIN Direct just SMTP as a transport, that's secure message transport protocol, as the transport standard with SMIME secured content objects exchanged between entities. We're still really talking about what John mentioned earlier regarding the certificates. We're really talking about exchanges between entities. So making it simple in our mind would mean cleaning up the core specification work that's already underway.

Remove the optionality as much as possible. Remove the necessity, those requirements that require the sender to know something, the capabilities of the receiver. Remove both PLS and SMIME wrapping from the core specification as options for protecting against information leakage. I'll talk about that a little bit later, but SMIME wrapping simply means you create an SMIME package that contains an encrypted SMIME package, so you kind of double wrap it. Finally, don't require the domain name service as the only mechanism for certificate discovery and distribution. We also recommend that there be a standard for certificate discovery and distribution. Especially since these capabilities are emerging right now, we really need a standard for all of them to build to.

Is it direct? Again, we said this is undetermined because it does allow the receiver the reject content that doesn't meet specifications without constraining the reasons for the rejection. Our recommendation is to make it direct, so keep the NHIN Direct scope, as intended, as a secure exchange of content objects from organization A to organization B. In other words, keep the content agnostic, so we're also recommending that it not specify what that content is. It should be, as you see at the bottom, the default should be human readable. It should be, at the very least, human readable. But it can be text. It could be unstructured. It could be semi-structured. It could be structured. It could be an XDM object that's exchanged. But the specification itself should not say it must be an XDM content object and that the sender should be able to send, and the receiver should be able to accept a variety of these unstructured, semi-structured, and structured content.

Scalability, yes, we believe it's scalable for the purposes for which it was designed. Our recommendation is to make it very clear what the intended purpose and usage are. I think all of us know that e-mail is quite scalable. All we need to do is look at our own e-mail at any given day, and we can see it handles some pretty high volume. But it's not really well suited for workflows that have a high transactional volume or point-to-point exchanges that require mechanisms to deal with complex discovery and addressing and routing and even extensive processing of the content itself. But these are really workflow issues outside of the control of the basic technology itself. In other words, they're not really a constraint on SMTP or SMIME themselves. They're really constraints on using this in environments where there's a high volume of transactions.

Also, as I think probably we all know, there are usually organization placed constraints on how large an attachment can be, so if you have a large image in the attachment, it may be that your local policy might reject that attachment. But again, that's not a limitation of the standards themselves. That's a limitation on the local policy, so our assessment is that it is scalable.

This one was the area that we had the most discussion is, is it secure, and our conclusion is that, yes, it is. By default, the NHIN Direct uses SMIME and X509 digital certificates, which I mentioned a while ago, to secure the content end-to-end from the sender to the receiver. SMIME does all of the functions that are really required for secure exchange. SMIME, using digital certificates, confirms the identity of the sender and the receiver. It encrypts the message content itself. It integrity protects the message content itself.

The only residual risk with SMIME is that the header itself is in the clear. SMIME ... is that the header itself is in the clear, so if you sent an e-mail that was encrypted, the content was encrypted, SMIME encrypted, but the subject line said Dixie Baker's HIV report is positive, that's not a good idea. It's called data leakage. It's sort of a covert channel for conveying sensitive information. However, that data leakage problem can be managed through policy and guidance, but that was really the subject of our conversation.

The core specification contained not one, but two ways of dealing with the leakage problem, leakage issue, neither of which is required. It says, well, it should provide the capability to establish this mutually authenticated TLS transport channel between the sender and the receiver for all communications. And it also says that full message wrapping is both recommended and optional, but it also warns that some receivers may present such messages in ways that are confusing to end-users.

We also know that TLS itself is not real complex for routine use by applications. In fact, that's what it's designed for. TLS is the standards that's used when you go on Amazon and you go, okay, I want to buy this. They go, we're establishing a secured link, or they may not say that, but you'll see that little lock on the lower right-hand corner of your screen. Its clamp is shut. What's happening is that that application there at amazon.com is saying we're going to do something secure. I'm going to go out and establish a TLS channel that's authenticated, encrypted, and integrity protected while you buy this, whatever it is that you're buying there on amazon.com. The application itself called TLS establishes the link, and once you say submit at the end, the submit goes back and breaks down the link, and it's no longer there.

Well, as we all know, e-mail doesn't work exactly like – it's sort of always ongoing. It's always running, so an e-mail server is not exactly like an application, so an e-mail can't look at an e-mail and then decide to set up a TLS channel, so e-mail servers, therefore, are either always TLS or never TLS. But not all e-mail servers are capable of supporting TLS. So requiring TLS would introduce a degree of complexity that probably outweighs the residual risk from data leakage. Secondly, the full message wrapping is complex, and it represents some data integrity challenges as well.

Our recommendation is to specify SMIME as a standard for securing NHIN Direct content end-to-end. Remove TLS and message wrapping from the specification, the core specification, and address this residual risk through policy direction regarding suitable content for subject fields.

The team noted a discontinuity between NHIN Direct intended scope and the exchange model presented in the XDR, XDM specification, which is one of the five documents we reviewed. The XDR, XDM specification is sort of a way of getting from the endpoint. It still requires SMTP SMIME for the backbone, but it's really intended for a way for a small provider to convey, to send information, to exchange information with an organization that is implemented the IHE profiles and uses structured data. XDM is a standard for packaging structured data for, and it's usually used for anything to exchange information using anything from a UBS drive to a CD or anything. It's medium agnostic, but it just creates this package of structured data.

The team does recognize that a need exists for this on and off ramp capability to facilitate these exchanges between small providers and NHIN Exchange participants, those who use NHIN Connect,

NHIN Exchange participants. But we believe that how those endpoints, that on and off ramp are implemented to address this need is a deployment issue and is not appropriate to include in the core NHIN Direct specification. We do believe it's appropriate to include the XDR, XDM implementation as part of an implementation specification to increase the efficiency of content processing for these exchanges with organizations who have implemented IHE profiles.

We believe, however, that including this XDR, XDM specification as a part of the NHIN Direct core specification and part of the definition of NHIN Direct creates concerns with respect to three of four of our criteria. One, it increases the complexity. Secondly, it's no longer a direct exchange because it has this side processing that's done and the security is undeterminable because of two factors.

The XDR, XDM specification calls for additional work that needs to be done to separate the routing metadata and the content metadata so that right now they're interspersed so that the routing data really should be something that could be exposed. It should never have content metadata that could convey PHI in the routing metadata. So the work to do that, the preliminary work has already been done, but it hasn't been accepted by IHE. Even when it is, it's unlikely to become part of a core XDR specification itself, so we really can't say today whether they have adequately separated the routing metadata from the content metadata. We haven't seen that. As far as the five specifications we looked at and, in particular, the XDR, XDM specification, it's work to be done.

Secondly, the XDR, XDM specification has a security consideration section that is empty because it says that the security considerations have not been addressed pending the completion of a risk assessment. So we really can't say whether it's secure or not until this work has been done in these two areas. So our recommendation is to remove the XDR, XDM from the NHIN Direct core specifications and references to it, and to also remove it as part of the definition and scope of NHIN Direct, but rather treat it as an implementation specification for the ramp up, ramp down end of the exchange.

Questions? Everybody has left?

John Halamka – Harvard Medical School – Chief Information Officer

Thank you very much, Dixie. What I would just want to highlight is that, first, this is extraordinary work, and in very, very short time, I think you've built a brilliant consensus statement that really took into account your charge of evaluating whether this was appropriately simple and direct and scalable and secure. The two key take homes I see are that it isn't as if you're telling Arien and his team you can't include certificates in the DNS, but you certainly wouldn't want to say that is the only way to do it, and maybe they'll experiment with that in the short-term. But in the long-term, there should be standards for what will be robust industry practices for query and discovery of such certificates. That it is not— You're saying that XDR cannot be used by any organization. It is simply left if an implementer, for example, a hospital communicating with a HISP wants to use XDR to get to the HISP, nothing to stop them. It's just the HISPs are going to be SMTP and SMIME from HISP-to-HISP.

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

John, I forgot my last slide, which is my best slide. This is one that I credit at least the motivation for these insights to Doug Fridsma. Doug mentioned this earlier, but I think it really applies to this whole NHIN Direct arena is that the whole NHIN Direct should support Postel's law, which is to be conservative in what you send and be liberal in what you receive. And, that it should enable senders to send the minimum information necessary with high confidence that the identity of the receiver and the end-to-end security of the transmission. It should enable receivers to receive content object without constraints on the format or coding of the information that's contained in that object other than assurance of where it came from and its safety. Fridsma's corollary to that is that optionality among standards should be limited, but services should have maximum flexibility, and so our recommendation is that this committee adopt both Postel's law and Fridsma's corollary of principles in the development of standards moving forward, not only for NHIN Direct, but standards in general.

John Halamka – Harvard Medical School – Chief Information Officer

Dixie, I summarize that your notion is you're not preventing NHIN Direct from using certificates and DNS. You just don't want to limit it as the only way, and we want to move forward to standards for normal, what I'll call best practices for certificate discovery, and that XDR could be used by implementers, but it will not be part of the core specification.

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

That's right.

John Halamka – Harvard Medical School – Chief Information Officer

Let us open it up to committee discussion. Don't tell me you've stunned them.

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

Luckily, I was deep into the agenda.

John Halamka – Harvard Medical School – Chief Information Officer

Maybe ... the quality of your work is so high, so complete, and so clear that there are no questions.

Lorraine Doo – CMS – Sr. Policy Advisory Office eHealth Standards & Services

John, I just have a very simple question. For the TLS that you were talking about when you talked about the core specifications, did you mean core as the small letters or the CAQH CORE specification?

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

I mean the core specification for NHIN Direct. It's one of the five documents we reviewed.

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

Small letters.

Arien Malec – RelayHealth – VP, Product Management

Small -e."

John Halamka – Harvard Medical School – Chief Information Officer

Yes. This has nothing to do with CAQH CORE, which is a SOAP based exchange mechanism.

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

Yes. No, it has nothing to do with that. It's the specification for NHIN Direct.

Lorraine Doo – CMS – Sr. Policy Advisory Office eHealth Standards & Services

I just wanted to make sure because we have a separate set of issues there with other standards we're working on.

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

Yes. I know. Yes.

John Halamka – Harvard Medical School – Chief Information Officer

Dixie, let me ask you a question just based on my experience with implementing secure e-mail in the eastern Massachusetts area, which is, some years ago we got together as a community and implemented open PGP, Tumbleweed, basically a number of products that would give us SMIME gateways, organization-to-organization secure e-mail using SMIME. We'd found that worked really well. It was actually simple and secure. But these days, rather than do that, we found that just simply forcing TLS as a mechanism of exchange server to exchange server data exchange has worked really well. So I'm curious. I absolutely concur with your recommendation saying that SMIME organization-to-organization, not individual-to-individual, works great. But the consideration for not just saying let's use SMTP and force TLS from HISP-to-HISP, why not do that?

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

The difference is that that's a contained community, so it's all in one trust domain. Everybody knows each other. Everybody uses certificates that are recognized by each other ahead of time. In the environment where NHIN Direct will be used, there will be multiple trust domains, and these trust domains need to exchange certificates between them and, ultimately to do what you just described on a national level, everybody would need to have all of the certificates of everybody else.

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

I wanted to make a comment on going Postel here, but first I wanted to understand how TLS and SMIME are different with respect to the issue of who needs whose certificate.

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

Well, they're not different. They both need the certificates of the sender and the receiver.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I would weigh in on that if you wanted, Dixie.

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

Sure.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Wes, the way TLS is implemented, it's machine-to-machine trust, not person-to-person trust. It's fairly easy to get a lot of machines to agree on a small number of routes that they trust, but if you want to control your trust fabric or trust framework at a more granular level than machine-to-machine, you can't do it with TLS. Which is why we use the SMIME certificates, which can be allocated at the individual level to control for that. We have more flexibility in managing different circles of trust or trust fabrics with the SMIME approach the way we're using SMIME.

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

The current recommendation, I'm just having trouble understanding what's different between what is recommended. What is the change that the review committee is recommending?

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

The difference is, and I'd say, David, NHIN Direct, before we get to Paul Egerman telling us we're focusing on the wrong thing, the NHIN Direct is focused on exchanges between organizations, not people. So all of these comments, we are assuming exactly what Wes is pointing out that we're talking about certificates for organizations or machines, not people. But I would say the difference is that the entity, well, I mean, both cases. Actually, the e-mail server would have to go find the digital certificates in either case.

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

I'm still not seeing a difference.

Arien Malec – RelayHealth – VP, Product Management

When we explored this, and we really wanted to use TLS because it is significantly the simplest, the way that TLS works, and I'm going to go a little hard core for just a second, the way that TLS works is that the server first offers its certificate chain, and it offers only one. Then the client offers up its certificate that needs to map into that certificate chain. What that means, as a consequence is that even if the server and the client both have certificates that are in mutual domains of trust, the server is only ever able to offer one domain of trust. And what you end up with is....

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

Arien, I don't mean to cut you off, but I'm asking a different question, I think. What was in our documents, in the NHIN Direct documents, and what will be changed as a result of this recommendation?

Arien Malec – RelayHealth – VP, Product Management

The documents currently recommend that TLS be used even if the content is SMIME encrypted in server-

to-server communication, and the recommendation from Dixie's review or Dixie and team's review is that that recommendation be removed in order to facilitate the widest degree of interoperability where the data leakage problem is handled through policy. I think that's the summary of that slide. Is that right, Dixie?

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

Yes. Both the need, and it's not a requirement. It's a should, and we felt that a should for a TLS connection is not a good thing because you wouldn't know whether the TLS connection had been established or not, but both the TLS and the content, the SMIME wrapping recommendations would be removed.

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

Just in general, we know that as we work in IT projects that we solve a problem and run towards the goal, frequently defined another problem before we get there, and that's expected. In fact, often it's better to work that way than to try to solve everything at once.

One of the issues that will be coming in the future relates to what are the conditions under which Direct could be used to exchange structured data. I would like to suggest that there is an alternative to Postel's law or theorem or whatever it is, which was used by MinuteClinic and SureScripts in the work they did over a year ago. Which is to send both structured and unstructured versions of the data so that the sender does not need to know the capabilities of the receiver. I'm advocating for that, and just don't want us to go overboard in the Postel interpretation and use that as a way to rule out a downstream issue that will come up.

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

Yes. I had discussions with Doug Fridsma and Arien about that very topic this week, and I think that's really ultimately where we want to be is where both human readable and machine readable are exchanged in the same package, and the human does even have to know that it's machine readable as well. But the risk was that the information could be exchanged in a way that it would not be human readable at the other end, so that's why we have the default is that it at least has to be, for the little doc, has to be able to understand what they have and able to send it.

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

Yes, so I think we agree on the goal, and all I'm saying is that my reading of Postel is that it could be thought of as inhibiting that, and I would suggest that there's another law, which also applies, and our job is to decide which law to apply when.

John Halamka – Harvard Medical School – Chief Information Officer

Certainly, Wes, I think the notion that we've all had is we're decoupling content and transport, and so with everything that Dixie and team have said, I would hypothesize. Arien and Dixie, please response. This mechanism of using SMTP and SMIME as organization-to-organization transport is truly package neutral, and that anything could be inserted, structured, or unstructured, or both.

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

That's right.

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

I agree. I'm looking down the road.

John Halamka – Harvard Medical School – Chief Information Officer

Any other comments on the fine work that Dixie and team have done?

Arien Malec – RelayHealth – VP, Product Management

The one piece of the recommendation, so first of all, I want to compliment Dixie and the Privacy and Security Workgroup for the work that they did, and really deeply appreciate it. I know that it's going to help us make the specifications better, tighter, and better aligned with the policy direction and standards directions that both the Policy Committee and the Standards Committee have given.

The one recommendation that I have some nuance concern about is this recommendation we were just discussing. I believe, as a matter of policy, that we should be encouraging and mandating, in appropriate circumstances, organizations to receive a wide variety of content. That is that it would be from the perspective of improving the quality of the healthcare system, it is better, as a policy statement, to get the widest amount of information sharing and then help the smaller organizations, the smaller providers step up the staircase of or the escalator of interoperability to more structured content and more tightly defined content.

That being said, there are certain workflows where I believe, in the Direct Project, in implementation of the Direct Project specification, it will be important to error if the receiver doesn't expect something and doesn't understand it. Examples of that are if I have a goal of receiving structured lab information, it may well be appropriate, and I think many of the labs that we're talking with are planning on spending both PDF representation and the HL-7 2.5.1 representation. It may be very appropriate for both representations to be sent. But if I don't; if I'm expecting to get a structured HL-7 2.5.1 ORU message, and I don't, and I see it, but I don't understand it, it's important for me to error. That was really the intent of that portion of the specification, and I do believe that's an important principle, particularly around, for example, CLIA requirements. In certain domains it's going to be important for somebody to say, you sent me an HL-7 2.5.1 message. I expected to receive it, and I just don't understand it, and I need to be able to error it. I think Dixie mentioned that, and I just want to make sure that that nuance is in the recommendation.

John Halamka – Harvard Medical School – Chief Information Officer

Dixie, any objections to that?

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

No. But I think that's already in the core specification, and taking the two pieces that we recommended, three pieces to be taken out, should not affect that. The core specification already says that you have to let them know if there's any reason why you can't process it.

Arien Malec – RelayHealth – VP, Product Management

Perfect.

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

Arien, you were specifically addressing the slide from the review that took exception to being able to reject a message for any reason. Is that right?

Arien Malec – RelayHealth – VP, Product Management

That's correct, and really the intent of that is if I have structured information that I'm expecting to receive, and I just can't process it, it's important in those cases to error.

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

And to let the sender know.

Arien Malec – RelayHealth – VP, Product Management

That's right.

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

And the way it's phrased now, it says that they can reject it, period. I think other portions of the specifications say if you're not able to process something that you receive, you need to let the sender know.

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

The concern here is that the rejection be active in the sense of notifying the sender, and that that wasn't clear from the term reject, and that it be specific as to the reason. Is that what you're after, Dixie?

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

There are certain reasons that are acceptable and certain reasons that are not. We don't want a receiver, a large organization to reject an e-mail message from a small provider that has the health information that could be useful. We don't want them to reject it just because it isn't structured, but if they reject it for other reasons, like it's corrupted on route, it's got security problems, that's fine. In any case, it should let them know. I thought that's what Arien was talking about.

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

No, what I heard Arien say is that a legitimate reason for rejection was, I'm looking for structured data, and I can't find anything that looks like it.

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

And we do not think that's a legitimate reason for rejection.

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

Arien, am I misinterpreting you?

Arien Malec – RelayHealth – VP, Product Management

I think so, so I would submit as a policy goal that it seems like sending a PDF along with an HL-7 2.5.1 is a best practice. But if I have an EHR and a meaningful use requirement that requires me to import or include structured information, and part of my processing is, I see it. I see there's a PDF and a 2.5.1 message. I'm importing that 2.5.1 message, and it just doesn't work. Then it's important in those cases to surface the error back to the sender.

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

I think we have total agreement that it's important to surface the error back to the sender. What I'm not clear on is whether we have agreement that it's acceptable to reject a message because it only contained textual information, and I thought you cited a really good use case where I am receiving this information in order to put it into a record in accordance with meaningful use requirements. Therefore, it would not be acceptable for me to attempt to parse free text to structure the data.

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

I have to go back to what Carol Diamond said earlier about having policy drive the standards work. I have to say, I think this is the clearest case of a violation of that principle that I've seen in the committee where, in my mind at least, the reasons for which a receiver of information or recipient of information might reject it is very clearly in the policy domain and, frankly, doesn't have to do with the standards. This is something where we should have policy guidance that would drive that.

John Halamka – Harvard Medical School – Chief Information Officer

I think, if we summarized this by saying whether or not a rejection of a message occurs because of some aspect of the content being structured or unstructured as a policy decision. That, from a transport perspective, we have said one wants to insure the simplicity, directness, security, and scalability, and we have said SMTP and SMIME, the package will be delivered. If rejected for a policy reason, an error will be sent. We're probably okay.

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

Yes. There's a small interaction there, which is, if you're going to code the reason for the error, you need to know whether that's a valid code or not.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

John, just to slice this out a little bit, it is not appropriate to reject the content because the sender doesn't know what applications or capabilities the receiver has. In fact, that's a good way to break the system. And one reason to keep it simple and to keep the core specification as tight as possible is that any expectation that a receiver is running a certain app or would prefer more highly structured data or would prefer to use another optional standard is not appropriate.

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

As a corollary then of that principle, is it then safe to say that it is not within policy to ever use NHIN Direct to send structured data to an application that has to have structured data?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No, absolutely not. If two people in the system want to work out those requirements, they can. But as a core specification, the SMTP SMIME can't be rejected simply because the receiver says I'm running a more complex system than this physician in a small practice using a simple app, and I'm not going to accept it. I've got to say, the reason for this is also because it's not good for patients.

John Halamka – Harvard Medical School – Chief Information Officer

Let me just try to summarize this and see if we can achieve consensus that what Dixie's report is doing is providing a set of additional clarity with the removal of the requirements to use DNS as a means of certificate exchange, and is removing the requirement for the core specification inclusion of XDR. It is providing a transport mechanism that can be used for any stuff and a discussion of what stuff is transported over it is a policy domain rather than a technical domain question. Is that fair to say for everybody?

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

That's right.

John Halamka – Harvard Medical School – Chief Information Officer

Good.

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

I'm not fully comfortable with this, but we're out of time, so I guess it doesn't matter.

John Halamka – Harvard Medical School – Chief Information Officer

Wes, let us follow up on your concerns via e-mail, but I would just say, we are separating content and transport here, technologies, and the specification of trading partner, business orchestration is something that is left to a policy domain. As Carol has said, if two individuals want to send PDFs via NHIN Direct, go ahead. There's nothing wrong with that. It may not achieve meaningful use, but there's nothing wrong with it.

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

But there's also nothing wrong—I think we have—I don't have my own set of the slides up here, but we have a slide that says that the sender should be able to send and the receiver be able to handle unstructured, semi-structured, or structured information. As Carol pointed out, it's really an out-of-band decision if they want to jointly agree to exchange structured information. That's what they will send. But if the receiver rejects it, they have to let the sender know why.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

And to be clear, at least for this point of NHIN Direct and its objective, which was to identify a way to send secure information from point A to point B for this stage and this level of requirements.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Yes. I just wanted to jump in because I think it's important to understand that the context in which that exchange happens sometimes requires the use of some sort of a standard. While absolutely we agree that the sender can send and the receiver can receive any kind of messaging, unstructured to structured, there are some external forces that might require those senders and receivers to use a particular structure document. Among them, of course, HIPAA standards, meaningful use standards, other standards.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Sure.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

There is that context that is important to have in mind.

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

I'm hearing that the concern for policy is that there be a policy that every receiver always be willing to accept data that's only unstructured.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No.

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

I feel like that's a really strong statement for policy to make.

John Halamka – Harvard Medical School – Chief Information Officer

That is not a statement at all, Wes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

That is not it.

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

Well, then I don't understand Dixie's concern.

John Halamka – Harvard Medical School – Chief Information Officer

Again, Dixie, if you could restate it. The direct specification with your modifications can be used to exchange structured or unstructured data. It is separating content and transmission.

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

That's exactly right. NHIN Direct should be able to handle, both sender and receiver, unstructured, semi-structured, and structured information. It shouldn't matter. It should be, as we put in the slide, content agnostic.

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

I have to say, what I was reacting....

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

No, I'm talking about the policy requirement. We're not talking about the technical.

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

Right. What I was reacting to was the statement that we don't want to have a standard that allows a receiver to reject something for some reason, and I just don't think that's a standards call. I think that's a policy call.

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

I'm sorry. A standard, the biggest problem we had with HIPAA standards was not having standardized how to deal with error conditions. Well, other than noncompliance in general, the biggest problem. And to hear it being said that there are reasons that two people might agree that this transmission shouldn't go, but we cannot convey that back because the standard prohibits us from doing that doesn't seem to be really helping with the edge cases around interoperability. It seems to be hurting the edge cases in pursuit of a policy principle.

John Halamka – Harvard Medical School – Chief Information Officer

Actually, I don't think we have a difference of opinion here. Let me just ask Dixie. If a policy decision is made results in a rejection of a message, do you have any issue with reporting an error condition back to the sender?

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

No, that's what the core specification currently says.

John Halamka – Harvard Medical School – Chief Information Officer

Right. Wes, I think, because we are out of time, and we do want to get to public comment, I think we can conclude here that we have separated content and transmission standards. We have not imposed policy guidance in the context of our technical discussion, and that we should, through NHIN Direct, enable many different kinds of exchanges of structured, unstructured, semi-structured data, and restrictions on the nature of the data. Whether it is accepted or rejected may be said in meaningful use, but it is not said in the context of our committee's work today.

Let me just again thank everybody so much for everything we've discussed, and a quick summary. We have done an evaluation of the Direct Project very successfully. I hope those are useful recommendations to you, Arien and team. We have gone through the PCAST report, and I think we have both additional workgroup discussions through the ONC workgroup that will be formed to discuss it, but also ongoing incorporation of some of these major themes into our work ahead. We have reviewed these priorities in the initial standards and interoperability framework, and we've assigned some work to the clinical operations committee and to the privacy and security committee to support that effort. We will do additional work on certificates and make some recommendations in response to the Policy Committee's request, and we will have a forthcoming provider directory request that will also dovetail into this work. We will begin work on device standards, and there will be a workgroup together in January to look at the scope of that effort, so quite a lot of work in progress.

That worry that was articulated in our meeting in October by a testifier that we would be taking time off and slowing down has not come to pass. Again, thanks so much. I think, Judy, we do want to take some public comment if there is any.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes. Indeed, we do want to invite the public to make comment. While we're waiting, just a reminder, the next Standards Committee meeting is on January 12th, which is preceded by the Implementation Workgroup hearing on January 10th and 11th, and I will get that draft agenda out to you later today.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Judy, do we know the location of the hearing?

Judy Sparrow – Office of the National Coordinator – Executive Director

The hearing and, I think, the committee meeting will all be held at the Wardman Park Hotel here in Washington, D.C.

Coordinator

We do not have any questions at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director

Happy Holidays to everybody.

John Halamka – Harvard Medical School – Chief Information Officer

We have achieved an on time end of our meeting, and I do, again, want to wish you all a happy and safe holiday. Thanks so much for everything you've done through our 20 meetings. I'll write up as many as these comments as I can in my blog and put that live by Monday. Safe travels and Happy Holidays, everybody. We are adjourned.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you very much.