

**HIT Standards Committee
Draft Transcript
July 19, 2012**

Presentation

Operator

Ms. Deering, all lines are bridged.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Thank you very much operator. Good morning everybody, this is Mary Jo Deering, in the Office of the National Coordinator for HIT. I'd like to welcome you all today to the 38th meeting of the HIT Standards Committee. This is open meeting, a public meeting. There will be an opportunity for public comment at the end, and because a transcript is being made, and for the benefit of those on the phone, I'm going to ask all members to identify themselves when speaking. I'll begin by taking the roll. John Halamka?

John Halamka, MD, MS – Harvard Medical School

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Dixie Baker?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Anne Castro?

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

I'm here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Chris Chute?

Christopher Chute – Mayo Foundation for Medical Education and Research

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Tim Cromwell?

Tim Cromwell – Veterans Health Administration – Director, Standards & Interoperability

I'm here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

John Derr?

John Derr – Golden Living, LLC

I'm here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Lorraine Doo? Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – National Quality Forum – Senior Vice President of Health Information Technology

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Jamie Ferguson?

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

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

C. Martin Harris?

C. Martin Harris – Cleveland Clinic Foundation

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Thank you. Stan Huff?

Stanley M. Huff – Intermountain Healthcare

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Kevin Hutchison? Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – Vice President, Applied Clinical Informatics

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Becky Kush? Arien Malec?

Arien Malec – RelayHealth Clinical Solutions

I'm here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

David McCallie?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Good morning.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Nancy Orvis? Mark Overhage?

Marc Overhage – Siemens Healthcare

Present.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Wes Rishel?

Wes Rishel – Gartner, Incorporated

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Chuck Romine?

Kamie Roberts – National Institute of Standards and Technology – Associate Director

This is Kamie Roberts for Chuck.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Thank you very much. Cris Ross?

Cris Ross – Surescripts – Executive Vice President & General Manager, Clinical Interoperability

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Walter Suarez?

Walter Suarez, MD, MPH – Kaiser Permanente

I'm here.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Thank you. Sharon Terry?

Sharon Terry – Genetic Alliance – President and CEO

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Jim Walker?

James Walker – Geisinger Health System – Chief Information Officer

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Here.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Thank you very much. I'll turn it back to you, John.

John Halamka, MD, MS – Harvard Medical School

Well, Jon Perlin is at an AHA board meeting today and so we are going to have a very interesting meeting, a tight agenda today. To get you out before the thunderstorms start, that is our goal. So I know we have some opening comments from Jodi Daniel and then I'll review the agenda.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

Great, thank you John. Farzad is also out at AHA, and so I'm sitting in for him today. This is...this meeting I think last summer we talked about the intense summer camp that we had and I think this is called our summer break. This is kind of a lot more laid back than we had last summer at this time, but it's just to make sure that you're refreshed for when we kick back up into high gear soon. I just wanted to note a couple of things. One, I wanted, as all of you know, talk about the nominations process we had for our FACA committee membership. We did have an open call for nominations to both Health IT Policy and Health IT Standards Committees, and that closed on June 11. I want to thank folks who expressed interest, both folks who are on the committee who's terms are up, as well as others who applied and it shows that these committees are highly regarded, because we received a lot of applications and a lot of interest.

ONC staff is in the process of reviewing all of those nomination packages, to identify the best-qualified candidates. Our goal is to ensure we maintain a fair and balanced committee membership and that we get members that are as committed and have as good a group as we've had over the past few years with this group that has really set a high standard for folks to meet, and that pun was intended. Once the members are announced, we will send e-mail notifications to everyone that applied. In the meantime, of course we continue looking forward to working with all of you. And I just want to reiterate how much we appreciate all of the hard work of everybody who has dedicated countless hours and many times thankless hours, to all the hard work both on the committee as well as in the workgroups that provides such an important basis for all of our work, most notably, our standards and certification regulations.

I also wanted to just follow up on our governance RFI. As you all know, our comment period closed on June 29. We really appreciate all the thought and hard work that went into providing us feedback and comments, both from the HIT Standards Committee and the Health IT Policy Committee, as well as the 140 other commenters that we heard from. We did get a wide spectrum of comments on all 60 plus questions that we asked. I do think that we made the right decision to start with an RFI. We did get a lot of really thoughtful and challenging input that's helping us to really think about what our next steps are and how to approach the governance of the Nationwide Health Information Network. So we're carefully reviewing all the comments, we are listening. We're trying to learn from where we hear some common themes and we are determining what our next step will be based on those comments. So we're just in the evaluation process at this point. So stay tuned and we will keep you posted on our next steps, and with that, I'll turn it back over to John.

John Halamka, MD, MS – Harvard Medical School

Great, okay. Well, Mary Jo, I think you probably want us to look at the minutes of the June meeting as an administrative point before we begin. So having looked at those, are there any amendments or comments to the June minutes? Okay. Well none being heard, Mary Jo, those are approved by consensus. So when we look at today's agenda, now you did mention this was the non-summer camp. Well, for Dixie Baker, this is the...well Dixie, you're carrying the weight of the committee on your shoulders. So it is the Dixie show today followed by some updates from ONC. So just reflecting on some of Dixie's work, back in the HITSP days, there was something called the standards readiness criteria, and every time we looked at an implementation guide or standard, we looked at its level of adoption, its level of testing, its level of detail and appropriateness. So, if you are going to, for example, impose a standard on the country in an NPRM, you'd want to have some sense that it was ready for prime time. And so what Dixie and her group have done is really updated that work and other work that has been done it assess and evaluate in objective ways the standards we are reviewing.

Before the meeting, Doug and I were talking about the S&I framework, and you'll hear a fair amount about the S&I framework today and the role of testing in the S&I framework. And I think one would agree that if you defer testing to the certification processes, you have the risk of imposing a non-ready standard on the country. And so having your work as a rubric for the deliberations of both this group and S&I framework will be very helpful. Dixie will also give us an update on the trusted ID for providers in Cyberspace. Questions of how does one authenticate an endpoint, especially as we implement direct and we think about ways of transmitting data and ensuring it's not...ability and ensuring it gets to the right recipient and it's sent with providence, we better know who's on each end. And now that Cris Ross is the new CIO of the Mayo Clinic, what he is going to suffer, that I do every day, is screen scrapers,

keystroke loggers. The fact that username and password although convenient, actually doesn't say a whole lot about who's at the endpoint, or who's accessing the system. And so Dixie's report will reflect on what are those additional protections we may wish to consider and whether those are biometrics, challenge questions or policies and procedures to ensure that we are really sending and receiving data to and from who we think it should be sent from. So that's important.

On the ONC side we'll hear about the update on certification as we go from a temporary to permanent program and want to hear certainly about how we do that from a timing perspective and how those testing criteria get developed and circulated and applied and recognizing that as that first certification program was rolled out, time was short. It worked very well, but now we are going to get into a permanent steady state. So we'll hear about how that perhaps and certainly look forward to your report on where ONC, looking back on the last year to two, has seen some real progress, some measurable progress in certification. You mentioned the governance RFI and it is fascinating because I have read some of the comments that have come in there, too. And I was in Massachusetts State HIE planning meeting yesterday and the comment was made as follows, "We will absolutely defer to the federal government the enumeration of the certification for trusted exchange, but we don't want Farzad deciding who we trust and who we don't." So I think you will see some of these sorts of comments about what should the role of the federal government be. How far should it go? Should there be a formal certification program? And I, of course, only mentioned Farzad's name in jest. But I mean, that is the nature of the debate of state and local versus federal control and how this body and how ONC should contribute to governance. So, good luck on getting to an NPRM with that.

And then finally, Doug Fridsma will update us on the S&I framework and its various initiatives. And, I think of great concern to everyone on this committee should be as ARRA ends its era, you will see that the funding for S&I framework will be reduced substantially and how do we, as a Standards Committee, ensure that those initiatives continue to move forward, that the right priorities are addressed, that we leverage other organizations such as SDOs or other say NGOs or non-profit organizations who can continue work as funding is diminished for the S&I framework. And of course, anything this committee can do to encourage the allocation of funding to standards, we will certainly do because we want to help Doug and the S&I framework activities. A last couple of comments that before the meeting, a few folks approached me with some interesting ideas and so Mary Jo, these are probably things that ONC will need to debate assignment for. It's wonderful when people come up to you and say, I want more work.

So Jamie Ferguson highlighted that the FDA has issued an NPRM on the universal device identifier specifying the GMDN standard, as well as a variety of ISO standards and, hence, that there is 120-day comment period and there's a set of standards that are going to be imposed on device manufacturers. It's probably a reasonable thing for the clinical operations workgroup to review that NPRM and make comment on the selection of standards, the standards readiness and implementation guide quality and that sort of thing. And certainly, there has been a debate for many years about what standards one should use to identify devices uniquely. And so there are choices in the NPRM we should review.

And Leslie Kelly Hall mentioned that, as we think about consumer engagement, patient and family involvement there are terminologies we will develop that may or may not be in SNOMED today, that may or may not be in Kaiser's contributed convergent medical terminology and there are many groups working on consumer-facing vocabulary elements, that ultimately should be included in the UMLS. NLM should have them in that vocabulary and code set library that they have announced they will be hosting. And so certainly Leslie, look forward to your thoughts and your group's thoughts on how do we converge many of the efforts on consumer-facing terminology and ensure that we do get all the appropriate terms put into the National Library of Medicine repository. So, see, it's not summer camp, not afterwards, you know, we do have a lot going on. We do. So with that, look forward to the agenda today and we will start with

Dixie Baker.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay. I have two presentations this morning. There, is that better. The first of which is a preliminary recommendations from the standards evaluation...on standards evaluation criteria. This work is a work in progress by the Nationwide Health Information Network power team. I thank everybody who has served on the Power Team, and especially those who dial in for every single meeting and always have a lot to say. Those are particularly appreciated. Okay, I wanted to remind you again of...I know we need...I've have shown this picture...actually, this picture, a version of this picture appeared in the RFI, but I improved upon that picture. Basically, it depicts how a particular standard might move from being an emerging standard, immature emerging standard to the point where it can actually be piloted to the point where it's really ready to become a national standard. And there are the two matrices on this are the maturity of the specification and the adoptability of the specification.

The power team has identified three criteria in each of these areas, maturity and adoptability. The maturity criteria are the maturity of the specification itself, in other words, the maturity of the specification as documented, the maturity of the underlying technology components that are used in that specification, and the degree to which that specification has been adopted in the market. There are three adoptability criteria and those are the ease of implementation and deployment of the specification; and the ease of operations of a system that's built using that or an implementation of that specification; and any kind of intellectual property that may impede operations. So I'm going to go over each of these criteria areas, each of these criteria. For each of these criteria, have identified a set of attributes that really contribute to that criteria. And for each attribute, we have identified a number of metrics to be used to really measure that attribute for a given specification. So I'm going to go through the maturity criteria and then the adoptability criteria. And what you'll see is I will first show you the attributes and then you'll also see the metrics. All of this is draft, but this is our first complete presentation of this work. We have made our first cut at all of these criteria, all of the attributes and we have identified and are recommending some metrics in each of these...for each attribute.

So maturity of a specification. We've identified four attributes, the breadth of support for that specification, the stability of the specification, how much it's really changing any more, the interoperability among the number of independent implementations of that specification, and the adoption, how broadly the specification has been adopted. You'll see, hopefully you can read in your handout, we've identified a number of metrics and for each attribute these metrics will allow an evaluation team to assign a score of either low, medium, or high. And to the extent possible, we tried to make these as measurable as possible without creating artificial implications of measurement. You know, in some point, for example, we considered like 30% adoption, but we soon realized really that, you know, that 30% sounds good, but how is that actually measured, and we concluded that actually using that as a metric may be sort of artificially sort of shoehorning a specification into a numerical metric when it really is impossible to assign a numerical value to it.

So I won't read all of these bullets in here, but I would really encourage you to read them and review them...the metrics on your own and to send me any comments at all that you have about these metrics. As you'll see, our next step really is to take this and to apply it to an actual specification to see how it works in real life. But either as you're sitting there now, read through them and comment when we...at the end when we have the comment period, or if you look at it on your trip home or whatever, after you get back to your office, if you have comments we would certainly welcome them. So I thank you in advance for your input on that.

There are two pages of the maturity of the specification itself. The second set of...second attribute under the maturity criterion is the maturity of the underlying technology. And note that this set of attributes is actually evaluated for each technology component within the specification. And these attributes are the breadth of support for that technology, the stability of that technology, the interoperability among the number of independent implementations of that technology, the adoption, the platforms that are supported by that technology for that technology, and the maturity of the technology within its life cycle. You'll notice that these are very similar to the attributes we assigned to maturity of specification, except that these really apply to the technologies themselves, technology components that the specification uses. The maturity of the technology within its life cycle considers both how mature it is, whether it's just emerging, whether it's just using pilots, whether it's really being adopted by industry, but also whether it's falling off the other end. You know, as technologies mature they do reach a peak and then they start to decline and are seen less and less. And we wanted to incorporate both as the technology matures and as support for it diminishes in the life cycle, technology life cycle. There are three tables here that set forth the maturity of the metrics for measuring the maturity of the underlying technology within. And you'll notice these attributes that I've just talked about are in that left-hand corner, and then again, you'll see low, medium, high across the top and the metrics within each of these areas.

Okay. And the third criterion here is market adoption; the third criterion under maturity is market adoption. And the attributes that are considered under...in assigning a rating to market adoption, are the installed health care user base, how broadly its actually used in health care itself. The installed user base outside of health care, because some of these specifications that we use, as you well know, are not health care-specific, but are used by health care. Some of them are adapted for health care and some of them are really...especially the clinical vocabulary standards, for example, are completely health care-specific standards. So we want to consider both the installed base within health care and outside of health care. The third attribute is future projections and anticipated support. Where we see it going, do we see it stalling? I'm sure all of you, certainly us that are technology people, we know of many specifications that are out there and have been out there languishing for years and years and years and everybody knows they're going nowhere. So we wanted to include that as a future projection and where the specification is anticipated to go. And then investments in user training, how much of a real infrastructure is there out there for training users to actually use the specification? And as a specification matures, you'll see more and more support for training users to use it and to implement systems using that specification. And there is one slide showing the metrics in the market adoption area.

So moving on to the adoptability criteria. There are three criteria that contribute to the adoptability of a specification. The first criterion is the ease of the implementation and deployment. How easy it is to take that specification and implement a system and deploy the system using that specification. You may recall that we used to call that the complexity of implementation and deployment. And the second one we called complexity of operations, but in order to have them both...have all the criteria assignments move from low, medium to high, we flipped it over so that it now measures the ease of using that specification and the ease of implementing that specification. The second criterion is the ease of operations and the third is intellectual property.

So, there are a number of attributes under ease of implementation and deployment. The availability of off the shelf infrastructure to support the implementation, these are things like tools used for...software development kits, tools for the implementation, the worked examples of the implementation. All the things that a developer could reach out easily get to help them implement the specification. The deployment complexity, this is more measures of how difficult the deployment...real deployments have been, sort of report back, you've deployed this specification or you're attempting to deploy the specification, how easy or difficult has it been? You may recall that when the NwHIN Power Team evaluated the NwHIN specifications themselves, that we solicited public comment on how difficult or simple the implementation of the exchange specifications were. And we got quite a few people and implementers feeding back input to us on how difficult...how long it took them to implement how difficult it was relative to other things they had done. So there are a number of measures in there around how difficult it is and how complex it is to implement a particular specification.

The availability of conformance criteria and conformance tests to use. The fourth criterion or attribute is the availability of reference implementations. Developers love reference implementations, because you can just take them, you implement them, you've got a starting point, you can tailor them, you can improve upon them, you can make them available as open source so others can use...so this is...the availability of reference implementations is really an important attribute. The complexity of the specification itself. We talked about the maturity of the specification, but in some cases we may have a mature specification that is just really, really hard to implement. That's what this attribute measures. The quality and clarity of the specifications themselves. This touches on the language that's used in the specification, whether it's commonly used terminology. How deep it is embedded, how layered it is, how difficult it is to understand. The modularity of the specification, how easy it is to break it up into consumable piece, if you will, so that different development teams could really essentially develop different modules of the specification.

The separation of concerns. This is more alignment with the real world, how well the specification aligns with the business use cases that its intended to solve. The ease of use of the specification, the degree to which the specification uses familiar terms to describe real-world concepts. And the degree of optionality. The degree of optionality was a particular challenge for us, so I really want you to look at those in particular because in some ways, optionality is a good thing, and in some situations, it's not a good thing. So we tried to sort out when it's a good thing and when it isn't, and in those cases where it's a good thing, we wanted to give it a high score and in those cases where it's not a good thing, we did not. So, we tried to sort that out, but it was really a challenge for us, so your inputs would certainly be welcomed in that area. And there are three charts of metrics around ease of implementation and deployment.

The next criterion is ease of operations. And the attributes that we identified are the comparison between the targeted scale of deployment to actual scale deployed. You know, you might have a specification that says this is for...this supports a nationwide health information exchange, and in truth it really...if you have more than three nodes on it, it really gets hard to implementation and burdensome for everybody involved. So that is a comparison between the scale that the specification says it targets and what it really...how it really can actually be deployed, the scale at which it can actually be deployed. The second attribute is the number of operational issues identified in deployment. Again, you'll recall that when we solicited inputs on the exchange specifications, we got a number of issues that were identified. And some people said, well, I had hardly any issues, so this really is a measure of how many of these issues are really encountered when a specification is deployed. The degree of peer coordination needed, how much different...you know, you have within an HIE. You may have...you may require coordination among different nodes in a network or between different nodes in a health information exchange. So this is the degree of peer coordination, interdependencies between nodes is really what that is looking for.

Operational scalability; that measures the operational impact of adding one more node to the network. If you have a network within your hospital let's say, that you have 15 servers on, and you add a 16th one and the whole network comes down, that's not very scalable. So you want to be able to add nodes to a network without...with minimal impact on the other nodes, and that's what that attitude is intended to measure. And then finally is the fit to purpose, how well the specification responds to the use cases that it says it is intending to respond to. Okay. And the final criterion is intellectual property. In the attributes, the first attribute is openness, this means how available a specification is to everybody. Can you just go out on the internet and find it and use it and use it for whatever purpose you want to use it for? Or is it hard to find, is it easy to find or are there certain uses that its usage is restricted; that's what that's looking at. Accessibility and fees, obviously is how much it cost to use the specification. The licensing policy, I'm sure everybody here knows that licensing policies sometimes have restrictive terms in them and that attribute measures the...how much a licensing policy might be a barrier to adoptability. Copyrights and then finally any patents that are associated with the specification. And there's one slide for the metrics we have identified for intellectual property.

Okay. The next step, moving forward, and we are, we continue to move forward, July the 26th, next week, you'll recall that when the Nationwide Health Information Network Power Team evaluated the NwHIN specifications, one of our recommendations was that the nation really needs a third option for transport, and because of the broad use of and acceptance of RESTful exchanges, we suggested, we recommended that there be a standard developed specification developed around a RESTful exchange.

In other words, an exchange that really used RESTful technologies, RESTful being like a web-like HTTP, the same standards that are used for the web. And the ONC has been sponsoring, and its federal partners have been sponsoring the development of a RESTful exchange specification and at our next meeting, we'll get a presentation of that specification as it currently stands. It's not completed, but we'll get an update on where it is right now, and course anybody on the committee, and anybody in the public as well, is welcome to dial in and hear about that on July 26.

We're also going to discuss the feedback that we get from you today, as well as any additional feedback that you might give us via e-mail or phone call or whatever, and then we're going to start an evaluation exercise. We wanted to make this exercise relevant, but we wanted to make it doable within a limited period of time. We didn't want to make it overly complex so that the Power Team, gets an assignment for the next six months to a year. So one of the standards that we actually, you may recall, we discussed this when we discussed our comments on the RFI I think, no, it was on the NPRM for Stage 2. We discussed the info button, the HL7 context-aware knowledge retrieval specification standard. And so we selected that had as our trial specification to use to really see how well these criteria and metrics are responsive to our real needs in evaluating a real specification. So we're going to begin that on July 26, and hopefully we'll finish that evaluation in August and we'll incorporate any lessons learned from that evaluation exercise and report our final results back to you at our August meeting. Okay. Are there comments and questions?

John Halamka, MD, MS – Harvard Medical School

Dixie, if you think about the framework you've just presented, and the S&I framework activities, I am imagining that the direct protocols were actually highly mature standards with reasonable implementation guides, and the work you did was building consensus in the community for adoption of mature standards.

Oh and there were some details to fill in, like DNS use for certificate retrieval, etcetera. Query health uses some existent standards, but those aren't precisely sufficient for purpose, so there needs to be refinement of existent standards in order to get query health functional. And then I reflect on such things as the transitions of care activities that require completely novel balloting in order to get what effectively are new standards that are a significant evolution of what we have. So, using that criteria that you have just told us about, suggesting that in fact we could map out the difficulty or the nature of future efforts based on where we are in your continuum could be very helpful to ONC for budgeting purposes and to this committee to understand the life cycle of the work ahead. So, let's open it up to questions. I see we have Leslie Kelly Hall and Cris and Jamie.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thanks, Dixie, and I'm always amazed by the amount of work you're able to achieve and wonder if you sleep, so, thank you very much for that. I echo John's comments about sort of the natural tension between innovation and doing things we have never done before and pushing an envelope with the establishment of mature standards as a criteria. These seem to be naturally at odds. So is there an opportunity to create a criteria or a separate category that's sort of that innovator or that think-tank or perhaps that's met within the S&I framework. But I do believe that other industries can inform us and we should listen. And I appreciate the fact that in your first few sections, it does not include an assumption that it's a health care mature technology, but it could be any technology in other industries as a consideration for mature and then get to market adoption to actually health care. Did I read that correct is the question?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, you did, yes.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Okay that helps us to adopt other technology. But as we look towards taking existing technology and existing market-level adoption and apply it to new roles, like a patient and their family member, again that tension appears because we have mature standards, but completely zero in patients participation or family members participation. So this question is, how do we accommodate...there are two questions...this -- this natural tension between innovation and existing mature standards? And the second question, how do we accommodate new roles and usage of existing technology in standards?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Good comments, thank you. One of the points that some of our members repeatedly made, it's a topic that was frequently brought up, and still is that...and it's an important point to make...is that none of this that we are recommending is intended to be absolute. This is intended to inform a recommendation...we envision a team just like was described in the RFI. A team that would get together and ONC would give them a specification, say look at this. we need a standard in this area, this has been recommended. Evaluate this, and going through this disciplined...we intended this to be a disciplined way to objectively view and evaluate a standard. But we are adamant about there not be scoring mechanisms where you average out your score and if it's above 7 it gets to be a national standard, if it's below 7, it does not. But rather to inform a recommendation on that standard. And we hope that that kind of...and we're currently talking about process, by the way. but we are hoping that that kind of process where this is used to inform, but not to make an absolute judgment based on some score, that's the intent of using it.

The second part of your question I think, for me, reflects back to a comment that this Power Team made relative to the RFI, that we think that really, there should be a distinction between national standards that become codified in laws and national standards that are national standards, but may not be codified in law, and we think that that balance is important to encourage innovation without bogging it down with regulatory timelines. Are there other people on my team who would like to respond to that?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David McCallie. I'll use this as my question time, because I wanted to make a comment that I think somewhat addresses that, it's a little bit broader. But, we worked hard in this process to come up with criteria that you could actually test or measure to some degree. But when it's all said and done, it's still a very qualitative process and that I think our intent was not to believe that this process would yield a score, and if you got above a certain threshold it meant go forward; if you didn't meet that threshold, it would mean you don't go forward. If you look at that matrix of...do you have your first slide there, Dixie, can you put that back up?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Sure.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

I don't know if it's possible to go back to that. You know, in this...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, I just went by it, didn't I?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Yeah, there you go. You can't read it here, but there are nine quadrants or nine cells on that slide. The only two cells that are no-brainers are the lower left and the upper right. everything else is a gray zone that allows for the possibility of a standard to emerge and be useful in a certain space. So, I think that the criteria is just to help figure out how do you describe, how do you measure, how do you assess a standard, not to sort of say it's good or not good. So I think as new things emerge, someone starting from scratch would say, well these are the things I need to worry about, in putting a standard together that would work in health care's face. Here are criteria that will help me figure out how to make this a good standard. But it doesn't mean that just because it's new, it won't get attention. I don't think we had any intention, any intention to be so rigorous that if you don't reach a certain score; you don't go forward, I don't think that's possible.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Definitely, we intended to be...for this to be a disciplined approach, but not a rigorous scoring process.

John Halamka, MD, MS – Harvard Medical School;

Now, I believe Jim Walker has a related comment on this topic.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Um hm.

James Walker – Geisinger Health System – Chief Information Officer

I think we really ought to try to distinguish experiment and guideline or standard. I mean, it seems to me that this is not about saying you can't experiment, this is about saying, if you're going to impose this on the whole country, lay people, professionals, everybody else, that you ought to prove that it's usable and useful. And so I think that's the way to think of this. This is a control on the people who want to make everybody else do something; not so much saying you can't do experiments. So, it would be as if someone had a new idea for how to connect phones and they forced everybody to use a new, immature standard for connecting phones without proving that it was at least as good as the existing standard.

John Halamka, MD, MS – Harvard Medical School

And just to echo a number of these remarks, then I'll turn it over to you Wes, this is really a categorization or classification scheme, as everyone has said, it's not a judgment scheme. So, I received a couple of e-mails of late saying, how dare the S&I framework choose a standard for transitions of care that actually requires membership or licensure. All standards used in the country should be free and open source and etcetera. Well, I think free and open source sounds good; however, we need to look at the appropriateness for a particular purpose, the experience with implementation and support and all these other factors. So it's not a...it's looking at your scoring and then based on all of the criteria and scores, assessing what to do with it. By no means is it setting up a pass-fail criteria for the goodness of the standard. Wes.

Wes Rishel – Gartner, Incorporated

Thanks. I think that in fairness to ourselves in terms of managing our expectations, we take this nine by nine as a model, a paradigm. But I'm hard pressed to think of a functional standard that has ever been adopted without problems that show immaturity, okay? So what do I mean by that? Well, by standard I mean something more than just saying HL7 version 2 labs; I mean something that is specified in sufficient detail that two different agencies implementing the same specification should interoperate. They couldn't clearly both be compatible and not interoperable. But when you look at HL7 labs, the C32, most of the functional standards that we're talking about are...have been flawed in execution in the past. And so we have to think about the question that Jim asked about how...with what confidence can we roll a new version out on the public, when our old versions haven't been...I mean, just using SNOMED to describe clinical concepts has offered a lot of possibilities for a non-interoperability along with great interoperability.

I'm convinced that there is no analytic path to perfection with functional standards, with any standards, that there has to be that experience path that we're describing. I think that has two impacts on us. One, I favor looking at standards in terms of their continuity with prior versions, even where the prior...the total interoperability we got with the prior version was less than what we would have liked to have achieved. For example, the consolidated CDA is not really very new, there's not really a lot of new material in there. There's a lot of reorganizing material and fixing problems that are recognized in the

implementation of C32 and other documents. Therefore, I feel much more comfortable about the consolidated CDA than I would about someone...a whole new approach, you know, at the same time, because this is how standards get better is by not being perfect and the community adapting, adopting to them...adapting to them, as well as adopting them.

The other thing that is a bit of a soapbox for me is that I think we as a committee, have to urge ONC to build into its program the recognition that there will still be some roughness in standards as they come out and implemented. There needs to be a faster feedback loop than the two-year process we go through, if only to publish quick interpretations, things like that. Now in the regulatory phase, there's guidance that can be issued. I don't know that we have a mechanism for developing guidance about technical specifications, but I think that focusing on getting the early adopters of 2013...I'm sorry 2014, through the early adoption and getting the resulting guidance out to the more mainstream adopters I think is a very valuable way to ensure that the standards stick in 2014.

John Halamka, MD, MS – Harvard Medical School

Jodi, you put up your card so I imagine you may have related comments?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I want to respond to him a second?

John Halamka, MD, MS – Harvard Medical School

Sure.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Wes, those...that's really, really good comments. Thank you so much. And I'm hoping that our able research assistant out there, Todd Parnell, is listening and will capture both of those because I don't think we've captured the continuity with prior versions and I think that is important for us to capture. And you can envision the same specification being evaluated multiple times, it's determined, well, it's ready for pilot, then it comes back again, let's do it again. And there does need, in that process, to be some way to feedback to the ONC the experience gained across time, as a standard matures. So, I want to make sure that we captured both of those ideas. Thank you.

Wes Rishel – Gartner, Incorporated

John, can I respond to the response of my response?

John Halamka, MD, MS – Harvard Medical School

Of course, go ahead.

Wes Rishel – Gartner, Incorporated

Thank you. Thanks, I think that's good. I wanted to add two things. One, we have already agreed these are not hard and fast, pass-fail parameters, and we agree that we want to support new approaches as well.

We just expect more in the way of pilots and things like that for those approaches. Second, I think we have to recognize that we have issued what I believe is the best possible regulation in the NPRM with regards to transitions of care, functional information. But it is not a standard in the specific details; it is not a standard for which there has been any implementation experience. It wasn't even balloted until January. So the need for us to be agile and supporting it going forward is critical and I want to doubly emphasize that I am not suggesting we don't use it, I have faith in it because of the continuity with prior versions. The fact that most of the people who have implemented the prior versions will either help development or will easily adopt to it, but I do think that we have to recognize that in order to meet the requirements to raise the bar on meaningful use, we've had to get ahead of what would be the ideal path for functional standards.

John Halamka, MD, MS – Harvard Medical School

In fact, Doug Fridsma was suggesting that ONC's funding has actually reduced what would be a 36-month project to a 9-month project, and so when you accelerate to that speed, yes, you do have issues with industry testing and implementability. Well, Jodi has said her comment is actually not directly related, so let's get to the other folks who had their cards up first. So Chris and Jamie.

Christopher Chute – Mayo Foundation for Medical Education and Research

Thank you, Chris Chute. Extraordinary as always, Dixie, thank you. However, I was puzzled by your controversy on the issue of optionality. That is in and of itself, of course, a controversial topic, in my experience comes in three flavors. Basically, things that are rendered as an alternative to another fashion.

Things that are generally too hard to do, so you say, well, okay, you don't really have to do it. And things that are kind of interesting but not really necessary or needed. Now, that first and third case I think are pretty straightforward. I submit that we don't need to include them in most standards if they are either not needed or an alternative, which of course goes the ox of interoperability. It's that middle case that's the bother, things that are too hard. And while it's perhaps an elegant finesse to say, well, you don't really have to do it. As poor Cris Ross is going to discover to his horror very shortly, as CIO of a large multidisciplinary health care organization that receives referral input referral from sundry organizations in an unpredictable way, places like Mayo Clinic will have to deal with that middle case, and it's requiring these things that are generally regarded as too hard so you don't have to do it as the sender; it puts an unbelievable burden on the receiver who must, it is virtually required to handle these cases as they emerge. So I'm...I guess my primary view is that optionality is almost uniformly undesirable, and so I was curious where you would consider it to be good?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I'm sure David has a good example. I think you flashed your card up right away?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Well, I think, you know, not all optionality is equal. A standard that can expand and grow in a coordinated fashion has optionality, and that's a good thing. A standard where the optionality, if not agreed upon, causes it to fail is a bad thing. So I'm thinking about like, you know, something like SMIME attachments to a direct message. The fact that that's an open-ended space and can grow to allow for transmission of more sophisticated content as the industry is, you know, ready to leverage more sophisticated concept, that seems to be to be a good kind of optionality, albeit it does put a burden on a receiver that they may get content they can't handle. But I think you could deal with content that you can't handle in a reasonably flexible way without causing things to come grinding to a halt. So, I mean I agree in general that optionality should be minimized, but if you do incorporate it, it should be done in a way where it's part of the way the standard sees itself. It's an open-ended extensionable standard. That's not going to really help you very much. I mean, your point is well registered, but I don't think you can keep these things closed, particularly if they end up in regulation because of Wes' concern about the long cycle. There just has to be a way for them to grow.\

John Halamka, MD, MS – Harvard Medical School

Thank you. Jamie.

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

Thank you. Dixie, one of the characteristics of both the maturity and the adoptability criteria was implementation, independence and non-coordination among actors where things are rated higher if there is less coordination, or better if there is less coordination. So I wanted to ask if you could explain the rationale and the thinking behind why that's a good thing and then have a little discussion on that.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

We're really are thinking about interdependencies and the degree of operational impact coordinating with other implementations requires. So, you can have multiple players, and that's all fine and good, but if really the coordination among those multiple players bogs down operations and, may even cause you to take your system offline while you sync up with other nodes, that's the kind of interdependent coordination that we think is not a good thing.

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

So I don't think it's described...I don't think the criteria described sort of that flavor perhaps very precisely and so that's one thing.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay, that's good.

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

But also, I think we can all imagine use cases where that is an important concept and where that applies, but I think there are also use cases, particularly found in the concepts around health reform, delivery system reform, new models of integrated and coordinated care where in fact non-coordination is the opposite of non-coordination, right. So you want to improve the coordination and integration in fact among the actors. And so I would submit that this set of criteria is use-case specific and, therefore, it doesn't belong in the general criteria that in fact the independence and non-coordination applies to some use cases and specifically not to others. So it's not a characteristic of any, you know, published definition of interoperability or anything like that. So it's not about interoperability, in fact...but...so it...again, it can be very important for some use cases, but I think it's also potentially contrary to some of the goals of delivery system reform.

Arien Malec – RelayHealth Clinical Solutions

Can I just follow up to that, because I think I was the one who suggested this or at least contributed this criterion. And the intent was that if you can take two systems that have been developed independently without close coordination during the development process, close interoperability testing during the development process, and have a reasonable confidence that they will actually work together, that's a good measure of interoperability. That's not a measure of the business practice that you're creating with that system, so I may be creating a...if I take a specification for coordination in insurance or a coordination in something completely different like CRM, I may create highly coordinated business processes, but the intent is that I can take one implementation from over here, another implementation from over here without developing them in coordination, I've got reasonable confidence that they'll work.

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

Right. I can understand, you know and certainly, there are many use cases where that applies and where that's a good thing. But I would also point out that, there are a number of widely accepted industry definitions of interoperability, none of which mention this concept. And so...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

It's a different concept. It's really an operational interdependence that is a barrier...serves as a barrier to interoperability because your operations are interrupted in order to achieve the communication between two, intercommunication. It's an interdependency that is disruptive. And we obviously didn't capture that. So I would certainly ask you to give us some words to capture that, but that's what we really intended.

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

And I think that could be a very good thing, I would just point out that I think that's use-case specific.

Cris Ross – Surescripts – Executive Vice President & General Manager, Clinical Interoperability

Can I ask a follow-up question of you Jamie on this? This is pretty compelling and I think it's behind a lot of things that we are trying to do. This is intended to explore, not put you on the spot. Can you give an example of a use case where it wouldn't apply? And in that instance, is the criteria irrelevant or is it actually somehow erosive or blocked, something you'd want....because I'm struggling to come up with a contra-use case.

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

I think that integration of decision support components across organizations absolutely requires a higher level of operational and organizational coordination that's definitely not independent. So, I mean, I think that there may be cases in terms of device interoperability requirements such as FDA-regulated devices.

So I think there may be a number of use cases where operational coordination is in fact mandatory so it doesn't apply.

Cris Ross – Surescripts – Executive Vice President & General Manager, Clinical Interoperability

That's helpful. Thank you very much.

John Halamka, MD, MS – Harvard Medical School

I see there are many cards going up, but I know Jim Walker has a burning response. Go ahead.

James Walker – Geisinger Health System – Chief Information Officer

Beware burning responses. I guess, Jamie, I'm not clear, I mean I read this as saying that you don't have to have your technical people on the phone every day to keep the damn thing running, not that it somehow limits your ability to coordinate various levels of cooperation, whether it's at a business process level or at a technical device level. And I think, first of all, Dixie, thank you, I think this is brilliant the way your team has done operational definitions that even someone like me can read and have a relatively clear idea of what it means and how you would rate potential guidelines. But maybe one theme here is that this is about limiting what people can require of the industry more than it's about create...it's to protect the industry from burdens, not to add burdens. And I think...it seems to me that it does read that way. Maybe there are a couple of places that you could add the word required so that it's even more clear. But

Anyway...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah good. Good point, thank you very much.

John Halamka, MD, MS – Harvard Medical School

Now Jodi, it is your turn. And Floyd, you had your card up, are you still in queue?

Floyd Eisenberg, MD, MPH, FACP – National Quality Forum – Senior Vice President of Health Information Technology

For sure.

John Halamka, MD, MS – Harvard Medical School

Okay, so Jodi then Floyd.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

So first Dixie, I just want to say this is incredibly helpful as somebody who has to think about policy and our standard regulations to have a framework for having those conversations and thinking through what standards are ready for...or are appropriate to be putting or considering for regulation. I mean, this is incredibly helpful and I was involved in early discussions with Doug and his team at the kind of rudimentary level, and having some of this meat on the bones really helps. So I jumped to how we would think about...if you actually apply this criteria and think about the standards and look at this model for evaluating them, I think about, well, what do we do with that? So one of the factors I wonder if you considered, and would just be interested in your thoughts and input on is, the presence or absence of other potential standards in this space. So it if there are for instance are two standards that are at a maturity level or one is mature but another one is almost mature, maybe not pilot phase but close to the upper right-hand quadrant. Is that a factor to consider in whether or not a standard is...should be a national standard or the thought about having more than one national standard on a particular...for a particular capability or vocabulary or transport or whatever? So I just want to hear thoughts on the interaction of multiple standards and how that might play out in this thinking.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

That's a really good comment. Actually, we had...the kind of process that had been described to us was that ONC would select the standard...remember our early work last summer, we identified need as one of the criteria? And ONC said, well, we would determine...ONC, we, ONC, would determine need and the process envisioned would be ONC would come to this team very much like what's described in the RFI and say, we'd like you to evaluate this standard for us, it's readiness to become a national standard. So comment one is that the criteria and metrics that we have identified to date, to my knowledge...and I know them pretty well...I don't think there's any question in there that says availability of alternatives, although that was something we considered last summer, but I don't think it's in our current attributes or I don't think it's in our current metrics and I think we should consider adding that. The other thing is that we didn't consider, because we assumed this use case where ONC gives us a standard and says evaluate it and put a dot on there where it falls. We didn't consider really the case where ONC says, here's two standards, look at them and recommend which one we should go with. And that may be something we take on in our discussion of the process. but those would be my two responses to your question.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

I guess just to follow up, even if we came with one, if there was, you know, the fact that there is another standard or an alternate or a competing standard, I'm just wondering if that would weigh into your thinking on whether or not something is a national...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah...I don't

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

It just seemed like a criteria, and I'm just putting it back on you all to think about whether or not that's something to put on the list.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Absolutely. Thank you very much.

John Halamka, MD, MS – Harvard Medical School

Floyd.

Floyd Eisenberg, MD, MPH, FACP – National Quality Forum – Senior Vice President of Health Information Technology

So Dixie, I wanted to complement you and the team because I think this is...even if qualitative, especially if qualitative, I think it's a good metric for...set of metrics for those working on the standards to work towards. There's nothing that improves care better than knowing how you are going to be evaluated and help to work towards that end. I do think that it would be helpful, as came up in the discussion, to have a method to determine at what point maintenance of that decision or reevaluation needs to occur. And I'm not quite sure how to determine that at this point. And the other is some criteria for if certain issues are identified as this is really important, but using the example of a proprietary nature makes it really problematic, how would you assess prioritization to go back to ONC to say this is something that needs to be addressed quickly? But I think it's a terrific start and congratulations.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Thank you.

John Halamka, MD, MS – Harvard Medical School

Arien, did you have your card up still?

Arien Malec – RelayHealth Clinical Solutions

I did, yes. I just wanted to give, I wanted to respond to Chris Chute and give some examples of salutary optionability, because they do exist. In HTTP, for example there's an E-tag spec that allows you to tag entities and improve the cachability of resources. You can get the core specification working just fine without it. You get enhanced functionality when you...when both sides understand the E-tags and the associated work around it, but it's not required to make the core specification work. So that would be an example where there is extra benefit if both sides understand it, but no detriment to interoperability if one side or the other doesn't understand. So that's an example where optionality gives layered implementation with additional functionality. The negative example would be one like an HL7V2 content spec where something may be optional, but if it's included and it's important for clinical interpretation, there's a legal risk if it's not understood. And that's an example where optionality absolutely kills you.

In the direct specification, we tried to finesse an issue where we wanted direct to work for an ordinary SMIME e-mail client, so we included certificate of discovery, which is not an ordinary activity for those clients as an optional component, but it turns out that that's incredibly confusing. So that's an example where we're trying to get layered optionality but ended up impeding operability. So, there are examples of layered operability where optionality helps you and examples where optionality absolutely kills you.

Floyd Eisenberg, MD, MPH, FACP – National Quality Forum – Senior Vice President of Health Information Technology

Thank you.

John Halamka, MD, MS – Harvard Medical School

And Dave McCallie, did you have the card...ah, Wes, you're on my edge here, so we'll go Wes and then Jim.

Wes Rishel – Gartner, Incorporated

So, it's good that you got to me, because I was having trouble breathing about optionality. I started the effort to bring version 3 to HL7 with the catch phrase; optionality is a four-letter word. And I found...fortunately, I was able to sort of quietly get out of having to enforce that view. Optionality probably arises most through a failure of the standards committee to deal with all of the use cases they're trying to address. So, they recognize that some people absolutely need this data element; other people don't even have this data element. Rather than create two standards, they say, well, it's optional. That was the big problem with lab in the 2011 edition of certification standards. Optionality was put in to address two different use cases, the one for public health and the one for just reporting lab results. I am happy to say that the S&I framework fixed that in 2014; they parsed out the two cases and worked on it.

In general, we work in an environment, and even Mayo, works in an environment where their participating partners have systems of varying degrees of specification. And they have to make a business decision, not a technical decision, a business decision when they want to allow for that. So, for example, I actually don't know what is going on with synoptic reporting, all I really know is it's an attempt to do structured path reports. But let's suppose it's going well. Mayo in having a very large referral base could benefit by saying, well, we won't accept path reports unless they have synoptic reporting. And they would be able to drive more decision on the intake of these referred patients; it would be a wonderful thing. However, they would also get fewer path reports. And the business decision I suspect Mayo would make is, we would love to get synoptic reporting, but if we don't we're going to have a physician sit down and look at that path report and decide what needs to go into the system. When there is optionality...so synoptic reporting would be optional, okay? When there is a true option, there is an implied business process for the receiver, it's not free, there's an implied business process for the receiver.

Now, I very much like the 2014 edition transition of care approach, which says you must send certain data elements in the CCD format. And you've got some optionality in terms of which documents, specific document you use, according to where you are using it. And you must be able to receive certain data elements out of a CCD document without regard to which document format it is, because that's the point about CCD, it's the same in all of the different document formats. So what that has done, it has set a minimal standard for interoperability and said...and put that in the framework of a standard where two people who want to be interoperable or two organizations that want to be interoperable on more data can agree to, and if a third organization comes in later and wants to be, they should be using the same format because the standard has more capability for interoperability than required. And I think we need to recognize that good interoperability is where there is a good business decision to support... I'm sorry, good optionality is where there is a business decision to support multiple processes on input, because it is a burden on the receiver to have optionality. Jamie talked a lot about industry definitions of interoperability. I'd actually like to see some of those because the ones I've seen all say the ability of two systems to exchange data with enough specificity to support the purpose of the exchange, that is, they're kind of self-defining in terms of interoperability. And I know that a lot of money has been spent on some of those definitions, so, if there are better definitions out there, I'd like to see them.

John Halamka, MD, MS – Harvard Medical School

Jim, is in your card with yet another comment?

James Walker – Geisinger Health System – Chief Information Officer

No, this is a question.

John Halamka, MD, MS – Harvard Medical School

Okay.

James Walker – Geisinger Health System – Chief Information Officer

Since we've had this discussion, what, 18 times in our history, it just occurred to me to wonder is there a science or a technical discipline that studies the pros and cons of optionality and technical standards in different contexts? If there were, it would be very helpful to us because as one of my professors of medicine once said, I'm not sure we have discussed a fact in the last 15 minutes.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Building on that, there is no right answer, there's just an answer we can agree on and implement. And I think that we squirrel around trying to find the right answer when if we start with non-optionality, the market will drive new options that meet new market needs. And so I would encourage us not to be fearful of setting a bar.

John Halamka, MD, MS – Harvard Medical School

Well, Walter, last comment, then I'll summarize and then we'll move on to Dixie's next presentation.

Walter Suarez, MD, MPH – Kaiser Permanente

Thank you. This is Walter Suarez. Great work, Dixie, as always. A couple of quick questions or comments, one is, in the criteria I felt like the source of the standard wasn't necessarily very clearly defining terms of the expectations. In other words, one thing to evaluate the standard itself, another thing is to look at what is the source of that standard, what organization is. And there are some notations about the breadth of adoption in which, you know, two to five organizations support this or the authorship or author. But it seems to me that there is some more specific criteria that can be used to evaluate the author or the source of the standard. For example, is it an ISO standard? Is it an ANSI accredited standard? There's some criteria that can provide nor validity and certainly support, ANSI standards are supported by thousands of organizations. So I would suggest looking to that area specifically, you know the source of the standard and ask perhaps, some criteria about that.

The second comment is about the practical applicability of the model and the timeliness of the model. So, I was trying to think, we've gone through a couple of iterations at least of adoption of standards. One is meaningful use Stage 1; the other is going to be Stage 2. So in your view, how do you see this playing into the next wave, if you will, of standards selection and adoption? In other words, right now we have the S&I framework working on initiatives in which there's a lot of discussion about the specific standards to be adopted and recommended. Are they expected to incorporate this criteria? Have they incorporated some of it, I assume they have because we have been monitoring and working on that. But is this model going to be moving to that sort of S&I framework process? Where and when and how this model will be actually implemented.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I think that's a question for Doug.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Let me just pile on with regard to Dixie and the work she's done here. I think it's really tremendous. I think part of the value of this is that we begin to have some objective criteria of what success looks like, and it helps us define in some sense where we need to focus our energies to be able to get to the place where we have standards that are suitable for adoption. So if we have something that is...that appears to be scalable, it appears to be stable, it's built on existing technology but there's not a lot of adoption, not a lot of use out there, but looks like it has a lot of potential, then we don't need an S&I framework activity to necessarily to move that to the next stage. What we need is we need to support implementation and pilots and getting it out there so people are using it. If, however, we find that there are things that are out there that are being used, but don't...either they represent multiple alternatives, there's inconsistency in the approach that people are solving the problem, then that helps us say this appears to have...people are solving this problem in lots of different ways, but it's pretty close and maybe an S&I framework activity to work on issues around optionality or what's required or the minimal sets can help drive things forward.

So I think certainly this is something that will help guide where we'd want to go with some of those initiatives. I think it will help us determine what a successful initiative is. It will help us determine where to put our resources with regard to implementation or standardization or engagement with the SDOs. But I also think it will provide us some consistency with the HIT Standards Committee to say, we've got a lot of different standards out there, people have specific interests. If we have an explicit criteria that we all sort of agree that this makes sense, I think it produces a tremendous amount of credibility among the decision-making process to say we've got these criteria; this is how we score it. There may be some variation, but in general, this is sort of the next stage, is it's ready for adoption, it needs more implementation, we have to do some more work in the SDOs. So, I think there are a lot of places where we can use this. But I certainly will feed into some of the activities that I would expect to see in the S&I framework.

John Halamka, MD, MS – Harvard Medical School

Great. Well, to summarize all of these comments, and you know sometimes I'm always surprised by, the nature of how an issue gets digested by this committee. And so these were very, very helpful, is that Dixie has presented to us a framework. I think what can be said about health care in general and certainly, standards work and Jamie said this area and said this is that...and Leslie said it, it's not black and white always. Optionality, although sometimes evil, it sometimes can be okay. Intellectual property murkiness can be bad or it can be helpful. We just simply need a framework by which we grade the current state of the standards and implementation guides, and then in context evaluate those and it will basically provide us guidance as we go forward and deliberate. And I think we've all said this multiple times, just because something has optionality or doesn't have optionality, doesn't mean that it's going to be ideal for a particular purpose, depends on the context. Jamie highlighted issues where it's absolutely essential that organizations get together and tightly coordinate. But in some cases, like the direct project, maybe it's better they don't, right, it's content-specific.

So what I would hope is that Dixie, in the spirit of testing your own work, that the next step as you outlined is to take this framework, amended by some of the comments that were made today, and use the RESTful exchange example, the MITRE activity that I think is coming up, and see how it scores. And then we can look together as to how this framework is helpful to our future deliberations based on some examples of actually applying it. Does that seem like a reasonable next step?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

So, I want to make...are you asking us to use the RESTful specification as our test case instead of the info button?

John Halamka, MD, MS – Harvard Medical School

One or the other, I mean, some set of test cases. My sense was that you were going to do it on the RESTful...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

No, no, as I said we're going to do it on the info button because it's smaller and...

John Halamka, MD, MS – Harvard Medical School

Okay.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

...and more mature. However, I have asked MITRE to when they present the RESTful exchange to us, to do it...to gear their presentation around the attributes that we have identified, so that they can also give us some feedback on the attributes and metrics that we have identified. So...

John Halamka, MD, MS – Harvard Medical School

Great.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

...that particular specification is still in development and it's going to be far more complex than something that can be done quickly, so, we picked something smaller and more digestible for the test case.

John Halamka, MD, MS – Harvard Medical School

Right. So if you come back to us with comments on how your framework in a testing scenario, in this case the info button, has worked or not and how you would refine it further, then it can be a guideline for us going forward. But I think all good comments today to help refine our thinking on this topic.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes, thank you all, we really appreciate it.

John Halamka, MD, MS – Harvard Medical School

Well next, it's more Dixie. And you will talk to us about the hearing on trusted ID for providers in Cyberspace.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Now, do I advance...ah, here we go. Now I'm glad I get to present a much less controversial topic here.

John Halamka, MD, MS – Harvard Medical School

Biometrics for everyone.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Right. Last week there was a public hearing held here in Washington on the topic of trusted identity of providers in cyberspace, and I've been asked to give you kind of a synopsis of that public hearing, as well as some observations from that hearing. I want to say that the observations that I'll be presenting are the collective observations of those of us from this committee who were at that hearing and, they don't really reflect a consensus view of here's what we got out of the hearing, but rather our observations from having attended the hearing. And those from this committee who attended the hearing are Wes and David and Walter and myself. So thank you all three of you for your help in putting this together.

So the hearing was Wednesday of last week and it was co-hosted by the chairs of the Policy Committee's Privacy and Security Tiger Team, Deven McGraw, and myself as the chair of the Privacy and Security Workgroup of this committee. And the focus was on identity proofing and identity authentication for remote access or cross-organizational exchanges. And I want just to establish, to make...a common understanding of what I am talking about here. Identity proofing is the provision of proof of an identity that an individual or organization provides when they register for an account or they ask for a digital certificate; this is when they first get an identifier basically. Identity authentication is kind of in the usage space, it's not like an upfront process. Identity proofing is an upfront process. Authentication is when you actually want to do something or access something, you're required to provide an identity and then provide proof that the identity that you provided is indeed you. That's the process of authentication.

It is important to keep authentication separated from authorization, even though it's not always easy and we discovered that in it this hearing. But authorization is the process of once you have identified somebody and you said, yeah, I'm going to give them an account or I'm going to give them a digital certificate, it's deciding what they can do with that identity. So that part, that authorization to do things with the authenticated identity, is outside the scope of this hearing. Also outside the scope of this hearing is consumer identity. And it was openly acknowledged that this is really, really an important topic, but this particular hearing focused on provider identity proofing and provider authentication and the interoperability of identity proofing and authentication across organizations.

The hearing began with a number of comments from Farzad, so I want to give you kind of a summary of his remarks. Apparently, there was an initial hearing held by the policy committee some time ago and he pointed...on this same topic, identity of providers. And he noted that there were really two important policy developments that have occurred since that time, and that those policy changes or developments are really what stimulated the development of market-based identity solutions, which we certainly heard confirmed in the hearing, and also stimulated them calling for this second hearing. And those two developments are, first is the emergence of the national strategy for trusted identity in cyberspace, which is called NSTIC. NSTIC, the NSTIC document was released by the White House in April of 2011 and it's based on four principles; privacy-enhancing, that the NSTIC will be privacy enhancing and voluntary.

It'll be secure and resilient, it'll be interoperable and it'll be cost effective and easy to use, and I'll go into a little more detail about the NSTIC in later slide, but these are in Farzad's comments.

The second development is an update to the NIST special publication 800-63, which is electronic authentication guideline. You've heard the privacy security work group refer to 800-63 a number of times in terms of authentication standards. But it was...that document that was updated in December of last year, and that document identifies a number of minimal technical requirements for remotely authenticating the identity of users and provides guidance for each of four levels of assurance of identity.

Farzad said the status quo is not good enough and that we should be aiming to develop policy that allows for a high level of assurance for the trusted identity of providers without stifling innovative technology solutions. And keep in mind that technically, while this was hosted by both chairs, it really was focused on really getting input into policy primarily, and secondarily standards.

Farzad believes that the level of assurance or LOA 3 as identified and defined in 800-63 is a reasonable standard for identity proofing and authenticating provides. It requires the verification of the identity to receive the credential and multifactor authentication for remote access. And in this next slide, I go into a little more depth of what LOA 3 in NIST 800-63 actually requires. Unfortunately, at the hearing we didn't have this slide, so although we talked around LOA 3 throughout the hearing, there was never a single slide that says here is what LOA 3 is. So I want to make sure you get that, that this is what it really is. It requires the use of at least two factors for remote-access authentication. And as far as identity proofing, which I would remind you this is when you present yourself for registration for an account or a digital certificate and you want to prove who you are, that's called identity proofing. And LOA 3 requires verifying of the...verification of the identifying materials, including a government-issued picture ID.

Now, for authentication, which once again this is providing proof that the identity that you present is indeed you, when you want to access a system or exchange information or whatever, it requires...LOA 3 requires that you have at least two factors. Typically, a key encrypted under a password. But one of the primary differences between LOA 3 and 4 is that LOA 3 allows you to implement this capability in software and LOA 4 requires that you implement it in hardware. So, some of you may be familiar with the Department of Defense CAT card or the VA's PIV card, where the identity's actually captured on a hard card and that card, all of the authentication of the identity is done with that card and not on software in the system, and that's an LOA 4 kind of level; 3 you can do it in software.

Okay. There were four panels and I've listed the participants in each of the panels. Two of the panels were government participants; two were from the private sector. The first panel was focused on understanding the value of trusted identity of providers, and I have the participants listed there. There were...this one was from...we had one person from ONC and the others were from private organizations. The second panel was trusted identity, a changing ecosystem, and all of these were government participants. Jeremy Grant is the senior advisor, I think is his...yeah, senior executive advisor is his official title, but he is kind of leading the whole NSTIC initiative for the federal government. Really, a very good presenter, and he talked all about the NSTIC and laid that fundamental foundation about that initiative. Tim Polk is from NIST, and he's one of the primary authors of 800-63 version 1, and he gave a very good presentation about how they came up with that...with the changes. So and then the third presenter was from GSA.

Panel three was about trusted identity solutions in the private sector, and what happened to my...did I turn it off? Ah, there we go. We had six people from...or five people actually from private industry.

Scott Howington, who is with SAFE BioPharma, the last person I have listed there, provided written testimony, but he wasn't able to participate, but we had a participant from Verizon, from Equifax, from Surescripts, and from DrFirst and OneID, and their names are listed in your slides there. The final panel was trusted identity solutions in the federal government and we had Tony Trenkle from CMS, we had a speaker from...Cynthia Bias from DOD and VA, the iEHR Initiative and then finally we had invited a representative from DEA, but it's really unfortunate that DEA was not able to participate in this hearing.

It's especially unfortunate because it would have been useful to hear DEA's thinking around their new requirement for two-factor authentication for the e-Prescribing of controlled substances. You know, that's a really important requirement or...yeah, requirement that really is driving the need for two factor capability...to support two factor in authentication in EHRs.

Okay. Now let me go into the key points and observations. Through the testimony, we learned that there is no established or de facto standard for either identity proofing or authenticating providers in the health care industry. The current state of practice is passwords, which is LOA 2, not LOA 3, although passwords can be one of the two factors in LOA 3. But LOA 3 requires two factors. Jeremy Grant pointed out that five of the six vectors of attack in 2011 breaches were tied to passwords, so he was pointing out some of the vulnerabilities in passwords, and he pointed out that the health sector is the number one...was the number one target for breaches in 2011. The second point, observation we wanted to make is that the focus for identity assurance in health care seems to be starting to shift from an entity organizational level to the individual level, and most of the testimony presented focused on the latter, on individual identity authentication and individual identity proofing. Now, I can tell you that I'm not sure myself whether that is a function of who was invited to speak or whether that's a function of what's really happening in industry, but based on what we heard, you know, there was a strong shift in...beginning of a shift in focus to individual-level authentication and not organization-level authentication.

But I would point out that neither exchange nor direct requires identity assurance at LOA 3, two-factor authentication, and, so far as we know there is no requirement for individual level identity in either of those as well. And no recommendation...the Privacy and Security Workgroup did not make a recommendation for LOA 3 in our recommendations for stage 2 of meaningful use. And the main reason we did not, we actually had discussions around this very topic and especially given the DEA requirement, we know that EHRs are going to have to support two-factor authentication for prescribing controlled substances. But, we decided not to make that recommendation simply because the DEA is still developing their policy around two-factor authentication, so we didn't want to take the risk of going off in a direction that might be incompatible with what DEA ultimately comes up with.

The NIST 63...800-63, LOA 3 authentication does seem to be feasible and it seems to be consistent with the direction the industry is heading and the direction that product is heading, both within and outside government. Both the public and private sector seem to be heading towards LOA 3 authentication for, for highly risky...high-risk kinds of authentication situations. They also pointed out that mobile technologies had emerged as a key platform for LOA 3 two-factor solutions, so mobile technology's really helping us get to LOA 3 more quickly. The need for a high level of assured identity extends to every other health care provider, not only providers but nurses and pharmacists and dentists, all health care providers across the industry and even to the administrative staff that support those providers. It's really not a doctor authentication; it really is authentication of the entire care team.

And it's also important to assure that the policies and approaches used within an organization for assuring the identity of individuals who access health information within an organization are compatible with this need for high-level assurance of identity for exchanges between organizations or with external organizations. In many cases, the task of...in most cases the task of identity proofing individuals within a health care organization is going to be the responsibility of that organization. So it's important that their policies and processes used to identity proof within the organization are consistent and compatible with their policies for identity proofing individuals who will be authorized to exchange information between that organization and other organizations.

As I mentioned, both the government and private industry seem to be embracing the federal identity credential and access management or FICAM trust framework and NIST SP800-63. The FICAM, which we have discussed in this committee before, in fact, we made a recommendation for stage 2 meaningful use that digital certificates should be compatible with the FICAM framework. The FICAM framework calls for the secure, interoperable and privacy enhancing process by which federal agencies and the private sector can leverage commercially issued certificates, digital identities and credentials, and the federal government is leading this initiative, obviously. So far, four non-federal organizations, so organizations from private industry organizations, have been approved to be trust framework providers under FICAM. And then these trust framework providers, these TFPs, can then assess and accredit commercial identity providers who conform to the government profiles. And the four who have been approved so far by the government are Kantara, SAFE BioPharma, InCommon, and Open Identity Exchange. A gain, these are private sector organizations that have been approved to issue digital certificates and do identity proofing for federal identities.

CMS has reported in the hearing that they have identified risks that warrant LOA 3 assurances and that they plan to use FICAM certified credential providers to meet this need. They did point out that the policy and mechanisms to support that are still in development, but that's the direction they're heading. The support and momentum for the NSTIC initiative is definitely building. We expect that the NSTIC will emerge as the common basis for identity management for both the public and private sectors. But I do want to emphasize that there's no...you can't go out today and buy an NSTIC identifier or an NSTIC digital certificate. It's an initiative that's based around a number of fundamental principles but it's still in development. The NSTIC calls for an identity ecosystem, which is, they define as an online environment where individuals and organizations will be able to trust each other because they followed agreed-upon standards to obtain and authenticate their digital identities. And I also want to emphasize again that we're not talking about authorization, what people can do, we're talking about authentication of your identity. There is an emphasis on authenticating identity without disclosing private information and I think that this emphasis and this fundamental principle of NSTIC will be appreciated by both the health care industry and consumers alike. And I have a slide here that sets forth their privacy principles, and they're pretty...they're interesting.

It's not clear...there were a number of questions during the hearing about cost, and it's not clear what an NSTIC credentials will cost because the business models are still emerging. But it did seem that the cost...it was clear that the cost of digital certificates are going down dramatically and have been. The commercial marketplace around NSTIC is developing solutions based on these principles and 800-63.

The Dr First, OneID, Verizon authentication solutions that were presented during the hearing all meet LOA 3 requirements and are consistent with these NSTIC principles. But it is important that there's no such thing as NSTIC compliance at this point or compliance mechanisms or NSTIC certification process because they just don't yet exist. It's an initiative, not something that you can go out and get tomorrow.

So the NSTIC privacy and civil liberties principles, these were presented at the hearing. There's an emphasis not only on the authentication of identity, but authentication of identity while preserving privacy. There is a requirement to minimize the sharing of unnecessary information and share only the need to know attributes. An example that was given was that an NSTIC identity would be able to say that, yes; this person is over 21 without disclosing the person's birthday, birth date. There should be minimal...minimum standards for organizations such as adherence to the fair information practice principles, or what we commonly refer to as the FIPs. The NSTIC identity should be voluntary and private sector-led. The individual should be able to choose to have an NSTIC identity or not have an NSTIC identity. And individuals who participate should be able to choose from public or private sector identity providers, as long as those providers were ultimately certified as NSTIC conformant. And then it's important that there would be no central database of identities of everybody who has an NSTIC identity. And finally, an important principle is that the NSTIC identity should preserve anonymity. So, you should be able to prove who you are and then go about doing things anonymously. That's an important principle, especially in interactions on the web, because there are lots of interactions and participation that people want to do, but they want to do anonymously.

So the summary observations is the momentum is building toward a highly assured identity for the health care industry, with several critical forces are coming together here. First is there is, I think all of us recognize, there is an increasing vulnerabilities and workflow impact associated with the use of the passwords. Once you have 20 passwords, you're almost forced to write them down, which of course is a bad thing, and to reuse them, which is another bad thing, or to use the same one 20 times, which is another bad thing. So...and people on street are becoming increasingly aware of those vulnerabilities. There is a rapidly dropping in cost of digital certificates, so it used to be to get a digital certificate it would cost two and three digit pricing, depending on the type of certificate you were acquiring, and that was just five years ago, and now you can get doubling tall certificates for a dollar, and in some cases free.

So there's...as a result, there is broader adoption in all sectors.

DEA has announced that it will require high, LOA 3 or higher, authentication for all prescribers of controlled substances. And the VA is using high, greater than LOA 3 authentication with all of their internal providers, and it's looking how to expand this requirement to external providers. And then finally, Tony Trenkle announced that CMS plans to move as early as you next year, to requiring all of its contracted providers to use high LOA identity proofing and authentication when conducting business with Medicare. But again I return to the current HIE state of process...state of practice still relies on passwords. We had a discussion about this in the Tiger Team earlier this week, and it's very clear that the current state of practice is very clearly passwords. So, this is not going to change overnight, there needs to be a road map for progressing towards LOA 3 and not a sudden requirement for LOA 3. I would also stress that when we...the total discussion throughout this hearing was about exchanges between organizations, none of the discussion was about authentication within organizations. And we'd like to know your feedback on what you think about an LOA 3 requirement for authenticating individuals and entities for exchange between organizations or remote access.

John Halamka, MD, MS – Harvard Medical School

Great. Well thank you Dixie for another fine presentation. So, just a couple of quick questions about LOA 3 and its definition. So, one of the things, I was always concerned about workflow, and so whenever we implement things like soft tokens or hardware tokens or biometrics in the context of existing applications, sometimes it creates a challenging workflow; token's not synchronized, token is lost. So, two questions I guess about what LOA 3 is and isn't. Suppose every time I write an e-Prescription for a narcotic, a one-time SMS password appears on my personal cell phone, and therefore it's not only something that I know, my user name and password, it's something that I have, a cell phone. Although SMS may not be the most secure mechanism of delivery, you know hey, the likelihood that a hacker can get a one-time password sent via SMS within a few minute interval when it expires is low, would such a schema using passwords on cell phones be considered LOA 3?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Using passwords and not any other authentication...

John Halamka, MD, MS – Harvard Medical School

So, one time...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

...two authenticators are required.

John Halamka, MD, MS – Harvard Medical School

So that is, I use the user name and password, and then I have a one-time five-digit code sent to my cell phone for that particular instance. Is that LOA 3?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes. And how many times you have to present it is...how long that authentication lasts is a function of the application you're accessing...

John Halamka, MD, MS – Harvard Medical School

Right...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

...right, so once you present it, I'm making up a use case here, right. So, you authenticate yourself to an application at the other end. It say, yes indeed, I've got your two validated identities. I've set up a secure channel with you and I'm going to keep that secure channel right there until the end of our session that the PLS will create, yes. Those two authenticators are LOA 3.

John Halamka, MD, MS – Harvard Medical School

And how about something like...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

...I should caveat that, I'm not sure what constraints on the password there are, I didn't memorize that.

John Halamka, MD, MS – Harvard Medical School

If I were just to ask another related question, suppose we have a technology like adaptive authentication. Now this one may not be LOA 3. Turns out Dixie mostly hangs out in California. Today, she shows up in China. We're not sure we trust Dixie in China and therefore what we do is we ask in addition to the user name and password, a set of pre-assigned questions to you or present you some other cognitive puzzle to solve that is something only you would know. Is that LOA 3?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

What are the authen...?

John Halamka, MD, MS – Harvard Medical School

And the reason I ask these questions is, does LOA 3 by necessity imply hardware token, software token or...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

No, it does not. No, it does not.

John Halamka, MD, MS – Harvard Medical School

...biometrics.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

It requires two authenticators, and it does allow for the risk of a man in the middle attack. So, it isn't an absolute, this is secure no matter what, kind of a thing. Well, neither is LOA 4, but it does acknowledge that there's a risk of man in the middle attack, like a fishing kind of a man in the middle, for example.

It requires two authenticators, and usually...well, the question could be the second authenticator.

John Halamka, MD, MS – Harvard Medical School

Okay. So, we have Arien, we have David and now we have Jim. So, Arien

Arien Malec – RelayHealth Clinical Solutions

Thank you.

John Halamka, MD, MS – Harvard Medical School

We have Chris Ross as well.

Arien Malec – RelayHealth Clinical Solutions

So, I love the idea of NSTIC, I see my wife and daughter struggle with passwords on multiple websites, and a common identity framework I think would be incredibly useful for the nation. I worry though that NSTIC's applicability to healthcare is as cut and dry as I think is presented here. There are some challenges I think in healthcare, that are very different from the challenges of high assurance authentication for, for example, a banking transaction. In particular, the need for proxy roles in healthcare. So if you take the NSTIC approach to the extreme, we're going to be requiring physicians to need to do every claims transaction, because we need to sign that claims transaction and only the physician can sign the claim. Well, now we're asking physicians to manage the entire claims process.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

But wait a minute, we're not talking about digital signatures at all, we're only talking about authentication of identity.

Arien Malec – RelayHealth Clinical Solutions

Sure, some of the use cases I've seen for though for NSTIC in a CMS case are things that are explicitly, in most workflow practices, administrative in nature. And where you need to account for proxy roles, you need to account for workflow practices, where NSTIC is heavily focused on the need to authenticate individuals and for a healthcare use case, I think needs to explicitly acknowledge the need for proxy workflows. In addition, there are many workflows in healthcare where the relationship is either explicitly business to business, for example, a practice to a hospital; or where the proxy role is not uniquely identifiable to a person. So for example, many physician practices, multispecialty physician practices, have a referral coordinator who manages the work of the referral, and there may be multiple who cover for each other. You can't assign...and in some cases, when you refer over to a cardiology practice, you're not referring over to a cardiologist, you're referring to the practice. The actual physician to whom you're referring will get late bound. So if you don't accommodate for proxy roles, you don't accommodate for business-to-business transactions, and you assume that everything can be resolved down to a person, you may find yourself, I think you will find yourself in cases where identity assurance and authentication don't work with the NSTIC approach for healthcare.

I also get worried about applying NIST standards. I think NIST standards are incredibly helpful in defining levels of identity assurance and levels of authentication. There are some specifics, at least the last time that I looked at the NIST definitions; there are some specifics that are hard-wired for a government focused identity assurance and authentication case, that again don't neatly translate to healthcare. And one of the great examples is, in an OR setting you may have an unlocked...the risk of requiring passwords with three second timeouts when you're documenting a surgical encounter are very high, and the risks of poor authentication and identity assurance when you're working as a surgical team, every one of whom has access to a scalpel and the patient's on the table, the risk of poor identity assurance and authentication is very low. So, if you strictly apply a NIST standard to a case where you don't have the applicability of those methods, you may end up forcing a square peg into a round hole.

And then the last thing that I want to make sure gets on the record is that in machine to machine transactions, in particular in areas for health information exchange where you may have a person authenticating on one end to a machine and then the machine authenticates to another machine and maybe there's another person on the other end, there are approaches for two factor authentication for the machine...for high assurance authentication for the machine to machine transactions, that don't neatly fit the standards for two-factor authentication for person authentication. So for example, we use heavily the combination of IP white list and digital certificate as our two factors. That's not exactly something you

have and something you know, but if it does the job in terms of risk mitigation for that machine-to-machine interaction. So again, just to summarize, love NSTIC, don't believe that NSTIC is neatly applicable to healthcare, needs to accommodate for proxy roles, needs to accommodate for business roles, needs to accommodate for organizational identity insurance. And when we look at a framework for identity assurance and authentication in healthcare, I think we also need to accommodate for machine-to-machine identity assurance and authentication.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay. I just want to make sure, so we don't get in a raffle here, that all of your comments were excellent comments. But this hearing was only about remote authentication and organization to organization exchanges, it was not about surgical rooms. It was not about anything within an organization. So I just want to make sure...and I know you were using that example to refer to the NIST guideline, I'm fully aware of that, but I want to make sure that everybody else is fully aware of that. Okay?

Cris Ross – Surescripts – Executive Vice President & General Manager, Clinical Interoperability

This is Cris Ross. So Dixie, this is great, thank you. I think Arien's comments in some ways...I don't think I'm going to repeat exactly what he said, but I think it's an issue that relates to identity...your comment on, I don't know, one of the pages about focus of identity assurance seems to be shifting from the entity organization level to the individual level. Just a couple of sort of comments/questions about that. It certainly makes sense in a bunch of use cases you would need to have individual level authentication, lots of logical ones and some specific ones like electronic prescribing of controlled substances. But I guess the question I've got for you and maybe this is also a Jodi Daniel question is HIPAA liability binds to the entity level, and not to the individual level, for example. And there's also places where organizations exchange with each other which is any clinician at this location that performs some function where a clinician may not be known at another entity, right, where there's the ability to have more of a generic capability to have inbox and outbox, for an entity to communicate with another entity.

I take your point, but what I worry a little bit about is that somehow will create the impression that there isn't a need of entity level authentication, or that there may not be a role for entities to be actively involved in managing the identity and credentials of individuals, and what their roles are within that entity. So I wonder if you can comment on that a little bit, because I understand it's easier to do identity management on an individual level, right, human being level. But it feels like...I'm concerned that we'll lose something important.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Again, we're not talking about within an organization. And by the way, HIPAA does make individuals accountable.

Cris Ross – Surescripts – Executive Vice President & General Manager, Clinical Interoperability

In addition to entities for sure.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Right, in addition to entities. We're talk...and I would say that the big question is there are two parts to this. One is the policy as to whether you are going to require organization-to-organization authentication, right. And the other is the capability, whether you are going to have the capability. And we're kind of getting the two a bit mixed up. But we are talking about organization to organization and as far as the HIPAA, Jodi, did you want to say anything more about what he said about HIPAA holds the entity accountable, especially entity to entity exchanges, HIPAA definitely is the organization...covered entity level, not human entity level, right.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

I mean, the HIPAA security rule is flexible and scalable and has lots of standards that entities have to comply with. But there are also requirements for limiting uses of information by individuals as well, so, they do need to have...they need to think about individual level authentication and authority for accessing data as well as for sharing information outside of their organization. So, I don't know, and Dixie is right there, an individual can be held accountable under HIPAA for certain actions, at least under the criminal statute. So I'm not sure I understand what the concern is.

Cris Ross – Surescripts – Executive Vice President & General Manager, Clinical Interoperability

So, I probably wasn't very clear at all given your response. I'm really not talking about within an organization at all. I'm really talking about entities that communicate with each other about patient care, where there may be more than one individual who is involved in that patient care in both of those entities; or where there's not a known specific physician or other clinician with whom that exchange is anticipated or required. So, I guess my point is I think there's just a sense that, oh, if we just get individual identity figured out, that solves the whole problem. And it feels to me as though we're missing a whole class of workflow and requirements. I don't think that was the intent of the comment and I was just trying to create an opportunity to say no, no, no, we still need entity level authentication and we still need a relationship between individual identity and entity identity, so you can do role-based things as an individual moves between entities and so on.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, it's...I think I know what you are talking about; you're really talking about more from an HIPAA perspective, the accounting for disclosures that is clearly at the covered entity level. And exchanges between organizes within HIPAA are covered entity to covered entity, they aren't person-to-person. So I think he has a good point.

John Halamka, MD, MS – Harvard Medical School

As both Arien and Cris have said, the identity management problem goes beyond the individual authentication issue, it's workflow, especially in healthcare information exchange, is multifactorial. Now, we're running about 30 minutes behind, and we do want to make sure Carol Bean and Jodi and Doug have appropriate time, so let's just do some lightening comments. Marc Overhage on the phone.

Marc Overhage – Siemens Healthcare

It's always a lightening from above, the voice from outside. Thank you, John. Just a quick question Dixie, about, and it somewhat follows along the lines of the last couple comments. But, you made the observation, and by the way, nice summary of the meeting and highlighted really good stuff for us; about the ability to authenticate and then anonymously take action. And I think one of the areas that's a good example of where we might have different requirements, at least for a part of our healthcare enterprise whether it's patients or providers, presumably we don't want any anonymous activity happening, even by authenticated individual. We're required, aren't we, to track who those people are or did I mishear something?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

No. The NSTIC identifier as envisioned would allow an organization to develop an application that allowed for anonymous actions to be taken and the NSTIC authenticator would work with it. However, within healthcare, we always want to know the identity person; the policy would require that the identity be known. I think you're getting into the NSTIC requirement for minimum necessary, you know, an application...for a particular use case, the minimum necessary might be the identity of the individual.

Marc Overhage – Siemens Healthcare

So I guess then only...I can't imagine very many healthcare use cases where you would allow anonymous activity, even for an authenticated individual. The related question that is critically important, I'm trying to be lightening here John, is probably even more important than knowing who the individual is in terms of controlling accesses, what their role is.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Right and we discussed that. That's really a function of the organization beyond the...it certainly is really important, but it's beyond the scope of this particular hearing, that gets into the authorization side.

And as we acknowledge, it's sometimes tough to keep the two separated. The example that was given at the hearing actually, was if you're a licensed physician, you might require that somebody be a licensed physician in order to get identifier to begin with. Well, you're already getting into the realm of authorization, just by requiring that they be licensed. So the two are...there's a gray area between the two, but in general, role is not an authentication function, it's an authorization function.

Marc Overhage – Siemens Healthcare

And it's also not one... (indiscernible)...because people may have multiple roles that they play and therefore the authorization will be different for those. And these are some of the tangles where, as others are alluding to, I think, that make it even if you can make this work in terms of identity proofing, you still aren't very far down the road and we have to solve these other things before we can say this is going to help us.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Well the way even operating systems work today is that authentication and authorization and access control are two separate things in the system. So, when you log on to an operating system or login to an application, that is one-step and it says, yes indeed, Dixie Baker has an account here. Now, step 2, what is she allowed to do? So those two are commonly kept two separate things. I mean, you might present in NSTIC to one hospital as a provider, or department director and in another hospital you might be a patient, but your identity is the same thing. It's up to them to say okay, there's Marc, that's him all right, but he's in room 42 and he's a patient. So that role is an assignment for the entity to assign, once they know who you are.

Marc Overhage – Siemens Healthcare

Thanks Dixie.

John Halamka, MD, MS – Harvard Medical School

So Dave, Jim, Wes, really quick.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David. I'm ashamed to say that I could talk about this for the rest of the day, which is not something I'm proud of. But there's an amazingly intricate interplay between technology and policy that literally you could spend the whole day and not even begin to get warmed up. But I just wanted to make a couple of high-level thoughts. First is, I suspect that in healthcare we need a specific definition of level of assurance for healthcare, an appropriate level of assurance. The NIST document is targeted, as Arien pointed out, for government use and it's a superb document, and the new version, the -1 version, is much improved over the earlier version, so, I actually think you ought to read it, it's really remarkably good. But, it's clearly not completely applicable to healthcare. So for example, one thing in healthcare that I think we all assume would happen is, that as a part of identity proofing, we would capture some assertions about the individual who's being proofed, that could then be carried forward in downstream assertions of identity. So, is this person, for example, a physician with a license? Those are things that could then help facilitate smart authorization decisions downstream, but really, they have to be built into the proofing process. And the current NIST document doesn't address those things at all.

Second is the distinction between level 3 assurance, which is a much broader thought, that two-factor authentication, which is what we often end up talking about. I think we want to decouple those. It may well be that we want to move in healthcare quickly to two-factor authentication without necessarily achieving full level 3 assurance of identity, because those are not the same thing, that's really John with respect to your questions. Third, the issue with NSTIC is the incompatibility of business models, not the incompatibility of standards. So, I'm a big fan of what NSTIC is trying to do, but I think in healthcare it'll take us a while to get there. For example, some of the providers of free identity want to pay for the service by charging the relying parties a fee every time the identity is asserted. Well, that might work fine in some models, but doubt if it'll scale well in healthcare, if every healthcare organization has to keep an account with every identity provider service and pay them a fee every time a doctor authenticates, depending on what kind of a fob he's carrying. That probably doesn't work in healthcare. I have some more here. Oh, third and final, I'll stop, is the group versus individual, we have to keep distinction in our mind between authenticating the individual into the system on the one hand, and healthcare interchange messaging between systems on the other. It may well be the case that some of our standards today don't carry the individual's cryptographic proof of identity, even though that individual has been thoroughly authenticated into the system for which the message originated. So, those are really separate issues that we have to keep straight. And given that there are virtual people in healthcare, like Arien's example of an inbox for a consult service; we may not ever be able to have a complete one to one mapping between the authenticating user and a message that is a legitimately authenticated message going across the network. And I'll stop there, but I could keep going.

John Halamka, MD, MS – Harvard Medical School

Jim?

James Walker – Geisinger Health System – Chief Information Officer

Quick question Dixie. I'm reading 3, 4 and 5 on the slide as saying at least level 3. Is that accurate?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

James Walker – Geisinger Health System – Chief Information Officer

Okay, thanks. And then quick observation. I'm guessing there may be places where anonymity is useful in healthcare, at least in operations. You could imagine it would be spectacular to be able to send a questionnaire and say how is that thing we just implemented working, and know you sent it to all your nurses that it was only nurses who responded, but you had no idea knowing which person was associated with a specific response.

John Halamka, MD, MS – Harvard Medical School

And Wes.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And reporting in safety issues within a hospital is another example. Good.

Wes Rishel – Gartner, Incorporated

Trying to be lightning fast. We don't know what the ask is, I mean, all the time in my work I take phone calls from clients and I'm always asking what the ask is. And I usually don't know the ask until I know what are you going to do with what I tell you? They'll ask a question, but until I find out what they're going to do with it, I don't know. So, I don't know what the ask is here. I think that...I have heard that technology for proofing the identity of people to a level of assurance of 3 is growing, technology...the technology of authenticating a previously proofed person is growing. I think that we haven't talked about when it is that you exchange a proofed identity, rather than trust the organization to be able to find the proofed authority. We haven't answered the question of whether we are changing the principle of commutative assurance of identity that has been the basics of how HIEs are working, and until we know those about the asks, it's hard to evaluate the answer. Thanks.

John Halamka, MD, MS – Harvard Medical School

So Dixie, I would presume that today's report was simply your observations on the hearing that was held, it was not specifically meant to inform policy or technology, NPRMs that you are writing or considering.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Right.

John Halamka, MD, MS – Harvard Medical School

So, this is informational, and I think we...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And we will report these comments back to the policy committee, which is really, it was really their hearing and I think it's important that they hear these comments.

John Halamka, MD, MS – Harvard Medical School

Great. Well thanks so much Dixie for both reports and I think what we have from this whole group is a lot of valuable input and just shows the complexity of all the problems we're trying to solve. But you've brought us some tool kits, which are helpful along that path. Now I know Jodi Daniel needs to run, at some point, and Carol Bean...

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

...is back.

John Halamka, MD, MS – Harvard Medical School

Is back, okay, so can Carol go first or do you need to go first or do you need to go first or do you need to go first?

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

I think that's fine...

John Halamka, MD, MS – Harvard Medical School

So can Carol, please come up and tell us about the permanent certification program, and it's timing and criteria for testing, and all of those good things.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

I'll tell you what I can. Thank you for the opportunity to come here. Mary Jo caught me last week and said it's a while since this group has heard from you about the certification program, how about it. I said, sure, we've got lots to talk about. So, I will try briefly and mindful of the time, to cover four basic areas;

some program milestones, a little about test procedures, some updates with respect to the certified health IT product list and some communication. Am I driving?

W

Yes.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

Okay. Thank you. We have, as many of you know, had a recent reorganization at ONC. The activities with respect to certification are now an office. Growth over the past five years in certification activities are illustrated here, what began as a grant became a program then a division and office and I think we're on track for world domination next. That was, for the record, a joke. So, with respect to the permanent program, as again you know, the ONC approach for the mandated Health IT certification programs was two part, first we wanted to build something that we could stand up quickly and get active quickly, and that was the temporary certification program. It would be followed by...and built during the temporary program followed by when it was ready, the permanent certification program. The development of the permanent certification program has progressed over the past couple years, to where we do expect it to begin this summer.

I think that, important to note, that when it begins, it will operate initially in the 2011 certification environment, I'll talk more about that. It will continue indefinitely, are the plans at this point and so once it is fully operational...so we have proposed in the NPRM that is currently being finalized, there was a name change proposal. But, until that rule is finalized and decided, we will continue to call it the permanent certification program.

Briefly, the differences are the...remind you that we have a full accrediting body for both test labs and certification. Those two functions of testing and certifying were previously in the same body, what was known as the ATCB, authorized testing and certification body, will now be two separate bodies going forward, the test labs and the certifying bodies. Activities will be very similar, with the addition of much, much increased rigor and full-blown what is typically thought of as post market surveillance. So, recently, as in less than 24 hours ago, there was an announcement. Over a year ago in June, ONC selected ANSI as the ONC approved accreditor for the certifying bodies. In the past year, ANSI and ONC have worked together to develop program requirements in Health IT to train the assessors and ANSI has actually performed on site and competency and proficiency evaluations, such that yesterday there was a three way announcement, very carefully coordinated between ANSI, NVLAP and ONC. ANSI announced first round of health IT certification bodies accredited for operation in the permanent program.

These are listed here, some of the names should be familiar to many folks, but these are the certification bodies in this context. These certifying bodies, they're accredited by ANSI; they may now apply to ONC for authorization to operate in the permanent program. For more details go to the ANSI web site. This is ANSI news, but it's our news too.

With respect to testing, a similar announcement was made yesterday by NVLAP, which is an independent component of NIST to accredit the first round of Health IT test labs. Similar activities have been going on for the past year between NVLAP and ONC to develop the program, to get the program applicants evaluated for proficiency and competency to perform in this program. Here is the list of those entities, which have been accredited by NVLAP in the Health IT program. Will reiterate, for now both the test labs and the certifying bodies are accredited to work against the 2011 standards and certification criteria, so they will both do 2011 now and 2014 when that is appropriate to be seen.

The temporary program is planned to sunset when the permanent program is determined to be fully constituted, that's the regulatory language, and is operational. What does it mean to be fully constituted and operational? Needs to be authorized by ONC to act in this program and posted on the ONC web site.

The application process should be fairly simple, fairly small, but would note that there is ongoing activity, we don't just stop and let...because there's stuff in process, there's stuff in the pipeline. And so there is a six-month period where the products that are in the pipeline right now in the temporary program have to get out of the pipeline. We're going to allow the ATCBs to operate in the temporary program, to empty that pipeline. Meanwhile, they are prohibited from accepting new applications. Any new applications must go to the aforementioned ATCs, the test labs, and certifying bodies in the permanent program.

Okay, fun stuff on test procedures, and this is one of the few groups I can characterize information on test procedures as fun. The current state, it says 2011 edition, the test procedures only allow for individual testing of each certification criterion. This is required by the rule and this adheres to the modularity principle, the ability to certify modules...to test and certify modules. In this process, the data and the results are independent in each test. Now while there is much interest in the status of the test procedures themselves for the 2014 criteria, I'm sitting close enough to Jodi that if I say a word about...no. we are not allowed to discuss that at this time, until the rule is finalized, because it would signal the content. And so, I do want you to know that we are working on them and we'll make what we're doing public as soon as it is appropriate.

A little cartoon here about unit testing and that's just to designate that each criterion is tested separately.

Now, there's been no prohibition of scripting on the part of ATCBs as they were testing these things.

They didn't need to do it in order, but that was entirely up to the ATCBs to do it. They did need to ensure each criterion was tested as an independent unit. However, the testing approach, by definition, is sub-regulatory in nature, so we're investigating feasibility of additional methods of approaching this. And we have heard very many comments on this, and a lot of interest in this. So, response is as always, we are

investigating the feasibility of scenario-based, clinically relevant testing methodologies. These we are proposing as an optional approach, in addition to the individual unit-based testing that is required, optional for 2014. In this approach, the results and data can be threaded forward from one criterion to the other one. It retains and continues to satisfy the modularity principle, but it allows you to sort of pop out, it allows you to string together the various criteria as appropriate and clinically relevant and in an order that is specified, sort of ahead of time.

The implementation workgroup is currently reviewing and providing input on right now we have four draft, clinically relevant scenarios and here's a little cartoon that shows how the results and data

from one are used to feed into another one and they are still continued to be unitary so that things can pop out. If somebody says, well no, I don't use in my system, you know, the modularity principle; I don't use number 1, so I want to be able to pop something in. We need to be able to go from 3 to whatever their number 1 is, if it's an additional product that's not inherently residing in the big thing, but they're bringing something else and then to be able to move to the next one. Obviously, this is several magnitudes, maybe not so obvious, but I will assert that several magnitudes of order more complex, especially with respect to the data requirements on this. I would note that we are proposing this as an optional approach, we'll see how it works, feasibility-wise, but I would note that if it's optional, while things are optional for vendor developers that means you don't...somebody coming for certification doesn't have to do this, but it would be required for the test labs and certifying bodies to be able to do it. Note they still need to do the unit testing. This still does not keep the test labs from doing their own additional scripting methods, but we would...if we do move forward with this, they would need to be able to offer that.

Some update of the certified health IT product list, here is simply the most recent update numbers. Things to note here are over 1400 nearing in on 1500 unique certified AHR products by over 800 vendor developers. I would note that these are unique products; what this means is that we have rolled up different versions of the same...of a product that is essentially the same operating under the same certification ID. If you consider all the different versions that are certified, that people can use for attestation, you get a number that's roughly 30% higher. Two other factoids that would be noteworthy here is that it's about a 50/50 break between complete and modular and 2 to 1 ambulatory to inpatient. We have two primary enhancements that have recently rolled out to the certified health IT productless website; one was a dot release that has two basic enhancement areas; one is to be able to offer hybrid certification, and I'll talk about a little bit more in just a minute and some additional improved navigation search and display capabilities.

We expect at the end of the year to do a large...another big rebuild of the chapel because we're essentially victims of our own success. Huge volume of use, we have about 10 times, actually more than 10 times the number of products in the chapel, meaningful use is moving much faster and much more than anticipated, and surprise of surprises, other programs are hitting the back end system to validate against our criteria. They didn't bother telling us about it, and so we're having to dig...we're just having probably about 1,000-fold volume coming into the chapel than we had anticipated. So in the short-term, we are trying to handle this by additional licenses; in the long-term, we're going to re-architect it. So, look forward to a pretty heavy rebuild on that.

I think the final substantive update that I would have is last month we introduced the capability of the chapel to do what we lovingly refer to as hybrid certification. And here, the target is providers who use both inpatient and ambulatory systems, can now attest to meaningful use, using both of those systems. What we have done is worked it out so that all products that are certified to meet inpatient criteria now satisfy, and that is a typo, all of the ambulatory, it's not...it satisfies the ambulatory criteria where

there is overlap between the inpatient and the ambulatory criteria. It does not satisfy ambulatory criteria that are not in the inpatient. So the underlying principle here is, there's certain criteria in both inpatient and ambulatory that are very similar and we did a lot of analysis and ruling and got support from our friends in OGC, that it was appropriate to use the...where there were similar or equivalent criteria in inpatient and ambulatory criteria, that the inpatient was...the rigor of the inpatient...to satisfy the inpatient was equal to or greater than the ambulatory. So where that functionality is the same, we allow the inpatient criteria to satisfy the ambulatory criteria. So what this means is that the eligible professionals who do practice in both of these settings, can now use the combination or the so-called hybrid technology to get a meaningful use ID and thus become eligible and attest to meaningful use eligible for the incentives. So in this way, inpatient...a simple way to look at it, an inpatient system can be seen at the module for an ambulatory provider, is one way to look at it, the easy way to look at it. There are FAQs that go into detail considerable detail on both the ONC and the CMS websites about that.

Finally, the last thing I want to say is we're going to do a complete rebuild of the ONC certification website an interest in providing more information, more of a self-service environment to stakeholders, improving the inquiry and complaint management process, etcetera, and that will come out probably very shortly. So, in a whirlwind, that is some updates for the certification program.

John Halamka, MD, MS – Harvard Medical School

Great, and Carol, thanks very much. So just a brief process question, so I understand this. So, ONC selected ANSI as the accreditor for the permanent certification program. ANSI accredited five organizations, and so now, does ONC have to authorize those five organizations that have been accredited?

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

Yes, as certifying bodies. ANSI is the accreditor for certifying bodies, NVLAP for test labs. But yes, they now must be authorized by ONC. The application is available. We have already had at least one of the entities request an application, we expect to have all of them request the application. The application evaluation will...it is very much simplified; it is nowhere near what it was before, because we have the accreditation process to build on. They've got to come to us waving their certificate of accreditation.

John Halamka, MD, MS – Harvard Medical School

So basically, there are criteria that are published or known. The application makes clear what one of these bodies must do to get authorized and is there is a time frame for authorization.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

Thank you. That's actually...I appreciate the opportunity to answer that. The requirements are they've got to give us their organizational information, point of contact information, show us their...tell us the scope of which they are trying to get authorized, show us their accreditation and agree to the principles of proper conduct, which are the same in the temporary program. We have said that anybody who submits an application by July 30th will be evaluated for authorization in the first round, we're not doing it on a one by one, we're going to do it in a way, just like ANSI and NVLAP did, that was intentional. If we find out that they all submit their applications within the next two days, we'll go ahead and review them and authorize as appropriate. If anybody...we know the universe is only at this point five, there are only five who have been accredited, so we know that no more than five will be applying in this first wave. And so, if they apply by July 30th, they will be in the first wave. We anticipate that that will be a very short, no more than a week to two, evaluation process. So we expect if things go as planned, and they do go ahead and apply for authorization, before the end of August we will have authorized bodies up and running, ready for business.

John Halamka, MD, MS – Harvard Medical School

Great. Arien, you had a comment.

Arien Malec – RelayHealth Clinical Solutions

Thank you. So this has been really helpful. One of the things that we saw in the stage 1 and associated edition 2011 criteria was that the test methods were really the touch-tone for what it meant to be X. And that it was significantly easier to start or to complete development; you had to start development kind of on spec, but it was significantly easier to complete development and get out of your internal QA when

you had the test methods to QA against. My, and I don't think it's too strong to say, my grave concern about stage two meaningful use and the time frame that we've defined for stage 2 meaningful use, is that if you play out a scenario where right now everybody's guessing on an NPRM, so they're guessing on effectively a guess, what functionality they need in order to get certified. They need to...if the HIT vendors need to complete their development and their internal QA, then go over to an accrediting...a testing and accrediting certifying body, and then get their software installed, upgraded, get physicians trained, work them through the workflow. And then get them fully on the meaningful use stage 2 workflow, and if you are a hospital, all this needs to get done before October 1st of next year.

The implementation work group recommended 18 months as the minimum time frame in order to get that entire process completed. And if you make some guesses about when the final rule will be out and when the testing criteria will be out, we'll be in the best case a little more than 12 months, in the worst case a little less than 12 months to get that entire process done. And if you mess it up, and you mess it up in just a small area, you may be, as an HIT vendor, in the very uncomfortable position of having an organization that you support miss stage 2 meaningful use for an entire year, which has significant financial implications for those organizations. So I've got a...I just want people to recognize, I want ONC to recognize and CMS to recognize, that we're putting HIT vendors in the position of having to guess on a guess, and if you get it wrong, the consequences for healthcare organizations are incredibly grave. And to point out that the time frame for getting all this done, where I do think the test criteria are on critical path, is so tight as to make even trivial mistakes consequential in terms of achieving stage 2 meaningful use.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

I hear you and listening carefully for an ask or a question. You've asked us to recognize, and I assure you that CMS and ONC do recognize that.

Arien Malec – RelayHealth Clinical Solutions

So the ask would be to delay or...and/or if delay is not possible, the ask would be to make sure that the final testing criteria are released with the final rule and to expedite the delivery of the final rule. I understand, trust me; I understand the complication of getting a rule like this through the regulatory process. And to the extent that understanding the importance of this helps, your colleagues in other places in DC understand the consequence of delay, basically anything that can be done to expedite the process and anything that can be done to put additional buffer with healthcare organizations, both of those two things would be material in terms of improving success criteria.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

I hear you and I'm going to tell you what we're doing operationally and then I'm going to let our policy person deal with that side of it. Part of the rule is the certification criteria, so you should be happy to know we are satisfied, we're saying yes, that the criteria are final with the rule...with our rule. And so that check will be done. The test procedures, as you know, cannot...the test procedures have their own process, test procedures have a whole set of things they have to undergo including ability for people to have input, comment, those kinds of things. So, obviously a simultaneous...we could either have the test procedures be a surprise or have input, and I think everybody agrees that having input is desired, so there will be, by definition, a lag. We're doing everything we can to make that lag as short as possible and to get the engagement involvement, we've got stuff that we're going to roll out basically the instant that thing hits the streets. Trust me, I'm going to have a miserable second half of 2011, but it will be very busy. It will be not miserable, let's just say busy, and leave it at that. But, we are doing everything we can to push it as fast as we can and to get as much input as we can of the relevant stakeholders. It will require the relevant stakeholders to participate and step up. And I know this is not ideal, but it is...from operationally, it's what we are given to work with. We hear what you are saying. We feel that pain

ourselves, double, because we're operating under the same thing and we have other people who are expressing considerable displeasure with that. But, with that, I would ask Jodi to deftly and diplomatically address this.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

So, we are in an active development of our regulation. All I can say is that we have heard these comments, we read every single comment we've gotten and we are required to respond to all significant comments, and we don't just say yes we heard you, we respond, we think through them, we have a very deliberate process for addressing them and we will do our best to accommodate as many comments as we can. But, I can't promise you what the outcome will be. And I can also tell you that we are working at herculean speeds to try to get the regulations out the door, and doing everything in our power to make that as soon as possible. We have lots of pressure from everybody; they're all saying get this out as quickly as possible. So, we are...as far as the regulations, we're trying to get it through our process as quickly as possible, and these regulations do sort of takeover and take precedent over a whole lot of other things we're doing in order to try to make that as short as possible.

Arien Malec – RelayHealth Clinical Solutions

So, if I read between the lines and I really appreciate this, good things take time. Getting good final regulation and good testing procedures is going to take some time, and I appreciate that. So the other side of that ask, in terms of providing flexibility particularly for hospitals, although I don't want to underestimate the complexity for ambulatory providers. But on the fiscal year basis, particularly for hospitals, providing additional flexibility in the time frame to accommodate for the reality that they are dependent on their HIT vendors, who are themselves dependent on getting the final test procedures in order to get their internal QA done and passed, means that we're in...we're asking that combined set of organizations to do hopefully the herculean possible and quite possibly the herculean impossible with, as I said, grave financial implications if they miss it.

John Halamka, MD, MS – Harvard Medical School

Great, thank you. Dixie.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes, I have a pretty straightforward question for you. On your chart on slide 8, I do see where it says that the table shows unique count and that any additional versions and same product aren't included. But my question is, are any of the certified modules also evaluated as part of some of the complete EHRs?

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

If they've been presented like that and some of the...you mean within this count?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah. If they're both certified as an individual module and also included as a module in complete EHR, would they be counted twice?

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

Yes.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay, thank you.

John Halamka, MD, MS – Harvard Medical School

Now Wes, did your card up for a new comment?

Wes Rishel – Gartner, Incorporated

Yeah. You described a process whereby there would be some consultation with the community on the test procedures. I didn't understand where that happens, is that in the INS framework? Is it a request for information? How does that consultation work?

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

We have lots of friends and things will be made public. The rules, the criteria and all of that, draft test procedures will be posted as available. We are going to hold workshops, we're going to hold...and they will be public, open, calls. We're trying to get as much as fast in as many different ways as possible. So, if there are thoughts that people have about other kinds of things, webinars. We're just really focusing on getting as much from as many as we develop those. I want to come back real briefly Dixie to clarify one of the reasons for this. If you remember...part of the point...the chapel serves two purposes and one is to just provide public aggregation of all of the stuff that's been certified and what it's been certified to, in technical terms there, stuff. But, it's also to be able to generate and ID that can be reported, a single ID where complete EHR has been achieved by a combination of the products. And so, a given product may be...when something is a component of a product or component of different products, it needs to be sort of accessible to the logic in the background to be able to build in to any number of MUIDs. And so that's one reason why we've got it like that, technical.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay. Thanks.

Wes Rishel – Gartner, Incorporated

So, second question. The tools and procedures...the tools and data, and procedures, for interoperability testing, how are they being developed? Are they being developed through this same process or are they being developed separately by the labs individually? And, what is being done to make those tools and appropriate sample data available before actual day of certification?

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

The process is similar to what was done in stage 1, so the tools are being evaluated and/or developed and the data are being generated to go with the procedures as part of the whole test method. Those will be available at the time the test procedures are available.

Wes Rishel – Gartner, Incorporated

You mean, they'll be available for comment at the time the test procedures will be available for comment?

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

Yes.

Wes Rishel – Gartner, Incorporated

Okay, thank you.

Carol Bean – Office of the National Coordinator – Director, Certification and Testing

Nodding, for the record.

John Halamka, MD, MS – Harvard Medical School

Great. Well thank you. Let's move on to Jodi's comments and we will catch up. It turns out we've seen a lot of the S&I framework material before. So, don't worry, we have an hour, we can get both Jodi and Doug.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

And I will try to get us back on track. I'm going to be fairly brief. I just have sort of a pull together couple different things that I thought folks might be interested in, I did this at the Policy Committee and somebody suggested it would be helpful to provide the same level of input here as well, just to give folks a flavor of some of the activities that are going on. I am going to start with a public service announcement, because I just learned that some of my postings for policy analyst positions went up on USA jobs this morning, so, if anybody is interested who is listening out in the world, please go to USA jobs. We're looking for good people both on regs and strategic planning. Okay, so that's my public service announcement.

And there's a couple of references in here to some S&I work, and I will go over it quickly, because I know Doug will be talking about it, so that'll shorten some of my time. So, Judy mentioned this last time, but I just feel obligated to highlight the fact that the work that all of you are doing, and that all of us are doing to meet our goals of improving meaningful use of Health IT by healthcare providers is actually really important work and is having an impact out in the real world. We had set a goal of 100,000 healthcare providers to become meaningful users by the end of 2012, and we achieved that by June, and the number of 110,000 providers represents almost 20% of eligible professionals in the U.S. And that really is a testament to, I think to getting some of these really great recommendations from Standards Committee and the Policy Committee and getting the right policies into our rules and into practice in a way that works for healthcare providers and hospitals.

We also can't enough thank the work that we've had, the yeoman's work, that has been done by our regional extension centers in working with primary care providers and specialists and particularly in small practices and in rural areas. The work of implementation, particularly among these small practices and folks who don't have staff that help them figure this out, is really...the RACs are really providing a huge benefit to these folks in helping moving them toward meaningful use of Health IT. And our office of provider adoption and support has been doing great work working with our regional extension centers to provide them with the tools and the assistance to help those docs.

I wanted to highlight this...we brought together some Health IT vanguards to discuss their work in achieving meaningful use of EHRs. And it was such a great and positive event, both the meeting at HHS as well as the White House meeting that happened the next day. We had a great diverse set of stakeholders from 34 states; we actually invited people based on input from our grantees across the country. And they discussed best practices to achieve meaningful use, Health IT adoption in medically underserved communities, leveraging Health IT for quality improvement in safe and secure exchanges of health information. And then the next day at the White House meeting, there was a discussion on Health IT was being implemented across the country and some success stories and areas for improvement. So great discussion of leaders across the country and really building that network across the nation of the Health IT vanguards that are really leading all of the efforts toward our vision of meaningful use of Health IT nationwide.

So, I can't say much about this, but, so our standard/certification rules are in process and you'll notice the absence of people like Steve Posnack from this room because he is working on making sure those regulations move through that process as soon as possible. But we are working closely with folks in the department, particularly CMS to align the rules. We know that it's critical to make sure things match up well so that there's a clear path toward implementing the meaningful use rules and our standards and certification rules as well. And I mentioned the governance RFI. I really want to reiterate how valuable the comments were from this committee as well as from the public in thinking that through. As John had mentioned, there were a lot of very thoughtful comments with lots of questions about federal government role, other folk's roles and what we can be doing best, and we are taking those under advisement and thinking them through.

I wanted to mention some work that we're doing with non-eligible providers in two areas. One, LTPAC, the long-term post-acute care community and the second, in behavioral health. We really have kicked up some of our efforts in these two arenas and have been also seeding some of that work in Policy Committee's thinking on meaningful use, so stay tuned for their thoughts on that and some directionality.

So with long-term post-acute care, we did hold a round table, and John can jump in, John Derr, if you have any other comments on this. So, we held a round table, we brought together a variety of stakeholders from across the country who have been really thinking about long-term post-acute care and Health IT to get insights, input and thoughts on what we should be doing to proceed and to better engage long-term post-acute care providers in the use of health information technology and in coordinating care with those who are part of the meaningful use incentive program. And we will be coming out with a white paper in response to that and stay tuned for some things that we may be doing in that space, we're looking to try to set forth a strategy with better engagement with the LTPAC community. We have our state challenge efforts that are going on in this space to try to work with the long-term post-acute care community on the ground and there's an S&I initiative focused on this work as well.

With respect to behavioral health, we're kind of following the model that we did with LTPAC, we're going to be doing a round table next week; again bringing together a set of diverse stakeholders. The focus of the roundtable is really on the integration of behavioral health and primary care, both the integration of behavioral health into primary care as well as the coordination between primary care and behavioral health providers. So that's sort of the focus and trying to basically get some thought leadership on directions and strategies we should be thinking about from a policy perspective on our standards perspective on behavioral health issues in that space. We did some work on quality measures with respect to behavioral health, and we had a contractor who delivered some work on quality measures last month.

And then thirdly, we've been working with a lot of effort on prescription drug abuse, and trying to link prescription drug monitoring program data in various states with prescribers and dispensers at this point of care. So, we're not looking at how to gather that data, we're not looking at what the right data is to capture, but there is a vast amount of information that's being held by these state prescription drug-monitoring programs, and they're often well under-utilized by prescribers and dispensers, in making decisions about prescribing controlled substances to people. So what we have done is identified...again, we did a round table last year at the White House. We brought together a variety of stakeholders to try to understand what the challenges were for doing that, and how Health IT can help to make that data available in real time to prescribers and dispensers. And we actually have now 7 pilots, some have already started and some were still kind of just signing on the dotted line to get them moving. But 7 pilots across the country with different types of approaches, to try to see how we can bring prescription drug monitoring program data at the point of care, so that when a prescriber is actually making a decision or a dispenser is making a decision, they can use that information. And we've already gotten some anecdotal evidence where it's had an impact on real people, who had information on them available through the prescription drug-monitoring program and affected the provider's decision-making and their discussion with that patient. So, I think that's really such a huge public health issue, it's a real practical work where Health IT provides an infrastructure to make better and informed decision making by providers.

This is an S&I initiative on clinical decision support that just kicked off, Health eDecisions Initiative; I'm not going to go into too much detail on it. I just want to mention it because from a policy perspective, this is sort of where, when we're talking about improvements in care using Health IT, having good clinical decision support is so critical to making that happen. And this initiative to take clinical practice guidelines and put them in common format so it can be shared and consumed by EHRs is really critical in advancing the use of clinical decision support through this technology. So, I'll let Doug talk more about what they're actually doing and that effort.

And then lastly I want to close with some talk about our consumer program. So, like the certification program, the consumer program started as sort of an idea of some thought leaders, and I'll look to Mary Jo as one of those in ONC. And then identifying an individual to sort of make sure we're thinking about consumer eHealth in all of our programs, to then being a program and now to being an office. And that happened in about a year and a half, from hiring our first consumer eHealth lead until now has only been a year and a half. So, we've made huge progress in the area of consumer eHealth and I personally feel a sense of connection to this work. We have our pledge program to engage the first stakeholders in empowering consumers to be partners in their care starting with providing them with access to their information. We now have 375 organizations that have taken that pledge, which is outstanding. And we had some of the pledge members highlighting their progress at the HGI forum.

So next steps on this, we will have an anniversary event; we launched our consumer program in September of last year. We will have anniversary event, the Health IT week, the week of September 10th. I don't have the date nailed down yet, but we'll be highlighting some of the activities of the pledge members, as well as lots of other announcements and exciting things to come. We are trying to do more targeted outreach and engagement among participants of the pledge community and really kind of build that community. We will be having some round tables on particular topic areas of interest in consumer eHealth, social media and underserved to be two of those. Excuse me. And we're working on papers to assess the impact of consumer engagement via Health IT and personalized medicine, so some thought leadership and some understanding of the landscape in those areas as well.

I wanted to highlight this particularly, because this is something that's taking a lot more of our energy and excitement, I think, and some of our enthusiasm. The pledge program is going to increasingly emphasize blue button as part of it, and we've been working very collaboratively with the VA on the blue button initiative. In June, we released a blue button mashup challenge, to challenge folks to use blue button data and mash it up, combine it with other types of data to address some of the triple aim objectives, lower cost, improved care and improved population health. So, we will be making an announcement about challenge winner in September, I think that is going to be part of the consumer event. And then we held a patient access summit at the White House to identify areas for technical work. The things that came out of that discussion was auto blue button, so now for somebody to get access to their information, they have to go into their...onto a website and hit the download button, hit the blue button to get a download of their information. But trying to figure out how to make that sort of a one-time thing rather than something that somebody has to do on a regular basis to continue to get updated information. Also out of that summit, there was a lot of talk about patient identification and authentication as an important component to the blue button work. And thirdly, standardizing content, especially for claims data, so that the content that people receive from blue button is in a more standardized...is received in a more standardized way. And then in August, and again I will defer to Doug to talk more about this, we will be launching S&I work regarding blue button and regarding...as a follow up to that patient access summit.

Finally, I just wanted to mention the cancer initiative. We decided that in the consumer program, we wanted to have a focused use case, and we chose cancer for a variety of reasons. But, one of the primary reasons was that it's something that is a condition that's prevalent across lots of different...across all different populations and nationwide, and that patients and families tend to be engaged, and so it seems like a good area to focus on, if we were going to pick a use case. What we've done so far, we held a round table with NCI and eHI on long-term research agenda regarding consumer engagement via...IT and cancer care. So, we're trying to encourage NCI to sort of focus on this area, and they got some great input through that. And then the next steps, we are going to have a pilot involving patient access to liberated data to plug into a platform. We're going to launch that in the fall. We've been working collaboratively with several healthcare provider organizations in Texas, as well as partnering with a major flat form provider, also to be announced soon, as well as several consumer cancer organizations. So, we're trying to get a partnership of a variety of different organizations, advocacy groups and technology vendors. And there's going to be, as I mentioned, this research component as follow up from the round table, as well as apps developer challenge. So, this is going to be an ongoing project that we're going to be having at least over the next year to focus on consumer engagement through IT, particularly in one population of patients. And so with that, I will open it up for questions.

John Halamka, MD, MS – Harvard Medical School

So questions for Jodi. I mean, maybe this is a dumb question that we can deal with outside of your presentation is as blue button as an initiative continues to expand and roll out, of course the concern is that free text unstructured files do not interoperability make. And so are there going to be some ONC suggestions on standardizing formats and using some adopted XML-based standards? But again, probably something for the S&I framework discussion.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

So, I will defer that to Doug for when he talks about S&I.

Arien Malec – RelayHealth Clinical Solutions

If I can ask...from Peter Levin that blue button is being rebranded as access as opposed to a specific format and that that rebrand of patient access to their own data is inclusive of getting structured data such as a consolidated CDA, so that the blue button label is less about the ASCII data format and more about patient access to their own data. Do I have that right Jodi?

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

You do.

John Halamka, MD, MS – Harvard Medical School

Very good answer. Thank you. Other questions for Jodi? John.

John Derr – Golden Living, LLC

I just wanted to say how the round table was extremely very, very good and I did read a draft of the white paper and I think it'll help us all John, when they start to include us in a volunteer fashion in MU stage 3, because it was very comprehensive. You caught not only the facts but the tenure and the emotions that were part of the meeting, I appreciate it.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

And I don't recall, I can't remember the final list for the behavioral health round table. But...and I also don't know the folks who are organizing this might shoot me for saying this but, I don't know if there's room at the table, but if there is anybody who is particularly interested in behavioral health and would be interested in participating in that round table next Tuesday, I think. Just send me a note and let me know and I'll see if I can get you engaged, because it would good to have folks in the committees to hear the conversation.

John Halamka, MD, MS – Harvard Medical School

Great, okay. Well, no other comments, then let us move on to Doug. And Doug, you have 45 minutes and again great news is that you have done such a great job in the last two meetings of setting the stage for this discussion that folks have a lot of the background of your slides.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

So let's hope the third time's the charm. I've tried to condense the slides down a bit. I want to provide at least a little bit of context. This is our third attempt to sort of have an ongoing discussion around sort of strategically where we need to go with the S&I framework. I'm hopeful that I can go through these slides very quickly and we can get to that discussion. As you know much of the S&I framework is currently funded through ARRA dollars, which we on our current estimate, expect those to expire in February of 2013. So, we need to have a discussion in this group to help us plan for the future and figure out how to do our priorities and figure out where we need to focus our energies.

So I think it's important to recognize that ONC is committed to continuing the rapid adoption of standards development despite the end of the ARRA funding. HITECH did give us the responsibility to support standards and certification criteria now and in the future, and that was not tied to the ARRA funds. So while the ARRA funds will expire in 2013, we're continuing to provide some degree of funding for the S&I framework activities and will continue to support coordination around those activities. I think we're going to have to be creative about how we do that and we're going to have to be very, very judicious in what we prioritize and how we get the work done. I think we are trying to work with the community to find ways to have the federal investments go even further. For example, we're working with CHCF to develop new standards for lab ordering interfaces and providing them a collaboration framework for that. We're working with our federal partners to make sure that we can be responsive to the HIT Standards Committee when it comes to the RESTful interfaces. And we really need to understand how we should proceed going forward, and I'd like to at least give you some of our thoughts about that as well.

So, you've seen this. There is a sweet spot for the work of the S&I framework, we've tried things that are very innovative and that are not well sort of coalesced, and that's probably not our sweet spot. If there are things for which there are extant standards and there's not a lot of disagreement about, then we have processes within the working groups to provide some advice there. But I think where we've got a need to achieve consensus, we've got some available standards to work with, and that we need to engage the SDO community. I think that's important. We've sort of broken it down, if you take a look at the degree to which an incremental approach works, and the degree to which you have consensus, there are different sweet spots we need to have. But there's a big chunk of activity for which we think the S&I framework approach is helpful, and some examples of where some of those fit.

We are exploring different ways to support S&I framework initiatives, all the way from full support, because it's a critical need that we have to be able to provide support for, with regard to meaningful use; all the way down to sort of best practices and self-service. Certainly, the LTPAC community has come together and coalesced and we've provided only limited support there, but they've achieved a lot of remarkable things that I think are going to be important in the future. Here's sort of our portfolio of standards that we've got, and this is sort of shamelessly stolen from Steve Posnack and sort of identifies those standards that are now coming into our portfolio that have been developed by the S&I framework activities or have been at least sort of coalesced together, as part of that. Our current line of initiatives that we've got...whoops, went too far...are here. It's kind of hard to read these here but I think what's important to understand is that within the transitions of care, we've got some pilots underway, we're working with a laboratory results interface, a second implementation guidance ballot there. We've got activities within query health that we're coordinating with HL7 that will provide us a QRDA cap 1, QRDA cap 3 and work on HQMF; that's being led by members of the structured document sig within HL7. And there's a host of other ones there. I think we are launching a new initiative around health eDecisions, to try to support clinical decision support and get some understanding on what are the pieces that we need to standardize that will allow that to grow and promulgate. And we're also working on creating some transparency in the work the FHA and our federal agencies that are participants there, to develop RESTful interfaces, primarily looking at things like patient ID and OAuth, and trying to figure out ways that we can provide yet another piece to our portfolio when it comes to those activities.

We're also realizing that as...part of the S&I framework activities were pilots and implementation, reference implementations, and I think one of the things that we've learned in this process is that we can develop standards and then we can use those pilots and reference implementations to support refinement of our standards. But in fact, maybe we've got the sequence wrong, and maybe what we need to do is provide implementation support to solving problems and then from that, identify where we need to standardize, what are the gaps that we need to do, and then feed that into an S&I framework initiative. And so, we're trying to take a portion of what we've learned in the S&I framework, and create an implementation support platform that coalesces all of the artifacts that we have within the S&I framework and brings together communities that are trying to actually implement and use. And maybe start to turn around that equation, so that as people start to identify problems to solve and then within there, issues that need to be addressed that may require standards or may not require standards. We then can then kind of change the order if you will between developing the standard and then testing and implementing to implementing a solution, for which a standard might be useful, if we want to have scalability and other things like that. And I think that follows much closer the direct model, in terms of getting the implementation and use out there first, and then determining what's the appropriate standard to use to be able to create a scalable approach.

So, one of the things that we see within the S&I framework, it's a public platform where the community can build consensus around solutions. We've identified kind of what the ideal use...the ideal sort of sweet spot for the kinds of things we need to do. We think that we can help identify standards gap for health information exchange, provide a flexible process and a set of tools that will enable us to accelerate that process. We're working hard to try to make sure that we've got milestones and metrics that we can start to track these things a bit more closely as we go forward. And that we're developing sort of the support we need both in terms of repositories for the standards products that are produced, as well as developing tools and resources that help guide implementations and provide ways that people can be successful in their use of those standards. So, we're trying to create a clear, public-facing vision for the S&I framework that allows it to be a platform with a purpose. We found that the best way that we can support this is that we provide clear goals and metrics of success, and then we provide policy guardrails to keep people kind of in the right zone, if you will. And then at every meeting we emphasize again the importance of those goals and those artifacts. So, we don't prescribe a solution, but we do prescribe or we at least try to articulate what success looks like.

There are some standards gaps that we've got. We're trying to figure out if we can improve the governance process for the S&I framework activities, to identify priorities and to sunset those activities that need to be put out there into a self-sustaining process, trying to declare criteria for when an initiative would be appropriate. Trying to create different tracks through which an initiative can achieve its goal and one of the things we're trying to do is simplify across this. We've only been a year and a half into this, but part of our goals and success is the reusability of components across different initiatives. And we've looked at it looking at transitions of care and query health, and we've identified some approaches in which we've represented that information that makes it hard to reuse. And so we're taking a look back at that, and trying to create more reusable components, which we think will continue to accelerate and provide ways of pre-coordinating, if you will, the interoperability that we've got. And creating a Wiki space so that community members can easily participate in multiple initiatives. We have heard the concern that there are too many things and it's too hard to track it and it's hard to stay engaged with everything. We may solve that problem next year as the ARRA funds begin to decline, but we do need to make sure that we're focused on those things that are going to be important for our success towards meaningful use Stage 2 and beyond.

So, the kinds of questions that we need your help and support with is what are the criteria for successful S&I framework initiative? What's the value that the S&I framework provides? And how can we continue to leverage that? I think one of the things that we've done is we've done a lot of analytics on what it costs to do a particular initiative, given what it is we're trying to achieve and what is the substrate that we start out with. I think we estimate that over the course of the last year, we've had 20,000 volunteer hours devoted to the S&I framework activities. And these are incredibly busy and incredibly smart people who have come to the table. I think we need to still consider success in the S&I frameworks is working on things that people care about, and making sure that we're getting standards used and implemented that provide inter interoperability. What's the role of the HIT standards committee in this coordination across this and how can we collaborate affectively to get prioritization, both within this group and beyond. Because there are other folks that are coming to the table saying, we're not part of meaningful use, the LTPAC community for example, but we want to be a part of this and we think that we can have a contribution that's significant, and we need to encourage those kinds of things to continue.

What support of information can we give to you that will help us do a better job in the work that we do? And what kind of flexibility should we build into the framework? What steps should we take to properly evaluate the success and metrics that we need to take a look at? So, I know that that's a whole bunch of questions out there. We established the S&I framework to sort of solve some immediate concerns and issues that we needed to do with acceleration of the standards development processes across various SDOs, and trying to get the right people to the table. I think I am always interested in continual refinement of what we do, because I know we can always do better and that's why I want to make sure that we one, identify and articulate what the value is, make sure that we're working on the things that people care about. And then also, where there are things that we can improve or if there are ways that we can leverage our current set of activities and resources to sort of set the stage for meaningful use stage 2 and 3, and beyond, I just want to get the input from this group in the discussion, about how we should proceed.

John Halamka, MD, MS – Harvard Medical School

Doug thanks very much for that presentation and I'll just toss out a straw man plan, because I'm sure there's going to be a rich discussion of your questions. So imagine that the S&I framework after February 2013 has a fixed budget of five million dollars, I'm making up some number, I have no idea, and that based on your experience, can say, oh based on the standards readiness, oh I compared direct, query health, transitions of care, we actually know a project is going to be a \$1 million project, a \$2 million project, a \$3 million project or so enormous we can't even take it on. So if what you did for us as a group is you used us as sort of a kitchen cabinet where you could say, you know, here's the list of all the things the S&I framework's been asked to do in the next year. We're going to put them, Wes I hate to say this, in the Gartner magic quadrant format, sort of, so that we can sort of see a dot here as to where it might sit in your recommended schema of things likely to be good for S&I. And then, whether it's the thing you've developed thus far or a variant of that, we get a sort of sense of is this a small, a medium, a large project from a budgetary standpoint. I would bet this group could say things like you know I'd rather have three smallish projects that have very high value to the community because of the number of transactions sent than one really hard wonderful informatics project that is likely to benefit the few and take a long time.

Or that sort of thing. I mean the quadrant plus a budget plus the standards readiness assessment and then we could offer advice. But anyway, let us open it up to questions and comments. So, Nancy Orvis.

Nancy J. Orvis – Director, Health Standards Participation – Department of Defense

Yeah, you mentioned, Doug, that your governance process, and I think the committee would be interested, and following on Dr. Halamka's issues, on where you are get...who or what departments are in that governance to help do the priorities, because I don't think that has been as apparent as it could be.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

So with many of our initiatives that we launched early on, using the ARRA dollars and the like, we had an HIT Standards Committee blog posting, we got public comment about that, we presented it to this group and we got some advice about how to prioritize things. I think many of those initiatives are still the ones that are on the list that we're sort of finishing up and that we're kind of bringing to conclusion. I think one of the issues that we have to think about is that in...with regard to a governance process, in a setting in which there are declining budgets, do we do the things for which people have money but may not have priorities? Do we try to put investments into those activities that we think are going to support the little guy or that are part of sort of a government or a role that we can play that the vendor community or the stakeholders may not necessarily proceed? Should we try to create...find the things for which we can get the most leverage, if you will, because people are interested and they want to implement or the like?

I think, over the course...so, we're about 18 months into the S&I, framework activity and I think some of the initial activities are beginning to kind of come to conclusion. There's been a few that we've added and that people have just approached us and said, listen, I have money and I want to do this in a public and an open way, and I'd like to leverage the S&I framework. In those settings, we have tried to provide them space to do that, but I think when it comes to sort of the dollars and the investments that we need to make with regard to meaningful use, I certainly would like to have broader input on those things. I think most of the more recent initiatives have been opportunistic. They have certainly been aligned with our strategy and they've certainly been things that we think are going to be important. But we don't, apart from the conversations that we have here, and in fact, it would be better if we could have had this conversation three months ago, because we've actually launched a couple initiatives in the intervening period of time. That reflects some of the challenges that we have with making sure we can be responsive to the needs and where the dollars are, aligned with where our strategies and priorities are, but still provide that kind of inclusiveness if you will.

John Halamka, MD, MS – Harvard Medical School

Thank you. Arien.

Arien Malec – RelayHealth Clinical Solutions

So first of all, I definitely agree with...thanks for the presentation. I definitely agree with John Halamka that this is implicitly, or explicitly a portfolio management problem. You got a pot of money, you've got to divvy it up and you need a process in order to do that portfolio management. One of my reflections on and this may just be my own cognitive bias. One of my reflections is that the most successful S&I initiatives have been those where there was a clear tie back to the policy goals for meaningful use, and a clear standards gap, either where the standard didn't exist or where the standard did exist, but in the case of lab or interoperability, summary of care, there were too many or not enough specificity. And in those cases, there is something at the other end that people have to hold themselves to, that is, you can't do a standards exercise, as a standards exercise. At the end of the day, the community understands they will be held to what it is that they come with and they have a vested interest in making that a workable, scalable solution. It does no good for Stage 3 meaningful use if you want to hold providers, and I'm making this up, but if you want to hold providers to integrate a care planning and you've got no standard way of defining a structured plan of care. It does no good to providers and to hospitals to hold them to those requirements without the enabling specification and everyone understands in that process, that they will be held to implementing and to using the appropriate standard. So my reflection is that if you can tie back the ask to at least two clearly defined criteria, number one is the policy need, either expressed as a Stage 3 meaningful use criterion or something that a federal partner desperately needs to get done either for their own mission or in order to serve the public. And number two, you can tie it back to a clear standards gap that fits the criteria, the sweet spot that you've defined, it occurs to me, that those two end up being at least some of the foundational criteria for saying, "yeah, this is appropriate to be a priority S&I project," versus, "it's nice to happen if somebody wants to sponsor it and put people behind it, but we're not going to put the energy and dollars of the federal government, or ONC dollars, behind that project. So those are at last two criteria that I think make sense as foundational criteria.

John Halamka, MD, MS – Harvard Medical School

Thank you. Jamie.

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

Thank you. So Doug, as you know, many other countries have national standards authority bodies that set standards that are required for government contracting and regulatory purposes. And despite having some aspects of regulatory authority, both in meaningful use and beyond it, ONC has not, I would say, really established itself as that national standards authority center, which would I think necessarily include coordination with other federal agencies on their areas of regulatory authority and so forth. But also greater involvement with the private sector and in industry standards. And so I think one way of addressing these questions is to think, if we were to look at the different models of national standards authority centers that exist in other countries, and think well, sort of, "What's S&I for? Is it to feed or to be a part of that standards authority body? Or is it sort of just to work on the list of priorities that ONC independently arrives at? And so, I'd like to get your view on the relationship of S&I to this kind of a national standards authority.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Well, I think it's been a longstanding discussion about the establishment of the national standards authority in some fashion. I think the work that's going on with the National Library of Medicine around value sets is sort of a good step in that direction. I think the establishment of these committees, the HIT Policy and Standards Committee, I think are another part of that puzzle. But there probably needs to be kind of a technical group that can kind of work through the hard issues around the standards, that could support the identification, the implementation, the testing, and the use of those standards. I certainly think the S&I framework could serve in that capacity, or at least with some modifications or changes could. I think, we've proposed, or we're exploring both where the sweet spot is, but then different funding mechanisms that would allow sort of full ONC support. Those things probably needed to be aligned with meaningful use and the priorities that we have there.

But there are some other things that maybe are, we want to provide limited support because maybe it's not something that we see in the next 18 to 24 months, but we see it as being important. And I think the LTPAC is a good example; they're really focused on sort of care coordination and care plans becomes an important issue with that. Now, it's not part of meaningful use Stage 1 or Stage 2 in a structured way, but we can imagine with ACOs that there may be some new models that would come out there. So, we see it strategically as important, but it isn't something that is front and center. In that role, we need to make strategic investments in the people that are committed to sort of developing those standards, and let them be the vanguards, let them lead the way. But how we do that and how we coordinate those resources, I think is something that still needs to have exploration. And I think once you start exploring that, then you start to get into the situation where the industry of the private sector comes and says we want to be a participant in this national standards authority, we have some technical issues that we want to resolve, you have a process and resources that would be beneficial. We can reuse components of other standards; we can kind of put things together and show how this might work. That kind of sets the stage as part of the building blocks.

And I think to your point about a national standards authority center, part of what we have to explore is given what we currently have, do we have the right pieces? Are there gaps that are missing and are there ways that we could leverage our existing resources that gets us to that goal, as opposed to starting with a blank sheet of paper and saying, "let's start from scratch and figure out how that should work."

John Halamka, MD, MS – Harvard Medical School

For example, would the combination of ONC, S&I and this committee be the US realm?

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Potentially, and I think that's a conversation that we'd like to have. I know that when...in the last couple months when I've done some international travel or we've had visitors that have come from other organizations, they look at our meaningful use regulation and they identify that as the U.S. standards for healthcare information exchange. And so almost defacto, they look at that and they see that as sort of that beginning of what might be standards authority. Is it complete? No. It probably needs to have other processes or other things in place, but certainly, others are recognizing that outside of the US as being sort of that core of what might become an authority center.

John Halamka, MD, MS – Harvard Medical School

We have eight cards up, so I'm trying to take them in order. David.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Yeah, thanks. David McCallie. I wanted to echo what I thought Arien made as two great points, which is that the S&I framework has worked best so far when there's a clear policy driver, especially if that policy is tied to a regulatory impact that is going to be binding in a sense on the stakeholders. And when there's some kind of a gap in the current standards or in the current profiles, so that S&I works as kind of a finisher, a profiling finisher service. I think that has worked well, it has an aggressiveness about a timetable that is faster than the typical standards and profiling bodies operate and that intense focus is overwhelming sometimes for those of us who try to participate in it. But, it's necessary to get something landed. And I think that's been a strength.

I think it's also done pretty well at serving as a hosting spot for nascent ideas that you want to get some community input. Which is really the other end of the spectrum, but is almost a second kind of purpose for S&I, is to be a place like something like query health or direct or RESTful health exchange can begin to emerge, and people can see it and participate in it if they want to, even though it doesn't have an immediate policy impact. So, I think those are all use cases that will persist. The policy drivers may get less important as we move past HITECH's authority and funding. But the need for finishing profiles in rapid fashion towards some specific accountable purpose seems like a keeper idea, and that part seems to have worked well.

John Halamka, MD, MS – Harvard Medical School

Wes.

Wes Rishel – Gartner, Incorporated

George Mora looked at how many people had discovered an exponential relationship and said it was Mora's law, and he said if Al Gore invented the internet, I invented the exponential. I'd like to add that Gartner invented the two by two quadrant, based on earlier comments. We're struggling with the eyes in the stars, the feet on the ground, the I&S framework has the ability to take the feet on the ground stuff and beat it into submission. That means going back into SDOs and saying give us what we need or we will

go somewhere else, that means creating an environment where...well-facilitated environment where people show up and pound out...finish the same fights they've been having for 10 years. And I think that as you prioritize, you are going to find that the dollar prioritization will continue to be on feet on the ground stuff. Why? Because there is an immediate imperative behind it, and there's nothing like a deadline to bring arguments to a close.

The eyes on the stars stuff, I would say that there has to be a way to make them essentially self-funding short of...I know in the government it's hard to charge for a service. But, the other kind of driving...the other kind of driver that can make something go forward is some entity willing to put some money into making it go forward, and California healthcare foundation, I think, has been an example. Thank God, that Blue Cross went commercial and left all that money behind. But I think we're going to find that

those efforts will, we have to expect some to succeed, some not to. We have to never judge success of any of them until they have gone operational and stayed in operation. And that for every ten that is suggested, one will get the critical mass necessary to get the S&I in premature and help to carry it forward.

John Halamka, MD, MS – Harvard Medical School

Leslie.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Doug, first of all, thank you for all the good work. And I have a couple of comments and questions.

First of all, I don't think you should underestimate the brand that the S&I framework brings, and that value in itself by being able to set a charge for initiative with a scope that's constrained and a deadline can move mountains. And so, as you look at how to accept new projects in place, I think the brand itself with those three criteria can really get work done. So that's one suggestion. And then the other is from the patient engagement subcommittee that we did, when we reviewed the NPRM, one of our overarching principles was that with every electronic health record function, there is a corresponding patient-facing system function. And so that can be a tact in standards in one of two ways. we can tack it on to the end of everything we do and fund a serial effort. Or we can say we want a two-fer and that any time that we evaluate standards, we evaluate whether or not the patient and their families are contributing members or roles within the system standards. It's very important because now as we say some of these efforts are concluded and yet we move forward to the next imperative which is engaging patients and families, they're absent from those standards that we are concluding. So, I'm not sure how we make sure conclusion also includes evaluating the patient and families participating and/or how we set the stage ongoing that says, we can get these two-fers, that standards development for electronic health systems have a corresponding impact for patient-facing systems.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

So thank you. I think one of the things, and I sort of alluded to this when I was talking about this notion of an implementation platform or kind of getting the problem out in front of a solution. It hasn't always been easy to get patients to engage in standards development activities. But it seems to me that patients and consumers, they have real needs that need to be solved using technology. And part of what you want to do is you would like to put the folks that have the need in the driver's seat to make sure they are getting what they want. And so, in some sense, you get a two-fer because the patient says, "I need to be able to access my information on an ongoing basis with updates that have feeds from other systems." That may also help us accountable care organizations and care plans, as we get feeds from lots of places that need to be updated.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

And sometimes it's just adding the role, the notion that a patient and/or their designee are potential recipients and/or participants; whether we're defining the care plan of the future or we're defining a coordinating care platform.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

And it seems to me that getting the problem we're trying to solve out front, probably, at least this is our hypothesis, will help us engage patients more because they're the ones who truly benefit, they're the ones who have the challenges that they're trying to solve. But they're not the ones who are going to determine how to represent in a technical framework, you know, the LOINC codes for their lab tests. But, they need to queue to say this is the problem and if you guys construct something that meets that need, I'm happy. So we have to think that through and I'd welcome sort of continued dialogue to figure out how we can make sure that we're working on things people care about that are aligned with the policies and I think Arien's comments about those priorities with consumers being one of those priorities, will help us do that.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Okay.

John Halamka, MD, MS – Harvard Medical School

I will be coming back to you guys, I'm just doing them in order.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay, thank you. At least my sense is that to this point, this committee has had very little involvement in establishing priorities so far. It seems like we mainly have reviewed what's going on and provided feedback, but not really part of the process. And I think, and I agree with what Arien and David said, that the most successful projects seemed to be linked to either a policy goal or a known gap in the standards.

And I think a linkage to this committee, a recommendation from this committee, would also make for greater probability of success.

One idea I have here is that our committee could consciously...I mean part of it is just being conscious of a connection between the two, right, and maybe we could consciously add an assessment of a need for S&I work whenever we make a recommendation. Does this have any implication for S&I framework?

It might provide that kind of linkage that we need. The second thing I wanted to say is that I think this committee, and we recommended this in our RFI comments, but this committee can have a role in the evaluation of the readiness of specs, too, as we move forward and as I talked about later. The third thing is that you report...I've seen you several times, mention the California Healthcare Foundation initiative for lab ordering interface, etcetera, and I think it would be worthwhile for S&I to actually incorporate the tracking of these external initiatives as part of your overall portfolio. You know, not just report, "oh yeah, we're just watching what they are doing." but make it really a part of what you are doing, because it'll save you money if somebody else is paying for it, as Wes pointed out. And this is a second area where I think this committee might help, is in identifying...maybe we could have even a work group or something to identify and discover and even prioritize some of the initiatives that are going on out there, that could be part of the portfolio that S&I tracks and contributes to, those are my recommendations.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Thank you, I think that's very helpful. I, even if there may not be explicit kind of coordination, certainly we are listening and the recommendations that came out of your Power Team last summer about transport standards, one of those was the last slide, just before the end, was to talk about RESTful interfaces. And the federal agencies that are part of the FHA decided this could be something that they could help and contribute to, and I encouraged them to do this in a way that would be opened and that would leverage some of the S&I framework activities. And I think that is one of the things that if not explicit, is certainly something that we consider as we think through the various problems. We are certainly paying attention.

But what you are suggesting is we need to make it more explicit, in terms of how we...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

We need to hold up our part in thinking about what we could directly suggest to S&I and I didn't see RESTful on your chart, so I thought...

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

We haven't officially launched it yet. It's on the Wiki at this point, it's sort of an early pilot, if you will, that we're working on. We're learning in the process about the best way to do this. Oftentimes we do what we call pre-discovery work, which allows us to figure out where an initiative fits into our portfolio, sort of that portfolio management piece. With the RESTful approaches, we didn't necessarily articulate that clearly up front, and I think we're in the process of doing that and it's becoming much clearer as to where it fits in our portfolio over the course of the time and effort. And probably I just need to update the slide, because...

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, that might be an example of where we've done exactly that, we've thought about what is needed here and made a recommendation.

John Halamka, MD, MS – Harvard Medical School

Though admittedly we are an advisory committee, you don't need to take our advice. But, if we could say you have 20 projects, we've prioritized 5, you chose 4, fine. It shows our formal influence. Five minutes, five comments, this is going to be tough.

Christopher Chute – Mayo Foundation for Medical Education and Research

Called me late in the rotation, it's hard to say anything original, but, I want to reemphasize and perhaps synthesize. There's been a lot of discussion about a national authority for standards, and it's, I think self-evident that such an authority, if ideally constructed, would comprise a Council, a representative Council or some kind of executive Council coupled with a deep technical form. Now HIT Standards Committee of course has Dixie Baker, maybe that's all the technical form we actually need. But it's plausible that a deeper technical form would be complimentary. And I'm simply reiterating the point that a tighter collaboration between the Standards Committee, and if you will, an extension of the Standards Committee in the context of the technical form into which something like the S&I framework structure might evolve, I think would address functionally the issues we need for national authority. Obviously, ONC oversees the whole thing because ONC is the only group that ultimately has, through HHS, regulatory authority. But the infrastructure and the tightening of those connections in particular, I think are going to be crucial.

John Halamka, MD, MS – Harvard Medical School

Thank you. John Derr.

John Derr – Golden Living, LLC

To long-term post-acute care...(indiscernible) very important...it's the only place where really that non-eligible...(indiscernible) and we start to talk about...a cornerstone for that effort and long-term, when we get into the longitudinal care record, then that type of integration is very important, too. So, I...this is the only place where all of our vendors and our providers get together to really come up with volunteer type things that we have to have, because we're not really in the legislation.

John Halamka, MD, MS – Harvard Medical School

Great. Stan.

Stanley M. Huff – Intermountain Healthcare

I would join with those that have suggested a US standards authority role, which I think could be a migration from S&I or maybe it's a little bit of a new thing. Given sort of this...that we're in potentially a transition sort of state, it seems like a good time to in fact maybe convene or organize a way of going through kind of the questions and saying what are...you know, what are our mission, goals, all of that sort of thing. The kind of thing I'm thinking about is that if you had that authority, we should make decisions about whether that's a standards-making body, a standards-adopting body, a standards-aiding body, that kind of stuff. Making principles and policies that say we...we've said these things but maybe not formalized them enough, we shouldn't adopt standards that haven't been implemented in a production environment, so we're not committing the country to do things that we don't know are truly feasible. You know, make statements about what's the scope. Are we adopting standards for the private industry, are we also coordinating and setting standards and obligating government agencies and departments to those standards? Do we also coordinate international activities? You mentioned that already, that you were talking and people view you as international. Maybe we ought to formalize the fact that, yeah, that's also a role of this group.

So I think in general what I'm saying is I think, I very much support the idea of a US standards authority, and I think we are at sort of a transition or a restart time, a resetting time which would be a great time to sort of formalize scope, principles. Let people know what this authority would do and what its work processes would be and what principles it works by.

John Halamka, MD, MS – Harvard Medical School

So based on the standards recommendation, Mary Jo, I do think we need a little bit more time for the discussion of these questions and now that we have teed them up, we've had an initial discussion, our next meeting in August will be virtual and a very good idea as you suggest. Rebooting is very popular in Hollywood this season, we can do it in the committee. Jim and Floyd.

James Walker – Geisinger Health System – Chief Information Officer

A comment on prioritization. With decreasing resources, the most important and scarce of which will be attention, and people whose attention is useful, prioritization will be so hard that it is unlikely that we will do an adequate job of it. And I think that one of the things, as Dixie and Chris said I think, is that to do really thorough prioritization, you are going to need an upfront body that is representative, transparent, and blah, blah, blah, and something like the Standards Committee. The other thing, is I think, you want to be very careful about your ability to cost account partial support and contracted support. It would be surprising if you were able to cost account and charge for those in a way that didn't keep you from achieving the core mission.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Good point.

John Halamka, MD, MS – Harvard Medical School

Floyd, final word.

Floyd Eisenberg, MD, MPH, FACP – National Quality Forum – Senior Vice President of Health Information Technology

Thank you. Just a couple of comments; I support all the other comments on a standards authority center as described by many of the commenters here. A couple of comments, though. I think that the thought that many of the things going on in S&I might be done, they're done to the level at which they were intended, but the depths of need is often deeper than that. So, we have to be a little cautious on what's completed, it may not be quite deep enough and so how do we get there. Looking at your questions, I fully agree with a longer time to really go through these. I might suggest, given goals and purpose for such an authority, we set criteria similar to what Dixie presented earlier with the NwHIN and it's based on reliability of the...and authoritative source of the kind of information we're looking for. The validity, the importance of trying to work on this standards effort and feasibility of getting it done and then use the same criteria to measure success of those efforts in S&I, or whatever this is.

John Halamka, MD, MS – Harvard Medical School

Thank you. Well, Mary Jo, let us return it to you for public comment, then very brief closing comments and we will adjourn.

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Thank you very much. Thank you very much, John. Operator, would you open the lines for public comment? And if you are in the room and you'd like to make a comment would you come to the table?

And I would ask all commenters to identify themselves and please stick to three minutes. Thanks very much.

Public Comment

Alan Merritt – Altarum Institute

If you would like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. If you're listening via your telephone, you may press *1 at this time to be entered into the queue.

John Halamka, MD, MS – Harvard Medical School

Okay, well let's start with Gary while we await for public comment from the phone.

Gary Dickinson – Centri Health

This is Gary Dickinson. I am a consultant representing Centri Health. I am a little bit baffled Doug, by some of the statements that you were making regarding the S&I framework. We worked...we toiled for five years in HITSP starting in 2005 and we had 17 vertical use cases that were developed under HITSP's

auspices in that time frame. And what we discovered in that process was that we were doing a whole lot of things that were really in common across those, but those were all set up as vertical efforts, as stovepipes. And when this S&I framework started last year, January of 2011, many of us had that same concern, that this was going off in vertical space where each of the initiatives was going to be relying on their own efforts to establish everything they needed within their realm to accomplish that. And we said again, we need have some...we need to defi...identify what the commonalities are across these initiatives, so we can in fact capture those, bring those into some kind of a repository so that they can in fact be reused over and over again by initiatives going forward, and by those who wished to take the existing initiatives and repurpose them in ways that may be specific to their particular implementation needs.

Okay. So in March of 2011, we put together an S&I simplification, at that point it was called S&I use case simplification. More recently we've simplified the name of it to call it S&I simplification. But if you go to the S&I Wiki, under the cross initiative on the left side, under cross initiative coordination we have simplification sitting right there. And we have gone through an extensive, elaborate effort to identify the commonalities across the initiatives that are in place today. And to catalogue and to componentize the aspects of those initiatives starting with requirements, looking at the scenarios, looking at the actions that are taken within the events and the actions that are taken within those scenarios.

Looking at the common data objects and the data elements that are being used across the initiatives; looking at the actors, the roles of participations. That is all catalogued very carefully. We haven't gotten through everything yet because it, in part, is a retrospective process. We are in the process now of bringing this to a concurrent review mode with some of the newer initiatives, so that in fact they are beginning to use had this repository.

The initial consensus on the simplification, what we call the core matrix, was achieved last summer and USHIK, under the auspices of ARC, has taken those components and incorporated those in USHIK. So there is now a repository of those components and when we get to the next stage of consensus on this, which we will do next month, we will in fact incorporate version two of all of those into USHIK. And this seems like a perfect opportunity to take this and use this as a vehicle to build on for not only the initiatives that have been identified here, but initiatives that may be upcoming. And in fact, for the broader community outside the healthcare industry to be able to use these things that have been so carefully developed and devised by these efforts for purposes of implementations. And I struggle to understand why this is not a centerpiece of what S&I is about and how S&I should be proceeding forward. Thank you.

John Halamka, MD, MS – Harvard Medical School

Great Well thanks. And certainly, Gary, as you finish up that next iteration, we will make that available to the committee for viewing. And Michael Fitzmaurice has long been a friend of the committee, and I know he's involved. Well, are there any comments from the phone.

Alan Merritt – Altarum Institute

Yes, we have a comment from Shelly Spiro, with pharmacy eHIT collaborative.

John Halamka, MD, MS – Harvard Medical School

Please go ahead.

Shelly Spiro – Director, Pharmacy e-Health Information Technology Collaborative

(Indiscernible), is that better? I'm sorry. My name is Shelly Spiro and I'm the director of the Pharmacy e-HIT collaborative representing, over 250,000 individual members of the majority of the national pharmacy association and key pharmacy organizations involved in health information technology. In Jodi

Daniels' presentation, she mentioned drug-monitoring program. The pharmacy e-HIT collaborative participated in the prescription drug-monitoring program in workgroup activities. In addition, the Collaborative members participated in the long-term, post-acute care and behavioral health initiative, providing medication related and electronic prescribing expertise for these practice settings. Pharmacists play an integral role in the inter-professional health care team in providing medication related patient care services, outside and in conjunction with the prescription dispensing functions. Hello? Okay, sorry.

Through the pharmacy eHIT Collaboratives' work, the pharmacy industry has a road map. This road map we can make available to the HIT Standards Committee. The road map outlines goals, objectives and strategies for pharmacists to adopt and implement the meaningful use of the electronic health record.

Pharmacists are trained through their access to patients and are in a unique position to assist in engaging patients in their health care. Over several years the Collaborative and its members have been working with the National Council for Prescription Drug Programs, NCPDP and HL7 on standards that will assist pharmacists in standardizing electronic documentation of pharmacist provided patient care services.

One such standard is a joint project between NCPDP and HL7 that will be balloted this fall for a standardized medication action plan, which is a structured document implementation guide for pharmacy system vendors. This structured document contains a reconciled med list, indications for each medication and special instructions. The standard document follows the HL7 standard for the consolidated CDA and can be shared with any certified EHR or PHR through a health information exchange or e-Prescribing network. This is due because effective January 2013, this medication action plan in manual form is a Medicare part D regulatory requirement for providers to hand to their beneficiaries, after their annual comprehensive medication review. Having this medication action electronically, using the structured document will help engage patients with technology and allow meaningful users of the electronic health record with the ability to obtain a consolidated CDA structured document with an active med list reconciled by a pharmacist. Thank you.

John Halamka, MD, MS – Harvard Medical School

Thank you very much for the comment. John Derr.

John Derr – Golden Living, LLC

We did hand out her road map at the last meeting, plus I talked to Jodi to put her on the roundtable.

John Halamka, MD, MS – Harvard Medical School

Thanks. Are there any other comments on the phone?

Alan Merritt – Altarum Institute

We have no further comments at this time.

John Halamka, MD, MS – Harvard Medical School

Great. Well thanks very much. So again a rich discussion. I thank certainly all of you for traveling to Washington in July. We will have a virtual meeting in August, correct, Mary Jo?

Mary Jo Deering, Ph.D – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor

Yes.

John Halamka, MD, MS – Harvard Medical School

And we will continue the discussion of the S&I framework with all the valuable feedback you provided.

So with that, we are adjourned. Thank you.

Public Comment Received During the Meeting

A suggestion for public input on test scripts, test tools, etc. would be to ask all companies with a 2011 Edition certified product to respond.