



HIT Standards Committee Final Transcript December 10, 2014

Presentation

Operator

All lines are bridged.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you, good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Jon White?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jon. John Halamka?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Here.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Andy Wiesenthal?

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Andy. Anne Castro?

Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Anne. Anne LeMaistre?

Anne LeMaistre, MD – Senior Director Clinical Information Systems & Chief Medical Information Officer - Ascension Health

Present.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, Anne. Arien Malec? Marty Harris?

C. Martin Harris, MD, MBA – Chief Information Officer - Cleveland Clinic Foundation

Present.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Good morning.

C. Martin Harris, MD, MBA – Chief Information Officer - Cleveland Clinic Foundation

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Charles Romine?

Kevin Brady, MS – Group Leader, ITL Interoperability Group - National Institute of Standards and Technology

Kevin Brady for Charles Romine.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Kevin. Cris Ross? David McCallie?

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

Here.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, David. Dixie Baker?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Dixie. Liz Johnson?

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

I'm here, good morning.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, Liz. Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Eric. Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Floyd. Jamie Ferguson?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente

Here, good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Good morning. Jeremy Delinsky? John Derr?

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

Here.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, John. Jon Perlin?

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Good morning. Keith Figlioli?

Keith J. Figlioli, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc.

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Keith. Kim Nolen?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Hi, Michelle, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Kim. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, this is Leslie, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Leslie. Lisa Gallagher?

Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy & Security – Healthcare Information & Management Systems Society

Here.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Good morning.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Lorraine Doo? Nancy Orvis? Becky Kush? Sharon Terry? Stan Huff?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Here.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Hi, Stan. Steve Brown?

Steven H. Brown, MD, MS – Director, Compensation & Pension Exam Program (CPEP) – Veterans Health Administration

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Steve. And Wes Rishel?

Wes Rishel – Independent Consultant

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Good morning, Wes. And with that I will turn it over to Jon White who I'm sure all of you have now noticed is our Acting Deputy National Coordinator. So Jon, I'll turn it over to you to make a few comments.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Well, thank you, Michelle and surprise, everybody, hi, I just want to say that I am just honored beyond words to be able to work with you all. I'm pleased as can be to be at ONC as the Acting Deputy National Coordinator. Of course many of you know me from our long experience together as the Director of the Division of Health IT at AHRQ, but I am now on a fulltime detail to ONC supporting Karen DeSalvo and Michelle, and Steve Posnack and all of the other amazing people at ONC.

So, delighted to be looking forward to our work together. I will just mention very briefly that you've got a great agenda lined up for the day that all of us at ONC are very excited about the release on Monday of the Federal Health IT Strategic Plan draft for public comment. Already have started getting some great comments some from members of the committee who saw me in a meeting yesterday. And, you know, I love the engagement and I love the enthusiasm and looking forward to making it...building on top of what we've got and making it better than it is.

On just a very small personal note, I do want to mention, since everybody spent a fair amount of time on this over the past year, that a 2014 JASON Report was released last week at AHRQ. I was the project officer for both of those reports. And this year's report builds on the previous year's report and says, you know, what there has been a lot of great progress in terms of interoperability. They're particularly excited about FHIR. They continue to advocate for the use of APIs.

I'm also pleased to point out that some of the members of this committee were briefers this year. So thank you very much for your time and effort in that and looking forward to carrying the cause ahead and with that I will close my comments. Thank you, very much.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, Michelle, does that mean that I get to run the agenda?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It does, thanks, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well so first welcome to Jon White. All of us have worked with Jon White at AHRQ for many years and Jacob's shoes are hard to fill but Jon White is the guy to fill them. Of course he's got that title "Acting" so, you know, Michelle whatever we can do to remove that "Acting" would be delightful, only if he wants to.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

You're very kind. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Welcome, Jon. So, today as Jon said, we do have a number of important items on the agenda. As I think you probably all saw the Federal Health IT Strategic Plan draft was released with its 14 objectives and five broad goals. And remember this is not the interoperability roadmap, but this is the set of broad goals across 35 federal agencies that is going to provide that foundation for what will be the interoperability roadmap that's going to be coming in 2015.

So, in a sense, I think of the Federal Healthcare IT Strategic Plan as strategy and the interoperability roadmap as tactics. So, I think they dovetail very well together. And of course this group will hear about them as yesterday the Policy Committee heard and there will be an opportunity for Standards and Policy to work together to offer comments and potential revisions to the Healthcare IT Strategic Plan.

In fact, Michelle, I believe that after we hear Seth and Gretchen's discussion there is going to be this notion of we have to pick two liaison members from the Standards Committee to join the HIT Policy Committee's Strategy and Innovation Workgroup to provide comments on that plan.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yes. Thanks, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, I think, you know, no one has been chosen yet, but, you know, just keep that in the back of your mind we do have to choose some representatives to be the cross Standards Committee/Policy Committee liaisons for the discussion of that plan.

So, we'll hear that and then Dixie Baker and Lisa Gallagher will give us an update on the Transport and Security Workgroup and there are a set of recommendations there on when to use two factor authentication and what two factor authentication to use, and what NIST standards should be used when evaluating strength of authentication and those sort of things. So a rich discussion that will also result in after our discussion and debate we'll ask for a vote to...as we usually do, to recommend that their recommendations go forward to ONC as ONC then will incorporate them into its future regulatory activities.

Then we'll hear from Jonathan Coleman on the Prescription Drug Monitoring Program some of the challenges that clinicians face across the country in using it, some of the potential opportunities for standard enhancements that would improve workflow and would foster adoption. And so really an interesting body of work which includes things like single sign-on and patient context management to link EHRs and state run prescription drug monitoring programs seamlessly. So look forward to that.

Then Steve Posnack will tell us about how our committees can come together and contribute members to two Task Forces, looking at the S&I Framework and data provenance initiatives, and then he'll give us an update on certification. So all good things.

And I understand that, just based on the timing of our discussions in December, and what will be on the agenda in January, January may also be a virtual meeting but then in February likely we would have an in person meeting and potentially even a joint meeting with the Policy Committee and that's still to be determined just because of the richness of what should be ready by February, the revisions to any of the strategic plan drafts plus any of the interoperability roadmap, you know, activities that need to be discussed those sorts of things.

And last comment I'll make before turning it back to you Michelle is some of you may have seen the HL7 press release on this Argonaut project. And I just want to make sure everybody on this call knows that Argonaut project is actually something very, very simple. Chuck Jaffe, in looking at the JASON Reports and the JASON Report Task Force Report, Jon White mentioned the 2014 report, which is quite good, said, you know, there's a number of activities in the JASON Report and Task Force response that require HL7 to accelerate some of its work and therefore some additional funding is necessary to accelerate that work.

So he called us and we kind of passed the hat around a whole lot of stakeholders just so that HL7 could have some funding to accelerate work in support of the JASON Task Force and the JASON Reports. So in kind of a cute marketing way, we said, oh, anybody who provides additional support to HL7 for their JASON work must be an Argonaut. So, you know, more to come on that but it is not a new organization. It is not any kind of new competitive initiative to the data access framework and the S&I activities or to the Stan Huff and other groups led HSPC work, all that work continues on. It's purely an acceleration effort.

So, in 2015 we get some of those foundational components that will help the JASON Task Force recommendations be a reality and maybe even enable ONC as it considers future regulatory improvement to incorporate some of the new work that once it's mature, per Dixie Baker's maturity framework, that it could be part of our EHRs in the future. So there you go. So, Michelle, let me turn it back to you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks, John. I'm going to turn it over to Seth and possibly Gretchen to walk through the Health IT Strategic Plan.

Seth Pazinski, MS – Director, Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

Hi, thanks, Michelle. This is Seth Pazinski. And I'm just going to provide some highlights of what's in the Federal Health IT Strategic Plan and then we'll open it up for any comments or questions that the committee members have.

So, first, I think, I just want to acknowledge all the federal partners that helped in developing...there were over 35 different federal entities from HHS and also outside of HHS who contributed over a series of months to the development of the document that we released on Monday. So, just wanted to acknowledge and thank them for their efforts in helping get to this point. And we can go to the next slide.

So why does ONC publish a Federal Health IT Strategic Plan? As a part of the HITECH Act requirement that established the duties of the National Coordinator one of the requirements is to update and republish a plan periodically. Our last plan was published in 2011 and ran through 2015 so a good time for us to make an update as well as reflect all that has happened with regards to the adoption of EHRs in hospitals and eligible professionals over the past several years.

One important note that's actually required in the statute from a process stand-point is that the plan must be updated in collaboration with the federal partners as well as the private sector. So the draft that was sent out on Monday represents the first part of that. So that's ONC collaborating with federal partners in the development of the plan.

That draft has a benefit of engaging the private sector and that's what we essentially kicked off yesterday with the Policy Committee and are continuing today is the two pieces of that will be engaging our federal advisory committees to get feedback from recommendations related to the draft as well as having an open public comment period which ends on February 6th.

And as far as what we're hoping to get in feedback from the federal advisory committees is, you know, if we need to shift strategic direction areas to identify those, to refine and get clarity around priorities particularly, also to help frame what it is that the federal government needs to do versus what is better left for private industry to do and then identify any gaps that people feel we have missed in the plan.

And a couple of just important notes on scope. So it is a Federal Health IT plan so not just ONC but broadly representative of all the federal entities that participated in its development. And the other piece to note is it is focused on federal activities. So it doesn't talk about what the private sector will do.

And I think part of the conversation over the next several months will be certainly, when the conversation gets into implementation and gets focused on the interoperability roadmap, it will talk more about that fuller picture of what both the the feds and private sector will do. We can go to the next slide.

So three key sources for input on the Federal Health IT Strategic Plan, so the first group was the Federal Health IT Council. So, this is a group of internal federal agencies that was established in May 2014 with the kind of charter to coordinate federal health IT policy decisions as well as provide a forum for discussing program alignment. And the first charge to this group was to update the plan and that's been the focus of a series of meetings with federal partners from May until the release of the plan.

The next phase, which is what we're entering now is to work with the federal advisory committee, specifically the Strategy and Innovation Workgroup under Policy Committee to get feedback, which we're asking for by the February Policy Committee meeting.

And then finally, public comments which again are open through February 6th and one other thing to note is, you know, there's a number of reports and plans, and strategies that have already been published that reference or are specifically about Health IT and John was speaking about the JASON Report in the beginning. So, we took a look at a number of plans as far as inputs into coming out with this draft strategic plan. We can go to the next slide.

So this is just a list of all the federal entities that were involved in the Health IT Advisory Council and that have made contributions into the draft plan and there are also, as you look at the roles, different agencies are going to play, you'll see them listed throughout the plan in the different objective and outcome areas.

And so these are all the members of the advisory council and I think, you know, one of the things to note here is just a broad perspective that this gives to the plan. You know the federal agencies listed here are purchasers, regulators, users of Health IT; they pay for care and provide direct patient care, protect and promote community health, as well as invest in infrastructure and Health and Human Services and finally, develop policies and regulations related to advancing science and supporting research.

So, I think also of note is that while a number of folks on this slide have been longtime partners of ONC there's also some kind of newer entities that folks may have not have seen before. We can go to the next slide.

So, high-level what, you know, does the Federal Health IT Strategic Plan aim to do? It aims to kind of signal three key points so one is a focus on improving health which is inclusive of but not limited to the healthcare sector. Also about advancing Health IT beyond EHRs and looking broadly at federal levers for incentivizing the adoption and use of Health IT as well as exchange of electronic health information through policy levers beyond the Meaningful Use Program. We can go to the next slide.

So this is a kind of high-level overall framework of the plan. It's intended to reflect the collect, share and use of electronic health information. So, the first part, the collection being about the adoption and continued expansion of Health IT and I'll highlight a couple of key areas within each of these goals.

So the first goal around adopting Health IT, the key points there are that it's about continuing the Meaningful Use progress. It's about broadening the focus of providers to include ineligible providers like behavioral health and long-term care. And then finally it's about broadening technology focus to be inclusive of telehealth, which was a priority identified by a number of federal agencies.

So the second part there, the share, this is really reflecting the vision paper that ONC put out on interoperability. So, this is about advancing the secure and interoperable health information and so it provides some of the high-level framework that was reflected in the building blocks so standards, certification, governance of health information exchange, as well as business and regulatory drivers and privacy and security.

The next three goals are all really about the, for what of the plan, so, you know, what is the Health IT and the exchange of information for. So, the first goal being about improving and strengthening the healthcare delivery system. So that is largely focused on the delivery system reform efforts and Health IT supporting that, but also signals a movement towards a focus on population health and looking at incorporating home and community services and supports into that infrastructure.

And the fourth goal is about individual and community health. So here, we deal with consumer access and generation of health data as well as advancing assistive technologies like sensors and other things like that, and finally also public health.

And then the final goal is about advancing research and there's a couple key points here, so a focus on providing usable open federal data sets while protecting privacy, patient-centered outcomes research, as well as advancing technology and analytics, and then finally continued study and learning on how Health IT can best be used to impact health outcomes. We can go to the next slide.

So, this is just the broad vision and mission of the program. So, health information being accessible when and where it's needed to improve and protect health and a mission consistent with the three-part aim of improving health, health care and reducing healthcare costs. We can go to the next slide.

So, these are just some broad principles that are reflected in the plan. These are intended to be guides as the federal government moves into implementing the strategic plan. You can go to the next slide.

So, as folks dive into the plan itself, you'll notice that under each of the objectives there's specified 3-year and 6-year outcomes and there is kind of a list of alphabet soup under each one of the outcomes that identifies what the particular federal agencies are that are making or plan to make some sort of contribution improving that outcome.

And so what we anticipate as the next step as we both kind of look to move into the interoperability roadmap discussion but also in following up with the next phase of internal discussions with federal agencies is identifying the specific metrics and milestones related to individual agency contributions to each of those outcomes. So you'll see agencies identified in the plan related to the specific outcomes. We can go to the next slide.

So this is kind of what to expect next as we over the next several months both continue the conversations with the committees to get feedback on the current draft of the plan but also start to work with our federal partners in identifying specific agency contributions. We can go to the next slide.

So this next slide represents the questions we've specifically posed to the committees and will be the focus of the Strategy and Innovation Workgroup as they deliberate in reviewing the plan. So, you know, does the plan address a broad vision for improving health? Are there any gaps that would require federal action in order to solve? And then finally are there any gaps or strategies that are better addressed by the private sector?

And as John noted in the beginning of today's call, we're also looking to have some of the...a few of the Standards Committee members join that Workgroup to bring that perspective to those discussions. We can go to the next slide.

So, this is just a couple of anticipated next steps so folks are aware of the dates. So, we released the plan on December 8th and actually there is an error on the timeframe for the 60 day public comment period. It actually ends on February 6th not February 5th.

And then finally we anticipate the Policy Committee bringing back their feedback and recommendations to ONC at the February Policy Committee meeting. Next slide.

So, here I will just pause and open it up for any members who want to share perspectives, if they've had a chance to take a look at the draft plan or ask any questions. And one of the things I would suggest for consideration is if there are specific areas that you want to stress as important for the Workgroup to spend some time diving in on, you know, it is a broad strategy that covers a lot of areas. So, if there's anything you think that are particularly important to focus on and that would benefit from further clarity from ONC we'd love to get that feedback as well.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, thanks very much and I would just encourage the folks on the phone to read through that plan. Michelle, if you could maybe send out that URL or the PDF just so everybody has the opportunity to look at it and focus on page eight which has the five objectives and has the 14, excuse me the 5 goals and the 14 objectives on it.

And as we just heard, it's expanding Health IT, advancing interoperability, strengthening delivery, advancing the well-being of individuals and communities, and then advancing research scientific knowledge and innovation. So, very much aligned with the triple aim and certainly would like to open it up to questions and discussions from the committee if you had a chance to look at those goals and objectives.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

John, Leslie Kelly Hall is in the queue and just a reminder to folks if you want to use the hand raising feature, John and I will work together to call on you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good, well Leslie, go ahead?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, thank you very much for the presentation and it's great to see the strategic plan with so much emphasis on interoperability. And I'd like to remind the work about the definition of interoperability put forward by ONC which includes all stakeholders of patient's access to information and the ability to provide input to make informed medical decisions.

And this idea of collaboration and shared decision-making I think is one that crosses all the federal agencies and is a key principle for ONC to promote. So I would just like to make sure that that is front and center. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Thank you. Are there other folks in the queue, Michelle?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

There are not.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Hi, this is Eric, sorry, I'm joining by phone so I couldn't electronically raise my hand. But, I read the report yesterday and it was refreshingly non-platitudedness. It was a really substantive piece of work so I want to congratulate the ONC staff on that.

There were two things I was wondering about. I'm not sure if I saw in there, one is usability, advancing Health IT usability and the second was workforce development and are those in there somewhere?

Seth Pazinski, MS – Director, Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

Yes. So the workforce piece is reflected on page 10, under the...so it's a part of the expanding adoption component of the plan. Although obviously the workforce piece and the skills there are cross cutting into, you know, the sharing of information as well.

But specifically it's reflected under the strategies, under objective 1 A. And then the usability piece is reflected under actually the next objective, so objective 1 B, which is on page 11. So, as you look at...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Yeah, that's the Health IT safety bit, right?

Seth Pazinski, MS – Director, Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

Yes. So, the...so, yes that section is both reflective of kind of safety and usability.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Other comments from folks who may not be able to raise their hands? Wow, Michelle, it's a quiet group today. It must be because I forgot to get their approval for the minutes that they're so quiet. I will do that in a moment I promise.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Oh, that was my fault for not telling you either, I'm sorry, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yeah, okay. So, I realize that folks...you know, this was a lot to digest and probably some of you haven't had the opportunity to read through the plan.

But, just as Eric raised the issue, you know, are there things that you think are gaps and this is a strategic plan. It's not tactical so that it doesn't enumerate every potential thing that we might do to be responsive to the JASON Report or other innovations that are happening in the marketplace.

But, I think as Eric states, it's thematic. And certainly as we thought of the Meaningful Use Program as Stage 1 being adoption and Stage 2 being interoperability, and Stage 3 achieving a learning healthcare system and use, I mean, it's following that same kind of construct in its general layout.

And Jon White, one of the things that Jacob always reminded me is, ONC does not equal Meaningful Use. So, I only mention Meaningful Use as historical context.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

I'm grateful to not have to say that myself. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay. So, before we go on to the approval of the minutes and then other agenda items, any other final comments on the process?

I mean, I guess I did note that we will have to choose two members. And Michelle, is there any specific process that you guys would like? Do you want individuals to self-nominate? Are you just going to huddle at ONC? Any thoughts on that?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

We were thinking that we would possibly use our new Steering Committee, which hasn't kicked off yet, to help us identify those two folks. But if there are people who are interested and want to self-nominate they can send me an e-mail as well.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Because, I realize it is often the case that we ask much of the people on this call. For example, every time we form a new Task Force, Dixie Baker chairs it and so we want to of course spread the wealth here and I think that's a great idea. If you send Michelle a note that you would be willing to serve as a liaison to the policy group for the discussion of the strategic plan then the Steering Committee can review those who self-nominate and then make recommendations.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And speaking of Dixie Baker, she's in the queue, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good, Dixie, please go ahead?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm either volunteering to participate or lead, but I do have a question. The question is, how this relates to the roadmap. Because you said that this is strategy and the roadmap is more tactical but the roadmap has already basically been developed. And so that's kind of the first part is how that whole...how does the roadmap come out of something that existed after the roadmap was put in place?

But, secondly, I would suggest that the...and I don't know exactly how this could be done but somehow I think that people who are participating in the roadmap activity are also participating in preparing the responses, if that's possible.

Seth Pazinski, MS – Director, Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

So, sure, this is Seth, happy to offer a couple points as far as how the plan and the roadmap relate. So I guess as far as, you know, how are they, you know, how is the plan and the roadmap being developed, you know, at the same time, I think, so one, there is a lot of, you know, overlap from, particularly the federal perspective on the individuals who are contributing kind of the...to both the development of each of those pieces and also, you know, the federal clearance process takes a while. So the document has been drafted for a little bit of time yet as it's kind of worked its way through the clearance process.

But a couple points on how they're different. So the plan has a broader focus in that it is specifically related to adoption, you know, that's not really a component of what the interoperability roadmap is looking at, that's, you know, focused predominantly on the sharing of information. So a little bit of a broader focus there and then also the scope as far as whose activities are reflected.

So the federal plan is really just about the federal activities and the interoperability roadmap is intended to be a shared conversation. So to also articulate kind of, you know, expectations and roles for the private sector which the federal plan does not address.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, good answer, Seth, you know, I recognize the clearance process takes quite a long time. And as you have 35 federal agencies working together each needs to touch the document, but, what I had certainly heard...ah, sounds like we've got a fax machine calling us here. Can folks still hear me?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes, we can hear you, that was...

W

Yes.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So what I had heard from both federal folks and industry folks was there was a sense, Dixie, that because this general strategic plan had been circulating in concept for a while that the interoperability roadmap really built on the strategic plan.

So, I know it sounds like a chicken and egg issue, but really the intent is that the interoperability roadmap gives us an execution framework for the kinds of principles that were laid out in the strategic plan.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay. I'm glad I asked the question because that's useful to know. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Any other comments? Okay. Well, thanks very much Seth for that and we look forward to getting you a couple of folks who will volunteer to be the liaison to the Policy Committee's Strategic and Innovation Workgroup and get all those comments and then hopefully in February we will all get together and listen to those comments and then get the plan finalized. And so...

Seth Pazinski, MS – Director, Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

Thanks.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, I heard a comment?

Seth Pazinski, MS – Director, Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

Oh, sorry, that was just me, I was saying, thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, thank you. So, Michelle, why don't we, before we move on to Dixie's presentation, ask if there are any edits or amendments to the minutes of the November 18th meeting?

Okay, well then none being heard, Michelle, why don't we by consensus, say that those minutes are approved.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks, John.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And then Michelle, back to you and we will hear from Dixie.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, well, thank you, John and I'm going to just turn it right over to Dixie.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay, thank you. And Lisa is in a conference in DC, an mHealth conference, HIMSS, and so she warned us that she would be calling in from a very noisy place, but she is participating and if she hears anything that, you know, that she needs to correct I hope she'll do that even though it is noisy.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you, Dixie.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

But, I'll be presenting it primarily. Yes, did I hear something?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

This is Lisa. I said, thank you.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay, all right, and today we're presenting the Transport and Security Standards Working Group recommendations on user authentication as that was framed by the HIT Policy Committee. So, next slide, please.

Okay, as I mentioned, this is based on recommendations that we received from the HIT Policy Committee and specifically they came out of the Tiger Team recommendations around...somebody is faxing. Some of the recommendations...the recommendations really spanned about a year and they came out of the Tiger Team.

One of those recommendations was to move toward multifactor authentication and that's the level of assurance level 3, they cited specifically in the recommendation, for provider remote access to protected health information. You'll recall that we discussed, in this committee meeting earlier, a couple months ago how about the ambiguity around remote access of protected health information.

In this case we're talking about multifactor authentication, basically under circumstances that need stronger authentication. Multifactor authentication first of all authentication means presenting evidence that you are who you claim to be and you have identification which is your login ID and then the authentication is what you present as proof that you are who you claim to be.

And authentication takes three forms, something you have, something you know or something you are. Something you know is most common, a password or a PIN. Something you have is like a hard token of some sort or a smartcard and something you are is like a biometric. So, those are the three types of authentication.

The LoA 3 is defined in NIST special publication 800-63 and we've discussed level of assurance in this committee before. But level of assurance, one of the requirements as defined is to use more than one of those three types of authentication. So, the multifactor are not like two passwords but two of the three types of authentication presented.

The second recommendation is to continue to identity proof providers in compliance with HIPAA. Identity proofing is what you do when you give somebody an account to begin with to prove that they are who they claim to be.

And third is to continue to be informed by the NSTIC, the National Strategy for Trusted Identities in Cyberspace, that we've discussed quite a number of times in this committee.

And finally, to engage with NIST and the NIST initiatives to help align the direction in consumer identity proofing and authentication and the use of third-party credentials with the needs of the healthcare industry. Next slide, please.

The Transport and Security Working Group heard from a number of people as input into the recommendations we present today. The first we heard from the Georgia Tech Research Institute that talked about Trustmarks, which are a kind of componentization of the components that went into...that go into a level of assurance.

So instead of having a strict level of assurance that include this type of identity proofing, this type of authentication and this type of protection of your authentication data, all bundled together as a level of assurance they componentized policy and technical components that can be matched and bundled together to create a particular level of assurance. So they presented that work to us, which was quite interesting.

We also heard from the OpenID Connect about OpenID Connect, which is a standard for federating authenticated identity. And the third, we heard from OAuth 2.0 which really addresses authorization and really feeds more into our next Workgroup task than it did into just authentication.

And finally we heard from NIST about new directions. They're in the process of really re-architecting 800-63 and the new direction is very much aligned with what Trustmark presented to us which is the componentization of these different factors that go into authentication, individual authentication. So, next slide, please.

The current...we looked at the current edition, 2014 edition, of the EHR certification criteria and standards to see what it said about authentication. And really all it says about authentication is to verify against...that the EHR technology needs to demonstrate that it can verify against a unique identifier that a person seeking access to electronic health information is the one claimed.

So, the recommendations we're presenting today are both responsive to the Policy Committee's charge that they gave us, but are also intended to strengthen what exists currently in the EHR certification criteria. Next slide, please.

First, we have three slides that we'll present in our recommendations. First, we saw, as we looked at the 2014 edition, there seems to be a couple of gaps. And one is that there is no requirement to continuously protect the information that is used to authenticate users. For example, passwords. If you store passwords in the clear in your machine then that's not going to...that's not going to really provide you strong authentication.

So we think that to strengthen what currently exists in the certification criteria, we suggest adding a criterion that says that the EHR technology be able to continuously protect both the integrity and the confidentiality of the information used to authenticate users.

And we refer to the standard that already is in the criteria for integrity protection and encryption and you'll see the citation right in there, that's the FIPS 140-2 Annex A which lists algorithms used for authentication and integrity protection.

Secondly, we recommended adding the criterion if passwords are used for user authentication that the EHR technology be capable of accepting only passwords that meet the guessing entropy guidelines that are in NIST 800-63 version 2. And entropy is just a measure of how difficult it is to get those passwords. Next slide, please.

To enable...this one is directly responsible...this recommendation is directly responsive to the Policy Committee's policy request and that is to enable EHR technology to be certified for having implemented multifactor authentication. So you'll notice that...or I would remind you that EHR technology today is certified as modules. So a vendor or EHR developer can choose which criterion they have their technology certified against.

So this criterion would be applicable to the technology that presents itself as being able to do multifactor authentication. And this would enable them to get that technology certified that it does indeed provide multifactor authentication.

So we recommend adding this criterion, this certification criterion, that EHR technology that's presented for certification be able to restrict access to the system or to one or more individual functions within the system, such as prescribing controlled substances, which does require multifactor authentication, to only those individuals who have presented at least two of the following three forms of authentication and these are those that I reviewed earlier, knowledge of a secret, possession of a physical object or a biometric. Next slide, please.

And then the final are more recommendations for ONC itself. The first recommendation is to continue to support the NIST effort to revamp NIST Special Publication 800-63 version 2 and to closely follow this move from level of assurance to componentization of trust and recommend appropriate identity proofing for query-based access.

The second one is to consider the data segmentation for privacy for authorizing access to behavioral health, which the Workgroup will address later in the work plan. And then the final one, but it was responsive to some of the recommendations from the Policy Committee.

And then finally, to track the development and piloting of the user managed access profile or more commonly referred to as UMA of OAuth 2.0 as a potential standard for consumer consent. And by the way back on that other slide, we did hear from the Workgroup Chair of the UMA Profile Development Workgroup. So, that's it. Are there comments?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, Dixie, thanks very much, I will start off with one question. Sometimes as we try to implement two factor authentication people tell me, biometrics are a challenging form of a second factor because it's hard to revoke and that is, you know, if a person is no longer part of your organization or is a bad actor, or whatever, I mean, I realize this is a little strange example, but, you know, you can't remove their thumb. So, any comments you have heard on what people say is, hey if you have a token you can revoke that but a thumb you cannot?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Not exactly like that, but as I recall and maybe Lisa can correct me here, I think the version 1 of 800-63 said that the biometric could not be the second form of authentication. But that's a good point. You know it would at the very least take drastic measures to remove them from you, but at least you can remove from the system.

I guess this is the real answer to it, what you remove from the system you don't remove the thumb from the system. What you remove from the system is the hash of the fingerprint that would be stored in your system. So it would no longer be in your system or it could even be stored in your system as something not to accept as a form of authentication.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And of course, you know, probably because we watch too many mission impossible films the idea that you could lift the facsimile of a thumbprint from, you know, a glass and then use that as an authenticator, I mean, my understanding of current technologies such as what is used today on the iPhone, it is thermal. So, really it's only living tissue that would be used to have that particular pattern.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, I only raise this because it is certainly very easy to issue a token, revoke a token, deal with other kinds of adaptive authentication, but if somehow your biometric credential is stolen than it is quite hard to revoke that. Good. Well, other questions in the queue, Michelle?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

David McCallie.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, David?

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

Yeah, just a comment on your last question before I ask my question is I think that, you know, the mere possession of the token does not mean that you have the right to actually use the token. The system should validate that the token is still considered an authenticated token. You would really like to know exactly who's trying to get into your system based on a biometric if you don't want them to get into your system. So whoever proposed that problem doesn't understand how to do things, I don't think. So, I don't think that's going to be a big issue.

But, my question for Dixie is, the proposal to add multifactor authentication was that...did you target that to every authentication inside the system, remote, etcetera or was...in other words the discussions that we've had in the past about limiting it to so-called remote access, it sounds like you are removing that and saying that any excess should go through multifactor. Is that correct?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

No, no, we're not addressing policy at all. When you use a particular, any particular authentication capability in certified EHR technology is policy not technology.

We're addressing only the technology and the certification of the technology to be able to do multifactor authentication should the organization that purchases the technology decide that under particular conditions that they define they would like to have those require multiple factors.

This just addresses the certification of the technology to be able to do that should the organization choose to configure it to support that policy.

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

So, that's a good clarification. But that would mean that the system should be able to do that at every possible access point?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

No, it would be up to the organization that presents it for certification. In fact, that's the way we worded the requirement that it could either be...for example if it's an EHR technology whose sole purpose is to do prescription of controlled substances or a module that does nothing but prescription of controlled substances, you might say okay, to authenticate to this module everybody must be multiply...must be authenticated using multiple factors.

But on the other hand, if the module that is presented for authentication includes a function within that module for prescription of controlled substances and I'm just using that because there's a law that requires multifactor authentication, as one function within the module then that EHR vendor might choose to just require the multi-factors when the user gets ready, you know, requests...tries to prescribe a controlled substance then the system would come back and say, well, before you do that you have to present multiple factors. So, it's up to the vendor how they implement it.

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

Okay, it's just...the question is along the lines of whether every time an authentication event could occur must the system be capable of multifactor?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, of course, yeah, it's capable, but that doesn't mean that you know...I mean, you're a technologist just as I am, you configure systems to do the functions that you want them in your operational environment to perform. But lots of technologies that you and I use every single day isn't...we don't use every single function that's there nor do we even turn it all on.

But whether the organization chooses to use authentication...to require multiple factors to authenticate for either the system or the individual function would be up to the organization.

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

No I understand where the organization has choice in how they deploy. The question is certification of a particular module there may be multiple points of authentication and re-authentication in the use of that module.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right.

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

Would way you worded your recommendation require that every single one of those authentication points, at least in theory, be capable of multifactor...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

No, no, just like any other module. The vendor goes to have it certified and says, here's my module, these are the criteria I want it certified against. And what we tried to achieve here was to say that if a vendor wanted their technology to be certified for multifactor authentication they would be able to present it with either/or both perhaps capabilities to either certify that that module always required, you know, use...require multifactor to authenticate to the module itself or that module included functions within it that would require multifactor authentication.

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

Okay. I'm still confused but we should take it off-line.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I think you're addressing a policy question not a technology question. This is...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, let me try to frame this in a way that I think would answer both Dixie and David's questions, which is imagine that an EHR has a mechanism of inserting dictation. You use your iPhone to dictate a note that might not be capable of a two factor authentication. I mean, it's the insertion of a note. Whereas ePrescribing system for controlled substances not only is capable but will only be certified if it has the capacity to do two factor authentication. Is that fair?

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

Yeah and the use case I was thinking of is, you know, sometimes the system might authenticate when you first log in with multifactor, but then while you're doing your work if the system temporarily times you out, you can re-authenticate with just a PIN and not go through the full...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right that's a different function David. Re-authentication is a different function from initial authentication.

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

Well, that's kind of my question.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Oh, it is that's a different...

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

And I guess that's a different way to pose the question. Does every point at which an authentication occur have to have multifactor? And I think your answer is "no" but I'm just not clear how that translates to a practical certification test that a vendor would have to pass. But I don't think we should take up more time of the full committee to debate it. I think it's a good recommendation. I just want to know the full scope of it.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right.

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

But we can take it off line. Thanks.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Sure, I'd be happy to talk to you off line, but I would assert that re-authentication after a time out is not the same as gaining initial access to the system, which is what we attempted to capture in the recommendation.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Other folks in the queue, Michelle?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Andy Wiesenthal.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, Andy?

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Yes, thank you, good morning to everyone. I have a question that I don't think I heard you or the committee address Dixie and that is password rotation or forced password rotation and an opinion about that.

Did you explore the data around whether...especially in an environment where according to NIST's recommendation at least you're promoting, if I understand the use of the term correctly, "greater entropy" of passwords which means they're harder for people to remember.

And so what opinions do you have about how frequent, if at all, passwords need to be changed?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, actually Andy that topic was brought up in our conversation. But we concluded that that's really not a technology. That's a policy, that's a password policy and while we would have our opinions about how frequently passwords are changed it's not...I don't think it's captured in the entropy requirements. And we ultimately decided to just recommend the entropy requirements and not the password management requirements. Lisa, is that right? You know this better than I do actually.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes, that's right. So we just focused on the technical requirements and we did view the rotation as an organizational policy issue. So we don't have a recommendation on that.

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

You know it is, but it's a...we can set a standard around it that's based on data. It's one of the most infuriating aspects of system use as we all know.

And so if there is actual research data around what contribution password rotation makes to system security and what actual decrements password rotation produces in system security I would suggest that we should have an expressed standard that guides policy.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

It seems to me if we wanted to say something about this, and of course this is just me reacting to your question, that from a technology perspective it would just be that the certified EHR technology just is capable of enforcing a password rotation or password changing password effective time limit, which currently isn't there, but, you know, from a technology perspective that would be what you would want to...you know, you wouldn't have technology be certified that it can require that you change your password every two weeks or something. What your technology would need to do would be capable of setting time limits for passwords.

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

No, I understand...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right I agree with Dixie, this is Lisa. Andy, here we're trying to specify something that can be certified in the module.

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Right.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

And really I think Dixie's got it right as far as that.

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

No, and I get it. It's just, you know, it seems like we're allowing this void to be there and as an end user I know what I do and I know what my behaviors are and in instances where I'm forced to rotate every 60 to 90 days and whereas the password itself that is used might be sufficiently strong, in fact the way I rotate them makes it weak.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Or in fact, to Andy's point, what you see is when you enforce 30 day password change and no one can remember them, they write their passwords down on yellow sticky notes and then put them on the bulletin board and that reduces security. And so one in fact asks the question, how about more entropy and less frequent change? Maybe that's the answer?

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Well, anyway it's not...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

No, I think...

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

I agree that it's not a technical issue, but to not have an opinion from either the Policy or the Standards Committee leaves organizations at a loss as to what to do and so they tend to take what they view is the most conservative path, which might actually be a wrong path and I just...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think, Andy, you make an excellent point as does John and perhaps Michelle we could research this a bit and talk it over with the Policy Committee's Privacy and Security Workgroup to see if there is anything that we may want to say on this issue.

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Thank you.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I think if anybody has anything to say it's a policy you know.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right, so we can bring it to them, though.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I mean since it came up here.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, yeah we can certainly take it back that the issue was brought up.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

And this is Stan Huff, I'd just like to, you know, join in with Andy. You know in the past people have said, you know, it's "best practice" to rotate at a certain interval either six months or a year. And I challenged them for the scientific evidence that that was in fact scientifically valid that someone had done a study to find out what the proper...you know, what the optimal time for rotating was. And there was no good science that I could find at the time.

It might be an area where we need to actually fund some research for somebody to do a good study to determine, because it doesn't...yeah, I haven't seen good science. All I've seen is, sort of, well, this is what we've done and this is what we recommend as best practice with no basis in science for that assertion.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, I can assure you we haven't recommended anything here that even is...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

No, I know it's not here, I'm just...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

That you have to, you know, change your password...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

No, yeah, I understand that I'm...it's a plea for the Policy Committee to do something or us, you know, in a different venue of the Standards Committee to do something. So it is tangential to your recommendation. I like your recommendation. I'm just seconding what Andy said, we need to address it somewhere.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I do think that in this re-architecting actually of 800-63 I feel, you know, very certain that they will be addressing that, but I think that this could be a comment to make, to be made to the, you know, to the people who are re-architecting NIST 800-63. And one of our recommendations is to support that effort. So, whomever we choose to...and ONC chooses to be involved in that effort can certainly take that message forward to that activity.

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

And this is...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

And let's reflect that in the letter, Michelle, if we can.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, thanks, Dixie.

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

Yeah, and this is David, I would endorse that as well. Because I think it is fundamentally a technical question of what degree a password rotation is correlated with good security. So it is a policy decision to enforce it but it's a technical question at its heart and ought to be addressed by technical standards people to do the study and make the assessment and recommendations. What's the probability of a false...I mean of a break-in, it's an entropy question, so just broaden the entropy question not to complexity of password but also to encounter a frequency of password change.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Hey, this is...

Wes Rishel – Independent Consultant

This is Wes.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Sorry, go ahead.

Wes Rishel – Independent Consultant

This is Wes. I just want to remind people we had testimony from Peter Tippett of Verizon on this and related topics and evidence in support of policy decisions going back probably three to four years. I don't know the extent to which Verizon has kept up that database that they use and it's got some limitations in terms of how data gets into the database. Nonetheless, it certainly would be a source of input for us to consider.

And I want to just say that in general, in all my work in standards which goes back to how wide is the Roman chariot. This veil between what is technology and what is policy has been a continuing source of frustration and misunderstanding in terms of promoting the use of security. And if we can find a way organizationally to deal with it bringing the right skills with regards to technology skills to providing the infrastructure of information that's necessary to support a policy recommendation, I think that would be enormous progress for any industry, certainly for the healthcare industry.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, I think that the need to...I certainly know this is in my mind the reason why we need to keep them separate here. I think in reality and in practice they are not kept separate. They're joined very, very closely and I don't know, you know, anywhere else where it's...

Wes Rishel – Independent Consultant

Well, Dixie, I have heard this from you so many times over the last few years and the end conclusion of that discussion is we can't do anything because that's policy and I believe that is a disservice to the community.

I'm not saying that it's done well anywhere else. I'm not saying that there isn't confusion. I'm saying we should find a way to deal with the confusion not continue to hide behind the quote "that's policy" issue.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

So, we...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

I wonder if, Dixie has made a recommendation that I think is very sound and that is that the NIST 800 guidance, which is being updated, might be the vehicle by which this conundrum of, how do you take sort of national best practices and put it in the context of guidance, which certification is probably not going to include a fixed password rotation schedule, but maybe certification includes the capacity to do password rotation and that the NIST document gives us the guidance as to what that rotation should be?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think that's exactly Dixie's recommendation and I agree with that.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, me too. I agree with that.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Hey, this is...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, we would all agree to help NIST with that, but Arien, I think I heard a comment from you?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah and I'm sorry, my hand raising feature I guess isn't working. Specifically, I have a bunch of questions actually following on Wes's questions that the most interesting issues here are actually policy issues and we really should find some way of addressing those.

Specific to password entropy, there's actually now a lot of research on the vectors of risk in password schemes unfortunately because there's now a lot of good black hat behavior that has been cracking passwords. The NIST entropy scheme doesn't hold up well in practice. Real world password entropy's scales nonlinearly with password length and so there's actually a flattening of the curve whereas NIST proposes that there is a significant, you know, there's a steep linear curve. It's not a very helpful metric. And it needs to be, in the real world, augmented by looking at passwords against dictionaries, looking at permutations of standard crack dictionaries, this is an area that's very complex, an area that's under pretty active research and I think it's premature for us to propose particular standards.

I'd also note that this is actually a policy issue and a risk-based issue. So we've chosen, in our own practice, to use simpler password metrics because they tend to be easier to remember and address the brute force attack vectors by timing out and locking out and requiring in person or requiring other forms of identity verification for people who are locked out. And that's been a very effective real-world approach to this.

So I'd be opposed to specifically calling out the NIST entropy metric as the item for certification because I think there are ways of addressing risk. First of all I think it's a bad metric and secondly I think there are ways of addressing risk that may be better and would fail that certification test.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay. Well, Michelle, do we have other folks in the queue to make comment?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

David McCallie made a comment and I'm not sure if he still has another comment.

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

No, that was...I raised my hand for the prior comment but I will endorse Arien's suggestion. I think that's a very interesting perspective.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so, if we play out that suggestion, which to restate it, Arien, is that in the recommendations from the Task Force there was a suggestion that appendix A of NIST 800-63-2 be the guideline for which certification is used as a measure of entropy, that rather than use that you feel like there's a risk mitigation that could be a multilayered defense that's put in place? What's the right wording for that?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah and unfortunately this is one of these policy technology areas. The right way to do this is to enumerate the real-world risks and then require EHR software or other HIT software to address those risks. That's not a testable...it's an attestable approach but it's not necessarily a certifiable or testable approach.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

It's really the HIPAA, that's what HIPAA already requires.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

It is what HIPAA already requires although HIPAA doesn't provide any good guidance on what the actual risks are.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right, right.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Because what I'm just wondering is if we move to that risk-based approach, how would you certify it?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

That's right and I think you'd have to attest to it or get accredited to it that your approach for identifying and mitigating risks is a reasonable and good one. There are frameworks for doing that. They're not certifiable in the sense of a NIST test. But, as I said, I think in this case the NIST test is a particularly bad one.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, I think our number...the first recommendation that says continuously protect the integrity of confidentiality of information used to authenticate users, which includes passwords, I think that already covers that.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Because they would have to...I mean they would have to say that there's the risk is that your password be disclosed. And then they would use...well, of course we're recommending they use integrity, protection and encryption to protect it. So that doesn't address frequency change or anything like that. But, what I'm hearing is that you're recommending we just delete that second part?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Correct.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

What you're recommending is really part of how the organization manages its own risk.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Correct and then to address the other questions on password rotation, some of the other things, I think it would be highly useful in the way that we've done for web security to put in place...to put in an enumeration of real-world risks that need to be addressed.

I think it would be highly useful to have a framework for having real-world risks in this area that need to be addressed. That would be a useful contribution. I don't know if that information exists in the research community but that would be a highly useful set of guidance to the community.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And will a NIST document do that, do you think, Dixie? Or is there some other resource we have to create?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Well, this is Lisa...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I don't think that that's something that you certify.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yes.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Let me put it differently, I think if we wanted to develop guidance in that area we could and we could work with the Policy Committee to do that. But I don't think what Arien...what Arien is talking about is really situational. Risk management is situational.

So, although some risks can be and need to be addressed in the technology, I think that really risk management is something that each implementer needs to do...you know, each implementer needs to do when they...for their environment.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

John, this is Lisa. I think that to your point about the NIST document, we can certainly give them input based on this discussion as they reconsider that entire document.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

You know we did recommend that ONC continue to work with them as they update the document and we can give them input on this specific topic and discussion so that...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

I guess to the point Arien has made about real-world risk examples all of us who work in operational roles realize the nature of the risks is continuously changing. So we are seeing spear phishing attacks where an individual is targeted and asked in a very sophisticated way to release their username and password to a bad actor. The bad actor then goes in remotely and does something which could include changing payroll direct deposit accounts, using e-mail for spamming, etcetera. So it leads us to believe that if you're going to protect against spear phishing, two factor authentication for all remote access may be a very good mitigation. You know it's not an EHR certification issue so much as it is an organizational practice. And so, you know, I guess...

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

This is...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Please, go ahead?

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

This is David. I just wanted to say that from, you know, thinking about the distinction between technology and policy, I think that maybe one approach would be to enumerate technical capabilities that are certifiable but then separate out into the policy space best practice on how to use those capabilities.

So for example, Arien, you know, mentioned measures of entropy as one technical capacity that a password system could possess but dictionary attack checks would be another capacity. And then a best practice might...and then rotation could be another capacity.

And best practice might, based on, you know, studies, actually suggests different trade-offs between entropy, dictionary rejection and rotation speed. But you could still certify against the capabilities, separate that from best practice that might evolve based on perceived risks.

Wes Rishel – Independent Consultant

This is Wes again. I think we're one, thanks to Andy, we have hit on a line of great difficulty for all security, which is the risk balance trade-off between protective measures and people trying to get their job done. We have identified that while there is no doubt that every industry feels this is an acute problem, we know that our fundamental ability to reach the strategic goals outlined in the prior presentation depends strongly on the use of EHRs by people who are very busy, under great time pressure and go on however long you want about that. So we know it's critical to our industry.

We have some issues about what are the levers that we can recommend to ONC? The guidance we've had over some period of time has been to focus on certification. And Dixie and Lisa have led their group in that direction. And this is an area that is not particularly amenable to certification. There may be some issues, there may be a possibility of requiring certification on particularly brilliant schemes, but those come and go so fast that it's difficult to do that.

Somehow, I think we need to find a venue or a platform, or a location to identify the policy issue as an unsolved issue and to do whatever can be done under the various laws that enable ONC activities to provide what support we can.

I particularly think that most password rotation schemes and so forth are based on best practices that are collected by saying, what do you do, what do you do, as opposed to what evidence do you have to support the scheme you use? And if there are initiatives that are needed...we just need a focus for that technically informed but essentially non-technical portion of Healthcare IT policy.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And in the past, you know, there's been NIST guidance and I've seen frameworks, there are numerous frameworks in the NIST 800-66 framework or COBIT, ITIL, ISO, etcetera that provided a metric as to do you follow risk mitigations and what are those mitigations as opposed to being specifically prescriptive.

And so, Dixie, I don't know comments from your experience in the industry to Wes's point. If some of the stuff is going to be hard to certify is there a framework we point to which then allow at least the enumeration of your risk mitigations?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I think that framework is 800-63. And I think that our recommendation to engage...and we've recommended...you know, we've spoken with ONC already about how we want to not only engage ONC per se but also help inform our own Workgroup and get our own Workgroup involved in that as well. I think that is the vehicle for us to influence, you know, best practices policies.

I also know...and unfortunately I can't cite because passwords are not my specialty. In fact, I can tell you that it's been proven that passwords are the least, you know, least effective of all authentication devices. But there have been considerable research done around passwords and how to make them work...you know, make them stronger.

And I think maybe what we can do...our Workgroup can work with ONC to find ways that our Workgroup can...and, you know, I don't know whether it will be...involve working with the Policy Committee or not, but at least work with our ONC staff that we have supporting us to find a vehicle to express these concerns and to find a vehicle to get guidance back to the industry because I think that it's obviously an area of interest and it's, you know, and it's an area that can be tackled. So I think that that's what we should do. That's what we should recommend.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, I wonder, Michelle, is that if we take all these comments into consideration if there is a restatement of the recommendations that Dixie has made that the committee might approve, which is, you know, it is certainly the case that if there is a future certification criteria for two factor authentication, which to David's point doesn't mean every point of authentication or re-authentication, there's probably wording where we can define what two factor authentication means. So that would be one recommendation coming out of the Workgroup.

The second big one is this great discussion of the intersection, often murky, of technology and policy which requires us to really point to an evolving framework which is a risk mitigation strategy as opposed to a specific certifiable or enumerated set of practices. And as Dixie and Lisa have proposed, that ONC, this Workgroup and NIST work together to ensure that that framework is available.

And then there are some other recommendations they've made which are nonbinding recommendations about what they see as emerging good practices like consider data segmentation for privacy type approaches to behavioral health, track the UMA standard as it might apply to OAuth for consumer consent.

And so, Dixie, I don't know if there is, what I'll call the friendly, amendment here of restating your recommendations in such a fashion that the committee might support?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Sure. My only question would be what we do with the entropy one. It sounds to me like the committee is recommending we remove that and in its place we recommend that we work with ONC and NIST to come up with guidance. Is that correct?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

That would be the friendly amendment I think.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay, okay, yeah.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, you know, I recognize that there may be additional discussions. So, Michelle, anyone else in queue?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Eric Rose did have his hand raised and so did Anne LeMaistre but they were a while ago.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, Eric or Anne anything you would add to that discussion?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

This is Eric, I just...I think that...I don't think that the United States is looking to ONC or its advisory committees to solve the problem of whether end-users should be forced to reset their passwords at 30 or 60 days and so I...but they are looking for us to make sure that the technology that is delivered to them allows them to make an organizational decision and enforce an organizational decision around those things. And I think that's where our focus should be.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And that's a very good statement.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so to the point that Dixie has made in her accepting of that friendly amendment, I was recently told by an external audit firm "Beth Israel Deaconess does not adhere to industry best practice in its password rotation schedule." And I asked the same question that Stan did, so show me the scientific evidence that tells me, you know, 30 days is the best practice.

I would love to be able to use a framework. It's not an ONC framework or a Dixie and Lisa recommendation but it's a framework, which as Arien told us, could be used so I enumerate my risk mitigation on authentication and authorization and then that would be thought of as "oh, okay, per this national framework you have adequately addressed appropriate protection." So I agree. We're not going to certify a 30-day password rotation as part of Meaningful Use Stage 3.

And Anne, comments you would make?

Anne LeMaistre, MD – Senior Director Clinical Information Systems & Chief Medical Information Officer - Ascension Health

No, John, I think you David and Arien adequately raised my points and I support the friendly amendment. Because, as you just pointed out, after all it gets down to while we need to be protective we also need engagement. And if we get too protective that will fall to the wayside.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, very good. So what we have then in summary is we take the recommendations that we've heard from Dixie today. We redact or replace 1 B with that suggestion that in working with the NIST folks, ONC and Dixie's team will point us to a framework that allows us to enumerate risks and risk mitigations rather than specifically calling out entropy as the technique to use. And so with that, are there objections to going forward with these recommendations as so revised?

Okay. Well, thank you. I think Michelle, we have a recommendation and that we can prepare a letter with those revisions. And this was a wonderful discussion.

And I think Dixie what you got a sense of is for all of us who are trying to keep ourselves out of compliance prison. It is an increasingly challenging world with increasing risks and regulatory complexity. So we all look forward to the kind of guidance that we will see in the upcoming 800-63 framework.

So Michelle, I think we are now ready to move onto Jonathan Coleman unless there are other items that you have?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

No, I think we're ready for Jon.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, very good and let me just quickly introduce this. As I said in my beginning introduction, the Prescription Drug Monitoring Program is a tactic for reducing opioid abuse, it is employed in many states in the US and it's a very effective technology. As an emergency physician, I actually use it in my practice. And the only challenge is it requires that I authenticate to a separate website, re-specify patient context, make sure I select the right patient, look at the data and then go off to a separate software system, my EHR, to take action.

And thinking about how we might achieve a greater degree of interoperability between prescription drug monitoring programs and those systems that are used as part of clinical workflow is the subject of Jonathan's presentation.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS - Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Well, thank you, Jon, John and Michelle and actually I'd like to start, if it's okay, with introducing Jinhee Lee from SAMHSA who will be starting the presentation today. Jinhee, are you on?

Jinhee Lee, PharmD – Division of Pharmacologic Therapies, Center for Substance Abuse Treatment – Substance Abuse & Mental Health Services Administration

Yeah, I'm here, thanks, Jonathan.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS - Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Thank you.

Jinhee Lee, PharmD – Division of Pharmacologic Therapies, Center for Substance Abuse Treatment – Substance Abuse & Mental Health Services Administration

So, thank you for inviting me and letting me talk a little bit about this. I'm going to provide somewhat of an introduction before Jonathan talks about the current phase of the project. Just to give you a little bit of background, I've had the privilege of serving as an agency co-lead on this project since 2011. And Jonathan Coleman is the initiative coordinator for I call phase 3 of the enhancing access project which has now morphed into the PDMP and Health IT Integration Initiative. So, I'll be providing the historical context to this project, in other words, phases 1 and 2 while Jonathan will provide an overview of phase 3. Next slide.

So before I begin I'd like to just briefly shed light into why SAMHSA has decided to fund this project since 2011. As you can see from the slide, CDC data shows that drug overdose death has become the leading cause of injury death in the US and it now surpasses motor vehicle death.

SAMHSA's 2013 national survey on drug use and health data also referred to NSDU shows that 24.6 million or 9.4% of the US population reported using illicit drugs in the past month. And then of these individuals 4.5 million used pain relievers and 18 to 25-year-olds as a group with the highest current use of illicit drugs. Most of these people are obtaining these drugs from family and friends. We have 20.2 million folks who need treatment but are not receiving it for various reasons. Only 746,000 persons ages 12 or older received treatment in the past year for use of pain relievers.

The federal government's response to this public health crisis includes the White House Prescription Drug Abuse Prevention Plan which is a blueprint for federal agency efforts on prescription drug abuse and has four main pillars one of which includes PDMPs or Prescription Drug Monitoring Programs.

The White House strategy included a goal to have legislation in all 50 states to establish PDMPs within 36 months. In fiscal year 2014, I am proud to say that we have 49 operational PDMPs. However, while most of the states have operational status they still need to think about how to get their providers to use this very important clinical tool. Next slide.

So this is how it all began, in June of 2011 the Office of the Vice President, ONDCP, the Office of National Coordinator for Health Information Technology and the Office of Science and Technology they hosted a roundtable on Health IT and prescription drug abuse. There were approximately three dozen leaders across public safety, healthcare and technology sectors that met to address leveraging existing technology to improve access to PDMPs.

This government led initiative, the enhancing access to PDMP project, it stems from joint efforts of this meeting and what came out of that was an action plan for improving access to PDMPs through Health IT. And this action plan identified how PDMPs are set up today and how we would like to see them going forward.

And fortunately, in 2011 SAMHSA was able to provide funding for the implementation of this action plan and ONC together with SAMHSA, ONDCP and CDC we partnered together to operationalize this action plan. Next slide.

So, for those of you who are not familiar with PDMPs, each state PDMP is established by their state law and so although there are a lot of similarities you will see some subtle differences in the PDMP Program from state to state. Having said that each state collects prescription controlled substance data as dictated by their laws and in some cases over-the-counter or non-controlled medications. All of the data that is collected comes from pharmacies and in some cases physicians who dispense at their practice sites.

The PDMPs can be used for reducing prescription drug abuse and diversion. However, they are useful to healthcare providers as they serve as an additional clinical tool to collect prescription drug data from a patient who may not be entirely forthcoming whether intentional or not and allows the provider to have a more accurate picture of their patient's control prescription medication history before the drug is described or dispensed to avoid an unintended consequence.

So, the PDMPs today are setup as standalone systems that are separated from the rest of the Health IT ecosystem. In order to access the PDMP a provider has to log into separate systems. So, in other words they have to log into their electronic health record, health information exchange, pharmacy dispensing system, and then also log in separately to their PDMP.

So what we envision for tomorrow and what is happening currently in some states is an integrated approach where the PDMP is integrated into a Health IT system and part of the provider's workflow. The provider no longer has to log into separate systems but can rely on technology to do this for them.

And I also...although this isn't the focus of the call, I also wanted to mention that SAMHSA supports two cooperative agreement programs that kind of as an extension of the Enhancing Access Project, and I'll talk a little bit about that later, but next slide.

So, the Enhancing Access Project identified three communities that had the potential to make clinical decisions about prescribing and they are the provider practices, emergency departments and pharmacies. I'd like to point out that while our project focused on these three groups we recognize that other practice settings are equally important and support the integration of PDMPs into all settings when appropriate. We targeted these specific settings only because we were looking for what scenarios could provide us with the most impact in the short timeframe provided with this project.

So the overall goal of the project was to integrate this into the current workflow of the provider and not create another step. We all know that providers have very limited time with their patients. Thus the aim was to have a machine to machine communication that did not necessitate action by the physician or pharmacist. Basically, we want to make the information flow more effectively not create new systems but make the systems we already have become more valuable by connecting them.

So, during phases 1 and 2 of the project we conducted a total of 13 pilots that tested the feasibility of leveraging Health IT to improve timely access to PDMP and provided proof of concept for PDMP integration. However, in doing so, we discovered that one of the current technical barriers to interoperability is a lack of standard methods to exchange and integrate data from PDMPs to Health IT systems so that it can be used in a timely and convenient manner. We also discovered that with the SAMHSA grant as we're scaling up some of the themes that we found were in phases 1 and 2 of the ONC project.

So, the PDMP data structures are based on existing National Information Exchange Model Architectures or NIEMs for PDMP to PDMP data sharing. But they aren't typically natively supported by electronic health record systems. So, phase 3 of the project of the standards and interoperability framework on PDMP and Health IT integration helps address this and I'm now going to turn over the presentation to Jonathan so he can talk about that.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Thank you, so much Jinhee I really appreciate the intro and all the background. And if we go to the next slide, you can see from the list of stakeholders here my job as initiative coordinator for this project has been really facilitate the meetings of the community where all the expertise lies.

And we've had extraordinary participation I think throughout this whole project, just within the S&I PDMP and Health IT integration phase of the broader project we've had 223 registered members, 166 unique registered organizations, 78 committed members who have been actively participating and now even though we are in the pilot phase of this project we still have roughly 60 or so people attending every week to hear the progress of the pilot participants.

So it's been very well-received I think overall by the community and we've been very fortunate to have a diverse community base including Health IT EHR vendors, providers and provider organizations, SDOs, federal-state agencies, local agencies and other participants including strong representation from the different state PDMPs.

So, the timeline at the bottom of the slide just shows historically the progress of the S&I initiative. And as I mentioned earlier, we are now in pilots. We do have an implementation guide which was voted on and agreed to through consensus in September and that was built on a use case and in turn was developed from the initial project charter which was ratified in January of 2014 so a lot of activity and a lot of progress in an initial space of time. If we could go to the next slide, please?

So, as part of the harmonization phase we developed an implementation guide that was built on recommendations from a Workgroup from different stakeholders and we called that Workgroup the Solution Planning Workgroup. And we looked at all of the different potential technical query and response paths from an EHR or pharmacy system to a PDMP and we got several complicated diagrams that describe those various workflows. And this slide summarizes some of those and focuses on the recommendations from the Solution Planning Workgroup.

So, on the left-hand side we've got the system that initiates the query an EHR or a pharmacy system. And it goes through one or more intermediaries such as a PDMP hub, a health information exchange or a pharmacy intermediary switch, or pharmacy network before ultimately being routed onto the PDMP.

And you can see at the bottom, on the left-hand side, typical standards that are included or natively included within EHR systems for example would include HL7, NCPDP SCRIPT and we also have ASAP web services which is a web services-based standard that is currently being used within the PDMP community.

On the right-hand side, and as Jinhee mentioned, we have the PMIX-NIEM standard for PDMP to the PDMP information exchange. So somewhere in the middle we have to figure out how to get the PDMP information into the EHR systems or pharmacy systems with the least amount of effort and the most amount of usability ending up with the user of the system.

So a number of options, option one, have the intermediary provide a translation. So to map the standards, the data from PMIX-NIEM over to either HL7 or NCPDP SCRIPT for example. Variant two is to actually do that at the health information exchange and then variant three is to have an interface engine or module which could be at the PDMP or at the EHR, or pharmacy system provide that transformation. Next slide, please.

So, we've developed the implementation guide and we are now going through our pilot participants and we've got those coming up on the next slide. So, I think we currently have 18 different pilot participants which is fabulous.

So we are testing the IHE now by working with our stakeholders and focusing on the standards, mapping or standards translation with the PDMP hub as the main conduit for serving as an intermediary between the querying system and the different state PDMPs. So, that's step two.

As we go through these pilots we'll get to step three where we will identify and we've already identified some gaps in standards for how certain data elements that are being reported to PDMPs can be in turn queried by Health IT systems and it's our hope and expectation that with the work of the pilots we'll be able to report back to the community on how the pilots have mitigated those gaps or handled those differences.

And then we'll be able to update the implementation guide and continue to provide iterative feedback on other challenges and John Halamka mentioned some of those in his introductory remarks also such as the privacy and security and building on some of Jinhee's comments to each PDMP is regulated and governed by its own state, so there are different rules surrounding how the PDMP information can be used or conveyed in some cases.

And then finally, the plan is to have all of these recommendations provided back to either the standards development organizations or another body to, I guess, finalize the implementation guide based on the lessons learned from the pilots. So if we move onto the next slide and I think we're close to wrapping up here and then we'll turn it over to questions.

You can see here who the pilot participants are, there are 18 in all. But I think it's worth noting that we do have a broad spectrum of stakeholders that are active and willing to participate in pilots and they're also all interested in various standards being mapped to the PDMP standards, the PMIX-NIEM data architecture.

So we're starting with NCPDP SCRIPT, HL7 and ASAP web services and we already do have an API that has been developed by the PDMP hub and that API is being used within the community, within the pilots to serve as a...I guess the interface or the conduit for that translation service to be then enacted and affected by the PDMP hub.

So we're making it as easy as possible thanks to all the good work of the community for the healthcare provider systems to be able to interface with the PDMP hub and get access to that important PDMP information. Next slide, please.

So, Appriss and OneHealthPort from the health information exchange are participating in the pilots as the intermediary or hub function. And then we have Kentucky, Washington State, New Mexico, Virginia, Arizona and Wisconsin currently on board as PDMP pilot participants.

So, I believe that concludes the presentation. If you move to the next slide, please, you'll see Jinhee, Jennifer Frazier and Helen Caton-Peters from ONC, their contact information as our federal sponsors and leadership are there. And I'd be happy to attempt to field any questions that you may have at this time. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, thanks to the both of you and just two quick comments and a question. So I had not been familiar with the ASAP web servers protocol and just for the group, I looked it up, it's an OASIS standard for asynchronous service access. We often think of SOAP as a synchronous protocol but what do you do if you had a long-running web services job, how do you start it, manage it and monitor it if you're not going to get asynchronous response? So for...it's sort of fascinating that you guys have figured out a way to loosely couple a set of actors using asynchronous web services. So, very interesting architecture.

So, an interesting issue I suppose, this is just one for Jon White, is that as we all get our hands around the S&I initiatives and their deliverables and their timing, it seems, for example, that there have been implementation guides produced as part of PDMP but I'm not certain, Jonathan, if we have actually seen those implementation guides through the Standards Committee, because they actually might have some fascinating aspects to them like, how do you manage identity given that we don't have a national healthcare identifier and if you've got multiple EHRs and multiple pharmacies contributing data about an individual, how does a PDMP database reconcile different names, genders, date of birth, zip codes, etcetera and determine who the patient is?

And that of course is...you know, as we try to solve a number of these problems together I just would hope that the PDMP implementation guide, as just one example, would come to us so that we could have a dialogue about it.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Thanks, John, so I am a big fan of implementation guides, it's not to say I'm not a big fan of standards, but you've got to use them. So, I think that you are actually foreshadowing some conversations that we will have at the end of today's committee meeting with Steve Posnack, so it's a great observation. I would support it and look forward to discussing that a little bit more.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Great. Well, other questions that folks have on the call?

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

David's got one.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yeah and then Wes Rishel.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, David, please, go ahead?

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

I'm glad to see the number of different experiments and pilot efforts that are underway. I'm a little dismayed to see that nothing was listed that would take advantage of our emerging interest in FHIR and in the notion of smart plug-ins. This seems to me to be a prime case of where a lot of complexity, particularly around things like disambiguating potential patient mismatches which would require human intervention could be delivered via a smart style plug-in with FHIR used to move the necessary data to do the punitive match.

So, I know that smart and FHIR are new and emerging and this is work that's been underway for a while, but I would hate to see us in trying yet another overly complex approach when a simpler approach is on the horizon, a potentially simpler approach is on the horizon.

So I don't know what the timetables are or whether it would allow an evaluation by some folks who are more familiar with where smart and FHIR are going but if it's possible, I would urge that this be considered. You know asynchronous SOAP does not sound like the future to me.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Right, so, this is Jonathan, if I could respond to that. I think it's an extremely valid point and due to the constraints, in some cases the financial constraints that currently exist within the, you know, for example, the PDMPs we...or the community made a decision to focus on those standards that are currently in place.

And so the ASAP reporting standard was one that was well known to the PDMP community and the emerging ASAP web services standards, which is more synchronous and RESTful in nature, was also adopted by the community for evaluation and testing.

But I think that our approach for the implementation guide is essentially agnostic to transport and what they're demonstrating is that those standards that are currently natively supported such as HL7 and NCPDP SCRIPT, and also emerging standards such as the ASAP web services standards, which is synchronous and RESTful in nature, lend itself well to other types of transport and infrastructure that are very, I think, similar in concept and practicality to FHIR.

So I do think that our approach would readily lend itself to API development, adoption and implementation in a RESTful way that supports FHIR.

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

So, this is David, just to follow-on. I mean, I think it's a good point to make a distinction between the standards and services that are working in the background, non-EHR, non-provider contact systems where you may have standards and standards expertise that's different than what you have on the vendor side, so that's an important consideration of communications to the hub from pharmacies and the like could be...you don't have to necessarily use the same standards as the integration of the information into the physician's workflow.

But I would say, on the other hand, when it comes time to integrate with the physician's workflow, particularly if it's an interactive conversation, if physician needs to look at something on the screen and perhaps ask questions or add some data to the information on the screen, that doing that with the tools that you currently list would be a ton of work and very brittle as opposed to a plug-in with a web App.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Right.

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

So, I just hope we don't go down the path of saying just because it's RESTful it's therefore good and we'll just put this real complex transactional interaction that the vendors now have to go spend huge amounts of energy building when a simple plug-in would accomplish the same thing with higher interactivity, higher bandwidth of information transfer and much less work.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

So, again, I think, David you're right on and our approach, if I didn't do a good job of articulating that I apologize, but it does support that. So, in this case we have a plug-in or an API that is presented by the PDMP hub which would then be doing the translation and the routing to the standards and data elements that are required and used by the different PDMPs in the different states which are not the same as each other, one state is different from another.

And so presenting this interface at the front end of either the PDMP hub or the HIE will allow multiple EHR systems, for example, to provide a web services-based query to that interface and then let the PDMP hub do the translation and routing to get that information and present it back.

We do still have issues and concerns around security for some of the approaches because in some cases there are rules and legislation that prevent the PDMP information from being exposed to the intermediary and in others it can be. So that's one obstacle that we're getting feedback from the pilots on and how they address that in their various implementations. And other is the patient identity, patient matching issue that was brought up right on point earlier on as well.

Currently, there are some implementations that use a pick list where they will send a query and be presented back with a subset of potential persons of interest that the provider would select and in others that is done more, I guess, at a granular level, more granular level to get a high degree of matching on the initial query so that a pick list would not be required. So these are some of the things that we're still working through with the community and learning from the pilots that we hope to build into the next iteration of...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, Wes...

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

So, I think...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, please go ahead, David.

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

Well, I was just going to say that's good to hear. I'm afraid we may be using web service and APIs in different ways. Probably too complex for this conversation to try to resolve, but I would like somehow to...maybe some of this gets presented to our API Workgroup for consideration as we wrestle with how to push FACA forward to just look at it and see if it's consistent with some of the OAuth work that we're doing as well.

It just seems like, you know, an asynchronous, yet another independent thing that's going to hit and impact with complexity and extra work that could be simplified.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, David, this is Arien...

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Well, the thing...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

This is Arien, I think putting this as one of our sample use cases and testing it against our proposed architecture to see if this is one of the areas that you could address with the architectural approaches that we're outlining I think might be a useful exercise.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And as...

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

I think that...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, please go ahead?

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Sorry, just real quick, I think the “A” in ASAP might be misleading. Our goal was for this to be synchronous, as synchronous as possible and part of the latency will depend on how timely the information gets reported to the PDMPs, not so much in the amount of time it takes for a query and response to happen. So from our perspective we’re looking at this to be synchronous.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so, as Jon White said, we will hear from Steve Posnack about ways in which the S&I Framework deliverables will be better coupled back to the federal advisory committees and certainly as we think about our committees and Task Forces the opportunities to do the reviews that have been discussed will be done because I think all of us have, you know, different takes on this where we could be helpful.

As David said, the idea that you would have a number of backend systems using unique standards to contribute to a repository is one set of standards. But having an EHR tightly coupled for real-time integration is a different set of standards. And many of us have had to wrestle with these sorts of things and probably could offer advice.

For example, offering a pick list, for the individual user to pick what patient they think matches correctly, is probably a horrible thing to do because then it is highly likely that you’ll get different answers based on different user’s behavior. Probably not something good for care coordination.

So I think we’re all anxious, Jonathan, to be very helpful to you and it’s probably, you know, part of our larger discussion to come with Steve Posnack. But, I think there was also Wes Rishel, did you have a comment?

Wes Rishel – Independent Consultant

Yeah, John, I think you’ve wrapped up most of what I had to say, but I just wanted to...particularly your comment about the current approach you personally are using, which involves re-identifying the patient and establishing context sweeps a substantial challenge under the rug that it could be perfectly appropriate for this phase in the evolution of this general capability, but as we look to the experience we’ve had rolling out standards and seeing their implications on user workflow it needs to be significantly addressed in the project.

Then I had one...a second question which is, we have a framework for talking about the maturity of standards. It would be interesting to find out according to that framework where ASAP stands now across industries. It’s not a standard I hear much about in general conversation.

I mean, everything...everyone is struggling with a way to describe what they’re doing is RESTful and we always enjoy the descriptions of SOAP-based RESTful protocols. But I think finding out what the experience is to predict how it scales up would be very valuable.

Finally, in reviewing the slides, I saw quite a number of stakeholders participating in the project, but no care delivery organizations. Did I just miss that? Is it in there and I simply scanned over the slides too fast?

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

I do believe we have care delivery and I can get the detailed engagement matrix over to you Wes if you'd like to have a look at that...

Wes Rishel – Independent Consultant

Yeah, I'd like to know particularly who they are, you know, if they're EHR users, what EHR they're using and so forth.

Janet Campbell – Software Developer – EPIC Systems

Right. I know that EPIC is actively participating and we also have NexGen and DrFirst...

Wes Rishel – Independent Consultant

Well, you listed vendors, you listed vendors and I think vendors is a great way to start, you know, at least you get a lot of work done that way. But until the vendors can plug in their actual users working on actual patients you have to regard the results as being quite tentative, you know, and I just want to emphasize we've seen that over and over in the context of previous efforts that the Health IT Standards Committee has been involved with.

For example, the workflow just to accept patient data from another system was much more complicated than anybody thought when they first talked about the power of the standards. So I want to say nothing negative about the progress we've seen so far or the importance of this. Just suggesting that we understand where we are along the process of getting ready to roll this out at scale.

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Yeah, no, thank you so much and I'd just like to comment that while you're right we do have the vendors listed on the screen, this is not a technology demonstration per se we are actually going ahead and looking to pilot, you know, first with test data of course and then ultimately with real data. And so the vendors I'll be working with, healthcare organizations to go ahead and actually to that.

Wes Rishel – Independent Consultant

Well, that would be great. I think we...

Jonathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Yeah.

Wes Rishel – Independent Consultant

Yeah, we'd like to maybe at some point, after you've gone through the process, talk to those end-users. I mean, I think that's, by John's own comments, I think, John Halamka's own comments were instructive at the start of the call or the start of the session. Thank you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And Wes, just so you know the ASAP standard was finalized in 2004 at the same time the workflow XML, WfXML was finalized. So you asked the interesting question, these have been around for a decade but is anyone actually using them in production and per the Dixie Baker standards maturity scale, where do they really sit in terms of adoption? You don't know. Okay. Other comments in the queue?

Jinhee Lee, PharmD – Division of Pharmacologic Therapies, Center for Substance Abuse Treatment – Substance Abuse & Mental Health Services Administration

I just wanted to add to what Jonathan had mentioned, you know, some of the pilots that are participating in this initiative are actually SAMHSA grantees and, you know, a requirement of the SAMHSA grantees is to integrate into those three different practice settings. And so we do...I mean, the ultimate end-user will be a provider. And, you know, that's information that we could actually provide after this call.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Michelle, anybody else in the queue?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Not that I see.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so, I think we would just summarize the comments as great presentation. We all applaud the progress that's been made and understand the challenges of EHR integration and look forward to working together because the answer may lie in some of the emerging activities that we are all looking at APIs and FHIR, and modularity that may make the job easier because the last thing we all want is to build a complex architecture that will be hard to sustain into the future.

So with that, let us move forward, Michelle, to Steve Posnack's presentation which is very timely because it begins with the S&I Framework Task Force.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Sure, thanks a lot everyone, great discussion that just occurred. I think the one thing may be to conclude on the PDMP presentation is, as John mentioned, it has been a great...I guess as all the John's have mentioned, it has been a great amount of work and we've received a lot of interesting and significant engagement and there's going to be this tension, which I think I'll use as a segue to my own remarks here, between challenges that stakeholders face now that they need to do and work on, and, you know, the opioid abuse epidemic as well as the use, mandatory use in some cases, by states to check prescription drug monitoring programs is something, you know, that...in terms of the problem that was trying to be solved by this first S&I Initiative work in partnership with SAMHSA was making what currently works better.

And I think, you know, David's points are certainly valid as Jonathan mentioned in terms of there are a number of areas where better mousetraps can be built to beat up that metaphor a little bit. And this is certainly one of them where both there's standard's work and technology work, as well as user workflow and other efficiencies that optimizations that can be taken into account, a total area for a lot of ripe discussion. But I wanted to make sure that, you know, folks understand that we are kind of grounded in where we were in improving today's current state.

In that regard, you know, this initiative reflects one of the many initiatives that have been taken on in the S&I community and I'll go to my next slide, please if you can. So, I'm just going to set up the agenda. We're going to talk a little bit first about two initial Task Forces that ONC would like the HIT Standards Committee to weigh in on, participate on and provide recommendations in response. And then I'll just give a quick debrief of the Certification Program Open Test Method Pilot Development Program. So, if we can go to the next slide, please?

At the prior November Standards Committee meeting I gave a presentation on the Task Force, interdisciplinary Task Force, creation model that we had proposed to follow going forward in the future to have some discreet questions answered in a more rapid timeframe by a more interdisciplinary set up of members in addition to other stakeholders that may be important for a particular Task Force.

And the first question that's on this slide was within that sample set of issues that we were keen to bring to the Standards Committee first. The second one, which should be of no surprise to the Standards Committee, based on that conversation in November, related to data provenance, a specific ask of ours to the Standards Committee as well.

So, starting with the first one, as many of you know, you know, and probably participated, we had the Health Information Technology Standards Panel for a number of years prior to HITECH and as HITECH was passed and our work evolved, HITSP faded away and the standards and interoperability framework was stood up in kind of its stead. And that kicked off in 2010.

So, as we look to January, I believe being the kind of 5th birthday of the S&I Framework the context under which the S&I Framework was created, the work that it initially took on which many of you are engaged in including the Direct Project, you know, the context under which the work that we need to take on is changing, the environment that we're in is changing, you know, the Argonaut Project, among many other projects in which we are engaged, that are outside of S&I, per se, are tangible examples.

And the question as we look to the strategic plan, which you heard a little bit earlier, the interoperability roadmap which is forthcoming, and the work that we have to look forward into the future for the next 3, 6 and 10-year milestones that have been introduced by the interoperability roadmap draft that you've seen, how can ONC evolve the S&I Framework to continue to support current industry needs and those anticipated into the future?

You know part of the anchor here to give you a flavor is, you know, to understand what's the best value add that this open collaborative community can provide, right? So, we have these number of steps that are laid out in the S&I Framework from, you know, use case development, harmonization ideas, implementation, you have these pilots and evaluation aspects and, you know, where is the biggest bang for the buck in the context today, five years later, post HITECH, that this type of open collaborative community can provide.

And, I think the other factor to keep in mind, as you may recall from our prior presentations, and, you know, was even emphasized in the one that Jonathan and Jinhee did, a lot of initiatives under the S&I Framework are collaborative and in most cases funded in a co-sponsorship relationship either with, you know, ONC and another agency or ONC and several other agencies in addition to the kind of in-kind support that many of you that participate in S&I contribute whether it be just the time and resources to engage in the discussions or at the point where the initiatives come into the pilot phase and, you know, the very much appreciated work that folks do to engage in the pilots.

So there's a lot of great work, a lot of success that we've had through the S&I Framework. And our request of the Standards Committee would be how can this continue to evolve to take on the pressing challenges that require this kind of open collaborative approach? And I think I'll leave it at that in terms of the framing.

The one probably single most important thing to frame is when we would expect recommendations back and for that our proposal is March. And one of the primary reasons for that deadline, in terms of the response of recommendations, is that we have resources that are obviously dedicated on annual basis to support the S&I Framework and the work that continues underneath it.

And as we look to prepare acquisition strategies or other situations which we would devote resources with our fiscal year appropriations, recommendations later in the year would not be timely enough to affect any of those decisions this year.

So there is a kind of a critical milestone for us in terms of any immediate feedback that could start to incrementally adjust how we approach engaging the community and the way in which we prioritize our resources through S&I Framework that's why I propose March here as the kind of critical timeframe under which to get some recommendations.

The second element here is with respect to data provenance. And we framed this question, which I won't necessarily reword forward for you, but we do have, based on the number of presentations that you've gotten on data provenance right now and where you understand the community has arrived at in terms of how it's viewed its work, I think an opportunity where in a very short time, and, you know, we will be soliciting volunteers from the Standards Committee here to have a very small but rapid commitment in the next few weeks to weigh in on this question and to provide some additional guidance that we could bring back to the community in terms of what would be a first step in the area of data provenance standardization that would be most broadly applicable and most immediately useful and so, you know, that gets to some of the points that David and others raised at the prior meeting whether or not there were...and maybe this a common theme for you, David, you know, the over complexity radar and other ways in which the Standards Committee could provide some specific, tangible advice in terms of what you all believe as something that would be the most broadly applicable first step of collaboration in the S&I community that could have the most immediate impact for folks.

So, why don't I go through the Certification Open Test Method Pilot Procedure updates because that will be pretty quick and it's more of just an FYI in terms of where things have landed and then we can open up to discussion or questions on the two Task Force requests. So let's go to the next slide, please.

So, as many of you know we initiated this pilot program in July to go through a new way to approach test methods, test procedure development and there were a number of steps that occurred between July and November. We're at the point where we've kind of looked through the results of that initiative. You can go to the next slide, please.

So, kind of bottom line conclusion to state that first, the community devoted an admirable amount of time and thought to the work that occurred and, you know, as a quick and dirty analysis between the test procedures that we currently have and the test procedures that came in the Open Test Method Pilot Program, you know, it's our assessment that they did not significantly differ from the current test procedures and that's okay. You know in some respect that's validating that, you know, the test procedures for the criteria that were selected by the pilot participants were focused in the right areas.

The other thing that we did take from this is with respect to participant feedback, which unsurprisingly in all of our work, right, people prefer to react to test procedures that are drafted rather than to create something completely from scratch and that was some of the experience that the pilot participants got engaged in.

And I think one of the things that you can continue to expect from us is increased transparency and the availability of these important artifacts for additional public comment input and that was one of the things that participants indicated, both they appreciated and some additional feedback for us in terms of more time to engage, more time to understand the test procedures. And then the last, I think, rekindling for connectedness between the certification criteria relative to this concept of scenario-based testing.

There were some changes in terms of the different test procedures that I won't get into detail, but, you know, some that were definitely value add and certainly our appreciation to the community for identifying them.

That is about it in terms of the prepared remarks here for the slides. So why don't we open it up and save the time for questions? I suspect that much of our discussion may be on the Task Force request and I'm happy to answer any questions or provide any additional guidance that may be sought.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well Steve, thanks very much. And one quick question for you on the certification program. And you may or may not be able to answer this, but with Stage 2 there was a sense that there was a waterfall method rather than an agile method used as it seems certification test scripts and regulatory writing occurred together and no one really saw the result until it was completely baked.

Do you sense that as additional regulations are promulgated that there will be this sense of certification script writing will be done outside the secrecy of the regulatory writing process enabling that more agile review and engagement in the community?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

So there's not an easy answer to that question. I think it is certainly our interest to provide the most amount of opportunity to the stakeholder community to opine and react, and contribute improvements to test procedures.

There are some limitations that, you know, we generally experience where if there are proposals in a proposed role, for which there would subsequently be developed test procedures based on their inclusion in a final rule, you know, disclosing that information in advance of the final rule would be kind of a process issues that we'd have to deal with.

I think, you know, that being said, we are exploring, based on the feedback that we received, a number of different ways to have this process be more iterative, be more transparent using some of the techniques that were identified through the open test method process as well as some of the newer processes that we've used for the 2014 release two test procedures, you know, some of the feedback that we received in terms of the test procedures for the original 2014 edition was this aspect of not understanding how comments were adjudicated and triaged and reflected in the final test procedures.

So, you know, there are a number of areas where we can see some improvement and that we're looking to, but I think again, circling back to the specific nature of your question, John, you know, some of the things...some of the aspects of what would be tested and how test procedures would be shaped are obviously driven by the rule and there is, through no necessarily interest of our own, a kind of waterfall technique, at least in the onset. But then after that I can see us, you know, more rapidly having some agility.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Because having gone through the certification of my self-built systems you immediately sort of sense, oh, I actually could have achieved the proof that you needed using scripts that were substantially simpler. And that's, you know, just the opportunity to offer that feedback. Achieve the result you want using a method that reduces burden for the industry.

So, I think there are many folks who, as you point out, may not be able to write test scripts from scratch but certainly would be able to react to test scripts and offer helpful guidance.

Well, Michelle, do we have folks who are in the queue?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

David McCallie and Arien Malec.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

David, please go ahead?

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

This is David, quick question and comment. First a comment, Steve, I appreciate the open request for input to the committee that's really great. I hope we can get you some good answers to your questions.

With respect to the specific use case that you gave around the extra data, metadata provenance tracking, I'm sorry, I blanked on the name, I wonder if the approach that got discussed in the kickoff of the new Workgroups whereby a Task Force could be carved out of the Workgroups to answer a very specific question on a very time-limited scale would work for something like that.

So, for example, somebody from the API Workgroup, somebody from the Content Workgroup perhaps some of the other Workgroups, just a small Task Force to address that specific question, make a recommendation and then disband. Is that in scope with the kind of thing you're looking for or is there some reason why that wouldn't work?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Absolutely and that is, you know, squarely the intent, you know, I think the committee here has an opportunity obviously to guide on the data provenance question whether there is...those of you on the committee in addition to some of the recruits from your Workgroups that you may be the chairs of that you feel would be best suited to, pending availability, to be on one month Task Force in this case to get stuff done and report out and disband.

You know, similarly with the S&I Framework question, you know, I think certainly we're open to having that be structured incrementally or in phases depending on how the discussions go but there is, you know, somewhat of a timing aspect as identified in terms of impact and progress in the near future that needs to be taken into consideration.

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

Good, thanks.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

In relation to David's question and I'm sorry, I'll turn it back to you David in just a second, a one month Task Force through the holidays? I wonder is there an opportunity to rethink that timing?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Well, the purpose and, you know, certainly open this to feedback here, you know, we purposely specified the question on which we would like advice to be as specific and tangible, and discreet as possible.

I don't think we see this kicking off before January. So there is, you know, the kind of, you know, three and half weeks prior to the Standards Committee's meeting on the 27th, which is why we felt, based on the way we framed the discrete question on which we wanted advice, if the interested parties were able, the question could be answered and, you know, again, please folks can let us know, the question could be answered in a few meetings that may not be very long from a Standards Committee commitment perspective.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, you know, obviously we want agility and we want efficiency. And certainly the Steering Committee can take this up and noodle through it just...Michelle, I'm sure you've had the experience of scheduling experts calendars and to try to achieve the formation of a Task Force, the scheduling of the experts, the gathering of their input, the review of their input in a couple of weeks might be hard.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

John, this is Lisa Gallagher, I also wanted to mention that the Transport and Security Standards Workgroup has data provenance on its long-term work plan. I think it's, you know, two more topics and we get to it. And it seems as though that schedule for that task for us is later than this timeframe and so I think this is something that maybe we can discuss with the Steering Committee and with Michelle and sort it all out.

Because, I mean, Steve is asking a specific question here. And on our work plan, we didn't have any specific questions assigned to us or asked of us but we knew that we would be looking at this topically somewhere on our work plan. Just a point of information.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very helpful. Well, David, please, did you have another comment you were going to make?

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

No, I...that's all. I wasn't thinking about the timetables but more about the process of using short-lived Task Forces, timetable issues have to be dealt with obviously.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, was that...Michelle did you say Arien also had a comment?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

He does.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, Arien, please go ahead?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

You know I think I'll withhold my comment. I'm understanding that Steve wants a Task Force for the S&I Framework evaluation and I'll be happy to volunteer for that and save my comments for that Task Force.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Wonderful. Thank you very much. Michelle, other folks in queue?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

That's it.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So, I think the feedback...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

This is a Stan Huff. I raised my hand, I guess it...I don't know it maybe not working or something.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Please go ahead, Stan?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, I may follow Arien's...I had a comment about the S&I Framework and if there's going to be Task Force then I guess I would volunteer for that Task Force and not raise the point here. So...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Okay.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

I think what you're going to see, Steve Posnack, is that there's going to be a great interest on the Standards Committee for engaging in that S&I Framework review and asking how, as you say, now that the scope of effort is different and the environment has changed, how do we all best work together and I think we'll have many comments and thoughts on that, so look forward to it.

And with regard to this general use of Task Force I think that everybody is aligned with that concept that we have Workgroups that will accomplish some of our tasks, but there will be some interesting multidisciplinary questions that are best answered by bringing together some experts from multiple Workgroups to answer a narrow question.

And I think we're going actually have to learn together how that is exactly going to work, be timed, to get to the kind of efficiency you want to see. And so maybe that Provenance Task Force is going to be our first opportunity to learn how the whole process will work.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, and I very much appreciate everyone's engagement and willingness to take this journey with us. I know it's certainly a little bit of a different model, you know, an evolution as we continue to find the most efficient ways in which to get advice from our advisory committees.

So again, appreciate all your engagement and perhaps willingness to withhold comments for future work which I'm sure I will certainly hear at that juncture and I think we are very much on schedule. So, thanks again for your time today and look forward to continuing to work with you on these topics as we get them going.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Steve Posnack of course, now holds the mantle of leadership for all of these various items in his office. So, we're here to help you, Steve. So, Michelle, I think what we have left, if there are no other comments, is the opening of the agenda to public comment and feedback.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Operator, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

If you are listening via your computer speakers you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

We have no public comment.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, given that many of the items that we discussed today were controversial, only internal to the federal advisory committee process, I can understand. And so thanks certainly to everybody on today's call. And this will be, I think, Michelle, our last meeting of 2014? Is that true?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

That's true so our...

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And our last meeting before the holidays and so of course everybody will be kept informed. There is a Steering Committee tomorrow. There is a chair's call tomorrow. So activities will progress and we'll certainly keep you in the loop as to whether the January committee will be virtual or where we are going with the Task Forces and the timing on those Task Forces, and other items that may arise.

But, I certainly wish you a wonderful and safe holiday. I hope you have a Happy and Healthy New Year. And we will reconvene in 2015. But, Jon White, I'll leave those closing comments and benediction to you.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Oh, well, thank you John Halamka, was there somebody else who had something else to say or is that just an unmuted phone in the background?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It sounded like an unmuted phone.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Okay, very good. Well, you know, off-line, this is when we we're getting ready for the start of the call, you know, I said that I was the least important person on the phone and that's still true. I'm grateful very much for all of your expertise and all of your attention. You know a time of change at ONC is a time of renewal and I think that you've seen some of those opportunities present themselves to you today so I am incredibly grateful for your engagement and for the hard work of Michelle and Steve, and Seth, and all my colleagues at ONC. And so I've got a lot to be thankful for this holiday season and look forward to working with you in 2015.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Great, well, thanks, Michelle, I think with that we are joined.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

We are adjourned, thank you John, Happy Holidays everyone and I hope you...

M

Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you, Happy Holidays.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

You too, bye-bye.

M

Bye.

Meeting Attendance					
Name	12/10/14	11/18/14	10/15/14	09/10/14	08/20/14
Andrew Wiesenthal	X				X
Anne Castro	X	X		X	
Anne LeMaistre	X	X			X
Arien Malec	X	X		X	X
C. Martin Harris	X	X		X	
Charles H. Romine					
Christopher Ross				X	X
David McCallie, Jr.	X	X		X	X
Dixie B. Baker	X	X		X	X
Elizabeth Johnson	X	X		X	X

Eric Rose	X	X		X	X
Floyd Eisenberg	X	X			
James Ferguson	X			X	X
Jeremy Delinsky		X			
John Halamka	X	X		X	X
John F. Derr	X	X		X	X
Jon White					
Jonathan B. Perlin					X
Keith J. Figlioli	X			X	
Kim Nolen	X	X		X	X
Leslie Kelly Hall	X	X		X	X
Lisa Gallagher	X	X		X	X
Lorraine Doo	X	X		X	X
Nancy J. Orvis				X	
Rebecca D. Kush		X		X	X
Sharon F. Terry				X	X
Stanley M. Huff	X	X		X	X
Steve Brown	X			X	
Wes Rishel	X	X			X
Total Attendees	21	20	1	22	21