

**HIT Standards Committee
Transcript
April 24, 2014**

Attendance

The following members attended the meeting:

- Dixie Baker
- Mike Lincoln for Steve Brown
- Anne Castro
- Jeremy Delinsky
- John Derr
- Lorraine Doo
- Floyd Eisenberg
- James Ferguson
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Jonathan Perlin
- Wes Rishel
- Eric Rose
- Christopher Ross
- Sharon Terry
- Andrew Wiesenthal

The following members were absent:

- Keith Figlioli
- C. Martin Harris
- Anne LeMaistre
- Nancy Orvis
- Charles Romine

Presentation

Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – 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 and it's actually the 56th meeting of the Standards Committee. It's been a little bit of time since we've gotten to meet together, so I'm excited to see everybody in person. As a reminder, this is a public meeting and there will be time for public comment. There will be two public comment sessions, one before lunch at one of the end of the meeting. A reminder to those making a comment, there is a limit of three minutes for public comment also, as a reminder throughout the day, if you could please remember to state your name before speaking because the meeting is being transcribed and recorded. Also, if you're following us on Twitter, the handle for today is #HITSC. And with that, we'll now take roll and we're going to go around the room, because we haven't seen everyone in a while. So we'll start with Sharon.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Sharon Terry, Genetic Alliance.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Becky Kush with CDISC.

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

Floyd Eisenberg, iParsimony.

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

Kim Nolen, Pfizer.

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

John Derr.

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

Jamie Ferguson, Kaiser Permanente.

Andrew M. Wiesenthal, MD, SM – Director – Deloitte Consulting, LLP

Andy Wiesenthal, Deloitte Consulting.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Anne LeMaistre, Ascension.

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

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

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

David McCallie, Cerner.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.

Jeremy Delinsky, athenahealth.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Jacob Reider, ONC.

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

John Halamka, Beth Israel Deaconess. Good to see you all again.

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

Jon Perlin, HCI and Vanderbilt University, good to see everybody as well.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Good morning, Karen DeSalvo, ONC.

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

Arien Malec, RelayHealth.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Dixie Baker, Martin, Blanck and Associates.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Cris Ross, Mayo Clinic.

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

Liz Johnson, Tenet Healthcare.

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

Eric Rose, Intelligent Medical Objects.

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

Lisa Gallagher, HIMSS.

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

Stan Huff, Intermountain Healthcare and the University of Utah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Leslie Kelly Hall, Healthwise.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Doug Fridsma, ONC.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Steve Posnack, ONC.

Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

Judy Murphy, ONC.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Jodi Daniel, ONC.

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

And are there any members on the phone?

Wes Rishel – Independent Consultant

Wes Rishel.

Michael J. Lincoln, MD, FACMI – Director, General Standards – Veterans Health Administration

Mike Lincoln, oh, sorry.

Wes Rishel – Independent Consultant

Go ahead.

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

I heard Wes Rishel and Mike Lincoln for Steve Brown, anyone else.

Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Amy Helwig, ONC.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Mike Lipinski.

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

Okay, and with that, I'm going to turn it over to Karen to make some opening remarks.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you Michelle. And thank you to everybody who came in today to this spectacular spring day in Washington, to sit inside for many hours and work on important challenges for the country. We have a really full agenda, which we'll go over in a bit, but it's just really wonderful to put some faces with so many names. So for me, this is my first in-person Standards meeting since I've been the National Coordinator and I was excited to get to meet everybody. I actually want to throw a little bomb in the middle of the conversation this morning, not a bomb, but Jon Perlin and I had a conversation recently and so we have a slight change that won't happen today, but for our next committee meeting. But since Jon and I both will be leaving around lunchtime, we wanted to go ahead and make the announcement this morning.

As many of you know, Jon Perlin has been our Chair for some time and he's such a hard-working man, and not only does he have this role, but he has the job at HCA and he's taken on a new hat as the President-elect for the American Hospital Association. And we so looked forward to him staying on the Standards Committee in that role and his other roles and also being our partner at the AHA, but we know he's got a mountain of work ahead for that very important additional job and organization. And so, in that vein, he asked if perhaps there could be some leadership transition so he could make certain that the Standards Committee had a Chair that was able to devote attention that it requires.

We're going to do this in a way that I've asked Dr. Jacob Reider, who's the Deputy National Coordinator to step in as Chair and mirror the structure that we have in the Policy Committee, where ONC is Chair. But the Vice-Chair, who will remain as John Halamka, is – runs meetings, the force of the day and that will help, I hope, keep the Standards Committee very tethered to the work of policy and ONC. This is an independent body and we want to have that independent feedback. So please don't misunderstand anything about it, it's really a measure of – or a way that we can keep what has seemed to work very well in Policy Committee a structure and see if we can apply that to the Standards Committee. So I also want to thank John Halamka for agreeing to stay on as Vice-Chair, he's done a tremendous job and intellectual prowess is known to all and has been a real resource for me and for all of us at the ONC and for this committee.

So, we will not make that change today, but since we're all in-person, we thought it might be good to do that. I wanted to just personally thank Jon Perlin, who I've known since before I became National Coordinator, but had a chance to get to know in this role. He is just a tireless worker, really committed to the vision and promise of HIT as the nervous system for healthcare, to make all patients' lives better and to improve cost and care. And we're excited to see that he's going to be lending that to the AHA as a partner, in addition to what he does at his institution. I have a tiny token to say thank you to Jon, a certificate of appreciation from us, but we'll be doing something more formal. Since we were in person today, we just wanted to pass off a certificate to him and I don't know if you want to say any remarks or if you want to do that a little later today. It's up to you.

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

First, let me just say thank you to all of you. This has been an extraordinary privilege working on something that I know that we are bound really by passion for. We see health informatics, not as an end in itself, but as a means to an end, that end being really the Triple Aim, better health, better care and higher value for our country. And that, I know, is what has bound us together, for those of us who have been here since the beginning. As Karen mentioned, I've known her for a number of years and I can't tell you what an extraordinary individual Karen DeSalvo is. She is really one of the standout heroes in the wake of Katrina and really as a practitioner on the ground, demonstrated the utility of electronic health records in terms of assuring the care of patients who were so horrifically dislocated from their continuity.

I think all of us realized it was also a case lesson in the discontinuities that are inherent to paper and certainly, we were forever bound by passion for the use of information. Because at that juncture, I had the great privilege of leading the Veteran's Health System and the electronic health records really assured that whether veterans relocated to Washington, DC or Washington State, their information followed them. And that's really also been a driving passion in our work together.

I would be remiss if I didn't thank someone who has really been a mentor to me in terms of understanding the importance of standards, in terms of achieving the Triple Aim, and of course, I'm talking about John Halamka. I never considered John as a Vice-Chair, I've always considered him as an absolute partner in this activity. And really been a privilege to share that partnership with someone with such a passion and intellect and really a practical understanding. We hear about his adventures at Beth Israel Deaconess and it's great to be grounded in someone who's really living this. I've tried to be a little bit of a blank slate about my home organization, but we're living the dream with you and the truth is that it's really exciting.

Just a point of personal privilege, I've tried not to talk a whole lot about my home organization, but we won an award this past week. We did a study as 75,000 patients, it was a comparative effectiveness, three-armed comparative effectiveness trial, looking at improving outcomes and prevention of MRSA. One was screening and isolating patients on admission to intensive care, another was screen, isolate and decolonize and the third was decolonize everybody, 43 hospitals, 74 ICUs, 75,000 patients, 280,000 patient/days. Answer, 18 months. Why was that answer available? Well, it was available because the information was able to converge, was able to be interoperable.

And I'll tell you a story is that first, the utility of that was that the answer, by decolonizing everybody reduced all bloodstream infections by 43%, for every 99 patients you decolonized, you avoided one bloodstream infection. That's on top of every other best practice down, so really, really proud of that. But I'm also tantalized, terrified by the notion that we didn't actually have to do the trial, that the answer existed all the time in the collected memory of all the healthcare experiences that came before. And as we look to the future and what we look to what's been accomplished over these last few years with the inception of Meaningful Use and HITECH and the acceleration. I know it certainly accelerated the implementation in our organization, I believe that our next study can come from that collective memory and allow us to really provide better care, better health and better value. In fact, that's how we'll approach things.

Finally, all of you members of the committee, as we look at this agenda, this is my segue to the order of the day, I noted it was the 56th meeting. And at one level, that seems like an awfully long time, but when you look back at another level, it's also an incredibly short time and the acceleration that Meaningful Use has provided for really using health information as a means to an end, it's absolutely extraordinary. And when I looked at the rest of the agenda, I saw there's an awful lot of work, a huge amount of work, the technical knowledge, the Implementation Workgroup, Clinical Quality Measures Workgroup, the Privacy and Security Workgroup's response to the NPRM. I mean, just an extraordinary amount of work, an extraordinary amount of knowledge. People, each of you with day jobs that I know are as equally challenging. But nevertheless, you made that commitment, I will forever be indebted as a potential consumer of healthcare, as an advocate for family and friends and communities on my AHA role. That's an extraordinary contribution that you've made and thank you for that.

And finally, the extraordinary staff of ONC. This – I know John, you I think were the one who coined the term, Office of No Christmas and indeed, this is the staff, Judy, Jodi, Michelle, Jacob, Doug, I know I'm going to leave people out, all – Steve, I'm seeing this here, but all the folks, your predecessors in the office, it really has been a group that demonstrated the best of government, the best public service, best of really mission-driven government service. It's been an absolute delight and so, with that, let me just say thanks, to offer my commitment to work with you from a slightly different vantage point and thank you for the extraordinary honor of serving as your Chair these last few years. Thank you so much, Karen.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thank you, Jon.

(Applause)

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

And Jon we'll do our best to keep you proud.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And with that, I will hand it over to the Chair and Vice-Chair to make their remarks.

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

Well, I think I've made my remarks, but before I turn it to John, I will – it feels really good to ask, are there any amendments, modifications or changes to the minutes? As always, again thanks to the ONC staff for a very sensitive and thoughtful recording of our past proceedings, to that we will assume consensus for the minutes and with that, turn it over to Dr. Halamka to walk us through the agenda.

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

Great. Well thanks so much. We will miss you greatly, but as I say, the work will continue and in your new role you will hopefully benefit from increased interoperability, standardization and data liquidity, that's the plan. Today's meeting is very important, first, we're all here in person, so very good that we can gather as we deal with a whole variety of issues, the 2015 NPRM, planning for 2017, even thinking about the future of this committee and how it does it's work.

So, as you may recall, ONC looked at all of our terms and recognized that there were limits associated with our terms and had to very thoughtfully plan for the future of this committee and its work, as people come and go. And looking at all of our workgroups, what ONC tried to ask is, how is our expertise organized? At the Policy Committee, of course, they have created an organization, which is sort of reflective of how healthcare is delivered and the policies to be made.

If we tried to mirror that in the Standards Committee, we would be putting Dixie Baker on 17 different working groups. Now, she might love that, but instead, what you will see is a strawman proposal, that is a first draft from Doug, as to how we might organize our expertise so we don't find ourselves divided in 17 different ways. And that is, how do we take Policy Committee or ONC questions and assign them to a set of domain experts who would then be able to issue a deliverable back to the questions asked. So I think you'll take a look at how Doug has organized us and look for your feedback, but it seems very logical to me.

We'll be hearing, I guess it's the Dixie Baker show today because we have a number of presentations from Dixie, the Privacy and Security Workgroup and NPRM feedback and really some important questions to ask on how we do identity management, especially as we're offering more kinds of interoperability to patients and families. And how we are thinking identity proofing for increasing numbers of payers, providers and patients and constituent organizations and third-parties should work in the future. Because as we look at the examples of the past, X.509 certificates for every entity everywhere and PKI in the cloud, they may not scale so well as we get to 330 million patients and third parties offering apps on your iPhone. So we'll hear from her about the NSTIC hearing and feedback on looking at frameworks, not specific standards and technologies.

And on the NPRM, I have to tell you, having read every presentation today that will review the NPRM for 2015, they are extraordinarily thoughtful and realistic, boots in the ground analysis from the Implementation Workgroup. Privacy and Security Workgroup looking at how do you enforce end-to-end security principles in a modular world, some very tough questions. And I look forward to delivering those to ONC, because ONC is, I imagine, I don't know this, but in the next few months is going to go dark into regulatory writing. And this is going to be an important opportunity for us to get in or comments to frame what are the societal goals with some of the operational realities that all of us face, so as those regulations are written, they are taking into account the input from all stakeholders. So we'll hear from Dixie and Lisa and Walter and I think we also will hear from Marjorie Rallins and Danny Rosenthal on the clinical quality side. We have a lunch break and then we hear from the Implementation Workgroup and then Steve Posnack, I think you're going to be talking about FDASIA today, a bit, okay. And then we'll get people back to their transportation.

So, I think so important that as we hear the comments today, that we weigh how it is ONC can write regulations that empower interoperability but also don't put limitations on innovation. I spent 12 hours yesterday going through the automated numerator and denominator certification for our ambulatory systems with CCHIT. Beth Israel Deaconess still self-builds its system and I believe we may be the only hospital who has actually survived the Meaningful Use Stage 2 certification to the point of complete EHR certification. I don't know, maybe there are others. But there are some really important lessons learned about the balance that has to be struck between moving us forward with regulation and creating burden and impeding innovation. I mean, as a somewhat silly example, it turns out our entire emergency department now uses this is the user interface.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

You were holding out on me –

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

Sorry. And so, when emergency physicians walk into the room of the patient, the data about patients, their problems, their meds, their allergies, their lab results, and the workflow of the department appears before their eyes in context for the patient they are treating in front of them. Now we were able to do this because three emergency physicians –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

(Indiscernible)

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

– yeah, in the middle of the night on weekends outside of the Meaningful Use mandates, decided this may be an important innovation to try. And so hence, I just urge us as we have discussions today, let's ensure appropriate regulations as well as encourage innovation, and that's – I hope, will give ONC the wisdom to write regulations that are balanced.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

John, you might tell the listeners what you were doing, because –

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

Oh sorry, for those who are listening, I was wearing a pair of Google Glasses, anyone can try these if they want – by the way Dixie, and these have WPA enterprise wireless security built in. They will only bond to the physical Beth Israel Deaconess Network. It requires three layers of authentication using QR codes as to who you are, where you are and who is in front of you. So when you turn them on you will simply see logos, desperately searching for Beth Israel Deaconess WPA networks. It won't work here in the fine Plaza Hotel.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates
(Indiscernible)

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

And by the way, it doesn't send any data to any cloud of any vendor. They are kept within the Beth Israel Deaconess firewall. So that is the agenda for today, here, I'll turn them on for you. And I look forward to our discussion.

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

I actually have to note that there was a change, a last-minute change in the agenda. So instead of spending our morning with Dixie, we're going to spend our afternoon with Dixie and the Implementation Workgroup is going to go first. So sorry for the last-minute change.

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

Okay, so there you go, it's now got the glass logo. You can play with the prism. And I'm sure your staff is going to tweet the pictures.

Okay. So let me make sure we have the updated agenda here, so we have gone through the introductory remarks and Doug Fridsma will begin with the work group evaluation discussion.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Great. Well, thank you. It's good to see everybody's faces, we've heard your voices over the course of the last couple of months, so, good to see the faces. So, what I'd like to do is just tee off a discussion about really trying to find a way, after kind of a couple of years under our belts in terms of how we've structured and organized our work, to try to think about going forward. How we can continue to be productive and really start driving the conversation around the standards that we need to support the various policy objectives of ONC and the administration. So, if we go to – oh, I guess I have the control here.

One of the things that we have talked about is what is the strategy that we need to follow? What are the things we need to do, with the standards that we've got within our portfolio? So, it can be distilled really into three basic appro – things that we've got to do. The first is, we need to make sure that people who are on the Meaningful Use escalator, if you will, continue to be successful. So we need to support the success of Meaningful Use Stage 1 and Stage 2. And that means that if we recognize that we have a value set for race and ethnicity in one of our standards and there's a value set for race and ethnicity in another standard, there – and we need to make sure that those are consistent. We need to make sure we take a look at our existing standards and we update them that we fix things that we find that need to be sort of brought together. Errata that might have popped into some of our public health reporting or things that we need to do to refine our standards of care summary and the like.

So we need to make sure we support these successes of Stage 1 and Stage 3 and then we need to begin to look at how to expand our portfolio. So we need to say, do we need to include long-term care? Are there behavioral health use cases that we need to expand, using our existing sets and kind of expanding that out to include ACOs, payment reform, some of the acquisitions that are going on with the VA and DoD, other kinds of administrative priorities. And then, because we're focusing on kind of the technology and the standards, we need to make sure that our standards portfolio remains fresh and that it's being able to use the latest and greatest that's out there. They say the only standard that you never update is a standard that you never use. And so if we're going to use standards, we need to continue to make sure that we are moving towards those that are simple, that are new, and that are more powerful.

And so for example, we have standards for transport based around Direct and we also have standards that use Web services. But we also have to think about the rest of the world and where they're going with these RESTful approaches that are using mobile technology and other kinds of standards and making sure that as we look across our portfolio of things we standardized that we continue to sort of update that. And that's something that spans multiple use cases. We want to be able to use our vocabularies across a whole range of different things. So we have to always keep in mind as well, that our job is to create a platform for others to succeed in the work that they do and it is not going to be a one-size-fits-all. There are going to be a whole host of different ways to do these things. And so a portfolio of standards, services and policies are going to be what's going to be helpful for folks to be successful in what they do. And we need to be able to build incrementally, we don't want perfect to be the enemy of good, which means we're going to constantly have to go back and revisit and update the work that we've got on board.

And so you've probably seen this slide before, because I show it just about every chance I have that talks about the five things that we've been trying to standardize to help us get to interoperability. So the five things we standardize are we standardize meaning, structure, transport, security and services. And services really just sort of take those first four, packages them together and provide a mechanism to sort of access that information. And so when we were thinking about how to support the ongoing work of the HIT Standards Committee, we really were trying to figure out a way that we could in some sense, almost matrix the kinds of work that's coming out of the HIT Policy Committee.

So the HIT Policy Committee might say, we want to make it very, very easy for people to get access to imaging information. Well, that's going to require some discussion around vocabulary, it's going to have to have some discussion around what that standard is for that image. It's going to talk about how you would move that information around and then how you would secure it. And that's going to be constant across many of the other projects. If it's imaging or whether it's care summaries, if it's patient engagement, or even if it's research, we're going to have to have that kind of conversation. Now the thing is, we don't want to create silos of excellence, we don't want our consumer engagement piece to be different sets of standards for vocabularies and transport than what we would have say to support research. Because when you talk about things like patient-centered outcomes research, we've got to make sure that those two things work together. And so we need to think kind of across the various user cases, what kinds of vocabularies we need, how to leverage the data structures that are there. How to make sure that we have consistency and that as we go from our current suite of standards to new and updated ones, we have an opportunity to do that.

And so, just – this is burned into your retina, everybody has that image so if you close your eyes you can still see it. And then we take a look at how we'd like to organize some of the work here. And there's a similarity to what we might see, that is, we think that if we can organize around vocabularies and information models, documents and data structures, transport and security, services and APIs and certification and testing with sort of an overarching steering committee as well. That is going to help us make sure we've got all the pieces in place.

So one can imagine that the vocabulary and information modeling group might be able to collect people who have expertise in that area, deep knowledge, that then can look across all of the various use cases that we have and say here is a consumer vocabulary that we need to add to our portfolio. Or here's a way that we can leverage the existing standards that we've got and apply that to some of those other use cases. And it helps us to make sure that we don't miss things like having separate but slightly different ways in which we represent vocabularies or information models or the way in which we have our documents and data structure, so there's a consistency across those things. And so it becomes almost like a matrixed organization in the sense that we've got policy objectives that are going to require us to be able to look at each of those things.

Now, my guess is if we look around the room here, there are a bunch of people who can probably articulate one of those places where they might be able to contribute. And if we need to be able to bring in other subject matter expertise, we can bring them in specifically to help us with some of those activities. It becomes very easy for us to focus and it relieves poor Dixie from having to serve on every single one of the projects, because she can focus one of those areas, we've got your name penciled in, and so we'll talk about it. And really sort of focus on some of those areas that we need to have. Now this is going to require a certain degree of support from ONC, to be able to help kind of distribute the work and create the integration that we need. But we also want there to be visibility and coordination between the Policy Committee and the Standards Committee.

And so we would like to be able to identify people who can serve as liaisons to the Policy Committee and vice versa, so that we've got folks that if there's something that's going on within one of the vocabulary groups or one of the data groups, they can also be participating in some of the policy groups as well. So that we've got this kind of closer integration, if you will, because of the need to really kind of take those policy objectives and marry them to the technologies that are there. That also educates all of us, there's kind of a cross-membership continuity, we get to know what is going on across these things, and I think that provides a much more robust and a much stronger committee, because we've got those kinds of relationships that are there.

So here's just sort of a use case that I wanted to kind of put – go through. And we could do this for a lot of different recommendations. So for example, patient generated health data, so the HIT Policy Committee will say, we want to make sure that patients who generate their own data have a way of getting that into the getting that into the system and having it integrate with the rest. So we then go to the Steering Committee and we say, what are the kinds of problems that we need to solve to allow that kind of engagement to occur? We might say we think, although there are lots of issues, we might think that the principal thing would be to take our consolidated CDA and figure out a way that is to extend that so that patients can actually author their information, put it into that format and have that content structured in a way that it computer can understand it.

So we might take that work and make a primary assignment to the Document and Data Structure Workgroup and would get recommendations. Now obviously that group might also say, is SNOMED the right vocabulary? Is there a consumer-generated vocabulary that needs to be handed as well, and we can then assign a subset of that work to the other committee. But there's sort of a main committee that we think is going to be charged with that work. And then once those things are integrated, the Steering Committee can make sure that that integration occurs across the various workgroups and be presented back to the HIT Standards Committee.

And so we think this allows us sort of the Goldilocks place, where we can get experts who know a particular area, who can then look longitudinally across many of the different policies and then there's that integration across our portfolio of standards. And then we create a way in which there's better kind of visibility across Policy and the Standards Committee, so that people kind of know what's going on and that we then, within ONC and working with the Steering Committee, can help to integrate that work more effectively. So with that, I'm going to go to the last slide here, and then just open it up for comments, if people have things to say.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel

So, just may I make a brief summary comment and that is, if you look at the nature of our domain expertise, it's typically around content, we transmit a package of information, the vocabulary and the transport mechanism, which is often related to security. We have to somehow figure out how to triage the requests that come out of the Policy Committee into the right buckets. We somehow would like to see a future interoperability state based on Web services and APIs and we certainly as we have testing and certification, want those, as I said in my introductory remarks, to be thorough, so we know the products interoperate, but not burdensome, nor stifling innovation. So I think what you heard from Doug is a construct which attempts to align our domain expertise with the work ahead.

But now let us open it up, because there are several cards that went up to comments. And I think, I see we have a raised hand as opposed to a card. So why don't we, I'll tell you what, in the interest of just trying to keep this orderly, why don't we go ahead and start with Floyd and we'll just go around.

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

Okay, so I just want to start by complementing the order. I think the structure you describe is very nicely put together. My only question, I mean, I like the categories and it fits really well with the work we've done, but, and I apologize for using Dixie's name in this, but are you really asking her though, or people like that to work, to work with many Policy Committee groups rather than many Steering Comm – Standards Committee groups? Okay, I just wanted to clarify.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

No, no, no. There would kind of a liaison identified, and it wouldn't necessarily have to be Dixie doing all of those – that work. But the idea would be is as the policy recommendations come, for example, if Dixie was working on transport and security, something you know a little bit about. We would be able to look across the board to say imaging, ADT, what are the transport issues there, and we might find in some of the circumstances, there's not a whole lot of work to do and we can sort of check the box and move on. Other ones we may want to actually think a little bit more deeply. But having someone who kind of thinks across, becomes, I think, very, very useful.

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

Andy.

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

I agree, I think the categories are great. As I read it in prep for the meeting, I was trying to think of use cases or problems that might not fit into one of the categories relatively easily and I couldn't. So I would put it to the rest of the committee, if we can't think of really outlier use cases, then let's just settle on the categories and not have a lot of debate about it. So thank you for doing that work.

And it also, from a personal perspective, makes me feel like I might get a little more connected with the work here, because I'm a – I was a relatively new member of the group, there were existing workgroups and it was really hard for me to get involved in any of them. And now I think we can restructure. I would suggest that, and maybe you've been thinking about this, that if each of those workgroups has a Chair, that's your Steering Committee, and they can have a formal process for triaging the requests that come from policy or from other input sources.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Yeah, that's a good suggestion. Thank you.

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

Thank you. David.

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

David McCallie, well you can – Doug knows he can count on me for a contrary – contrarian opinion. I think..

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

I would be disappointed if there wasn't.

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

So, not wanting to disappoint you, I'll give you one. No, it's only a concern and I will admit I haven't thought enough about it to be too articulate. But, the – any problem – as you know, any matrix organization runs a risk of emphasizing the wrong axis of the matrix, so you can optimize one axis to the diminishment of the others. The axis that this approach, which is highly logical, doesn't emphasize is the use case development, because the use cases cut across every one of these, or most all of them. So, I would be concerned that we end up experts in narrow horizontals, but that the issues in the field are driven by use case needs, which crosscut all of these horizontals, and that we need some way to ensure that the use cases get the right level of attention. And that that might in the stage of where we are today, be the dominant axis, actually the use case axis, rather than the sort of narrow, technical focus of layers of the architecture.

And I'll just throw out a conjectural possibility to think of it this way is, if you look at what HL7 is doing with FHIR, which by all appearances is going well. It generated a lot of excitement, a lot of vendor interest, a lot of interest from people that are outside of our typical world that have been drawn into it by its approachability. FHIR is at one level, an API, at another level it's transport because the FHIR definitions are closely bound to RESTful approaches, although they could be decoupled, it's clear that's not the dominant approach. It's also a data model because the resource definitions are all about data. And to the degree that you consider FHIR profiles to be a part of the FHIR workgroup's expertise, it's about vocabulary as well, although I think you could carve that off relatively safely.

So something that's as exciting as FHIR, really cuts across at least three and maybe four of these groups. And I don't have a counterproposal but I just think we have to be sensitive to the vertical use case axis of your matrix.

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

That's certainly a very wise comment, and as we presented some early thinking to the Policy Committee, they were concerned that we would find use cases that wouldn't be parcelable. Because we would find, oh, you know, there's going to be a little bit assigned that security and a little bit assigned that's content and a little bit assigned it's vocabulary and they're going to have three different answers and we're not going to be able to consolidate to a single answer. So, I think the concern is certainly very well taken and we hope, I mean as Andy said, for the majority of the use cases that come our way, they'll be parcelable. And FHIR, as you point out, could be a rich discussion on the content side, but it also could be a rich discussion on the API side, as we think of hmm, what the JSON report said is, you need more APIs and is FHIR an answer to that. So, we'll watch that.

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

Well, and just to pick back up and reflecting Jeremy's comment whispered in my ear, I mean I think you could imagine an alternate structure where you identify expertise in the group along these lines, and people register themselves as being particularly interested. But then convene workgroups around high level of important use cases, like say the JSON model, which is going to cut across every single one of these, if we were to push that forward. So your workgroup might be convened around something like JSON, populated by expertise drawn from committee members who have said, I'm really interested in and willing to us contribute on transport, but I'm not really good in vocabulary or vice versa. I'm really interested in vocabulary but not transport. But the workgroup itself would be organized around the deliverable, a use case that is going to become a certification test, become an incentive measure, is just a thought.

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

Great. Thank you. Arien?

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

Thank you, as usual, David has nicely – was a good predecessor for me, because he encapsulated a lot of the things that I wanted to say already relative to, this is the layers of the cake model as opposed to slices of the cake model. I would point out that right now we actually are too much use case driven and this might be a good natural corrective in the sense that take an example, immunization data. If I want to send it one way, I encapsulate it as a consolidated CDA document and send it over Direct. If I want to interoperate with a state-based immunization registry, I package it as a SOAP document with an HL7 2.5.1 message. And I don't actually know if the way that I do privacy and security with the immunization registry is interoperable, the way that I do privacy and security on the eHealth Exchange, in terms of the fundamental security primitives.

FHIR is a great example of an architecture, and one thing that I worry – so, anytime you reorganize, you either organize often in functional layers or you organize in service lines or business lines and there are predictable failure modes for each of those organizations. So I would encourage us to think about the predictable failure modes of this organization and in particular one concept that I fear is – would be missing is not just the concept of a use case, but also the concept of an architecture. And FHIR is a really good example of a coherent architecture for interoperability that defines across a number of different use cases and a number of different domains. It might be worth adding an architecture group, it might be worth looking at the Services and API as an architecture group. I'm thinking in terms of the discussion of ultra large scale systems and what the kinds of emerging architectures we need to see so that we can actually get coherent and consistency across the layers of the cake. Like Andy, I can't argue with the layers of the cake, they're the right layers and I think we – actually, it is a needed corrective to go with this model and I compliment the model.

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

Great – I think the intent was that the API and the Services group was to be that architecture oriented group. Cris?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So, following McCallie and Malec is always a bad thing and so I'm left with the cranky components of the comments as opposed to the substantive one. I guess, my observation is I think that interoperability is absolutely crucial and I've been on the Standards Committee representing different organizations and interoperability has been the one issue that has come with me from each of those organizations. So I have absolutely no question around the importance of interoperability, especially where we are right now. But I'm struggling with it feels as though this is – we have now made interoperability the only issue, and I worry about that. So I'm trying to map this structure and this focus against the issues that my organization is struggling with right now.

So I look, for example, at the topics that we're going to talk about during the Implementation Workgroup session and I don't see a natural mapping for things like CPOE, meds, labs, rads, images. I don't see issues around electronic notes, family healthy history, demographics, clinical decision support, patient list creation, patient specific education resources, implantable device lists, and safety-enhanced design. Everything around usability that we need to confront, issues related to – workflow issues in general and efficiency of operations, quality, general issues around numerator, denominator. So, I don't see the – how those issues map against this structure.

Now I know someone can say, oh, well but there's an interoperability view on all those issues, which is undoubtedly true. But I just see what our organization is struggling with what we dealt with in the Implementation Workgroup, there are still some fundamental kind of issues that I don't think we're done with that work yet. So if there's a way for us to put a principal focus on interoperability without making it the only focus, I would feel a lot more comfortable. I just feel like we're leaving ragged edges behind.

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

– again, we haven't really defined the scope and mission of each of these blocks, that the Certification and Testing block, as you think about that one, may subsume a lot of the activities of the Implementation Workgroup, because it's in effect taking interoperability to workflow reality.

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

Yeah, I think that from a – this is Liz Johnson, I was going to add on to Cris just for a second, John, just to say –

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

We're a pair –

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

The only thing I want to be careful about is that often when we get to certification and testing, all of the decisions are made and we want to be sure that we're in front of those decisions, at least from an input perspective. For example today, talking about 2015, ONC did a really terrific job of giving us an opportunity to really come to the table on all aspects before it became a reality for us, it's a really good way to do business.

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

So Doug, it sounds to me like a friendly amendment here, that as we craft charters, terms of these committees, that these concerns that have just been raised of well how do you actually analyze the impact on an organization of new policy requirements? Well, certification and testing covers some of that, but there's probably is just sort of real-world implementation that is also to be considered as part of that body of work.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

And just a kind of plea to the sort of holistic issue of when I think about what our EP in particular are thinking about as they think about, how do I change my practice so that I can do what's intended by Meaningful Use, not just the check off the issues, where does that land? And where would it be clear that a clinician would understand that their viewpoints and concerns would be appropriately lodged someplace in a non-fractal way, so that we could think about them holistically.

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

And this whole really base question of the articulation with the Policy Committee itself, which is, we often find ourselves in the position of the Policy Committee proposes a noble societal goal and then we say, well, as those who have to deliver that service, here's a complexity you may not have thought about. And how do you close that loop so that you then refine the approach to such a goal, as you point out. We don't want to just check the boxes, we actually want to improve patient care. Lisa.

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

Thanks, Lisa Gallagher from HIMSS. Doug, one question, I'm wondering if you can elaborate on the structure and the role of the Steering Committee?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

So I think part of what is going to be required, and I kind of like what Andy had suggested here, but part of the challenge is to make sure that there is some coordination across all the activities that are ongoing. I think it's – this is the HIT Standards Committee and so what we do is, we focus on some of those technical standards that are out there. Now, obviously there are implications, some of what we standardize is workflow, some of what we standardize is an implication of what that looks like. And if there's a need to put in some additional committees or to expand the charter of one of the existing ones that's proposed, I think that those are good things.

I think if we go back to, let's see, this slide here, just the whole notion of let's try to triage the work that's going on, and I think that's in large part where that Steering Committee would do, identify the type of problem to be solved, the workgroup to review and see if we got it right. And then help to kind of integrate if was a primary and secondary workgroup that was working on things, the Steering Committee could help with making sure that there's good coordination across that.

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

And at the end of the process, when a workgroup has a recommendation to take to the Steering Committee, it looks like there's an interim step to review it with the Steering Committee.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

I think that really reflects more of an integration piece.

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

Okay.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Yeah, not an approval, right –

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

Okay.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

– but more of a coordination integration piece.

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

And so the Steering Committee would be made up of members as well as government representatives?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Yeah.

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

Okay.

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

And I reflect back on the HITSP days, for those who participated in that activity, and there was this crosscutting committee that ensured that the various other committees were talking to each other and that the work was organized and collated. And that in effect would be the Standards Committee could both triage and collate. Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm sure everyone knows what I'm going to ask, but how does the consumer fit into all of this? We see on the policy side that swath of, I think there are committees across the policy, both for consumer and then privacy and security. How are you envisioning that being represented in the standards area? Because just as Arien talked about something, a use case of FHIR crossing all, the consumer and the patient does and they're so largely fragmented right now in efforts that are going on. It's so important to have a – have continuity around an approach, it's almost an architectural approach to supporting the patient and their family members, that has to be considered. What are your thoughts there, Doug?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

So, anticipating your question, yours was the example that we chose.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, Doug.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

The notion here is that we do need to make sure that there is a focus around consumer. And you and I have had conversations about this as well, we don't want the consumer space to be a separate but equal –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

– way of collecting data. So how do you prevent that? We have to be careful that in the HIT Standards Committee this doesn't become a re-adjudication of policy objectives that have been decided or have been recommended as part of the HIT Policy Committee. So there will be a focus within that about clear policy objectives that the patient – that are patient focused about patient engagement, things like that. Now, how do you make sure that those policy objectives are met not as a separate but equal system, but integrated into the rest of the fabric of the standards and services, the other kinds of policies that are out there that would support that. And so, that's why if the idea here is to support patient-generated health data, and we see that as primarily something that's related to content, but there may be vocabulary issues –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Totally.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

– there may be transport issues, we want to make sure that the ways in which we collect data, that we share data, that we represent data. All of those things in the consumer space are also well integrated into the way doctors measure quality, the way that registries and population health is managed and the ways in which research is done. And so part of the reason for this sort of set of building blocks and sort of focusing that attention is so that when those issues come up, we have a way of sort of integrating it across all those different use cases or verticals. One would expect that policy objectives would need to be refined in some way, into a use case, like what's the measurable thing that is demonstrable and certifiable and all those other sorts of things. That use case then defines the work that needs to be done within the HIT Standards Committee, to make that happen.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And when standards are being considered that are outside of healthcare, that are coming to us from consumer organizations, how would you see that working in this framework?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Exactly the same.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

So if you've got a FitBit that's collecting information, we need to have the Content Group or maybe the Vocabulary Group say, well how are we going to integrate this, this is a different set of information and resources. That's far better, I think, than to say, that's a separate thing that doesn't necessarily have to get integrated into healthcare. I mean, it's a challenge, we don't have an answer right now, but I don't think we – if all we do is focus only on consumer, and I – with all respect, we do have other things we look at Leslie. But, the – but if all we do is focus on that, then we run the risk that all we do is focus on the vertical and we don't have the conversation upfront about, well how hard is this to integrate the consumer information? What do we need to do in some of our other areas to make sure that that's possible.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So I would then think that with that in mind, the Steering Committee would act as that voice across and the way to make sure that we don't have a separate but equal –

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

– because we do know a bottom's up approach doesn't create that.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Nor does it top down,

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree. Thank you, Doug.

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

Thank you. Jodi.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Thank you, and I want to – this is actually perfect because I wanted to build exactly on this conversation. I think one of the thoughts in putting forward a Steering Committee is that it's really hard to get sort of the consumer voice. And even like the provider voice, the doc on the ground who is kind of just running their practice and has to implement all of this, get their voice into a conversation about standards and technology. And how can we best do that? And I think one of the things we may want to consider is on that Steering Committee, having sort of a stronger consumer and provider voice, who can also weigh in on how – what the priorities are. What things they would want to see from a consumer and provider perspective to help advise the working groups on where to focus, how to think about the use cases and the like.

So, we had heard a lot of, it's very difficult to find consumer groups that have the technical expertise that we can sprinkle across all these different workgroups. And same thing with kind of the provider on the ground, and so I think one of the things – one of the pieces of wisdom of having a Steering Committee is that we can then kind of concentrate that voice in a Steering Committee, that can help set the direction for the workgroups activities. And then also be sort of a check before the recommendations come forward to the full committee. So I think that that's a way that we can help amplify that perspective and – without, as Doug was saying, having folks re-adjudicating the policy – the recommendations that came from the Policy Committee through all of the different workgroups. So I think that that was sort of an idea of trying to get that kind of balance.

Also, to some of the other comments that were being made, I just wanted to challenge folks to think about what the best role of this committee is, remember, we have a Policy Committee. We have very – we have different charges for the Policy and the Standards Committee and how much we want to either – things back to the Policy Committee if we're identifying that there are issues or questions of a policy nature. Or whether or not that's something that the Steering Committee can help think through and what we may want to have this group focus on. So, in working on this proposed structure and we understand – this is a proposed structure, we really did want feedback on this and we're getting some really good input. That we were trying to figure out how we can best make sure that we're focusing on connecting the dots across these – the different technical pieces without re-adjudicating the policies that the Policy Committee is providing input on. And we would like to figure out how, as Doug had said, we can get the policy input into the standard conversations and vice versa, so that we have better integration and that there's a more seamless pass off between one and the other.

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

Jodi, just to amplify your comments, again, sort of thinking back to the HITSP days, because we had to struggle with these exact same issues, there were two kinds of committees. There was a technical committee and then there was what was called a perspectives committee, patient, provider, payer, so you ensured there was that perspective. And so what I wonder, as so far if I were to summarize the friendly amendments that I've heard, it's Certification and Testing should be recast as Implementation, Certification and Testing. Services and APIs should be recast as Architecture, Services and API and the Steering Committee should specifically, as terms of reference, be charged with ensuring the consumer, provider, payer's perspectives are applied both at the triage of information and in the what I'll call collation, the assembly of the outputs of the other committees. Yes, and Jon.

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

Recognizing there's nothing as immediate and past as the Past Chair –

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

Come on, you're still with us. You're not dead yet.

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

I think John's comments are – I would echo those, whether it's that exact structure, I think this comment about this coherence, whether it's – I really liked that metaphor of slices of a cake versus layers of the cake. And either way, the challenge is, whether it's a use case or whether it's a set of services, good parts don't necessarily equal a coherent whole. And I think this issue of coherence and the term perspective may even be better than that, I think is necessary and wherever it's incorporated, I think that's absolutely a recommendation that I would offer from my perspective. In terms of – and Jodi, to point, I think you're absolutely right is that it's not the role of the Standards Committee to re-adjudicate the deliberations of the Policy Committee. It is, however, as it's always been useful, I hope, to add a perspective on the adoptability, the maturity and frankly needs for further development as standards might apply to those aspirations. That's a – and includes this point that by the time you get downstream to certification, it's hard to retrofit in that perspective or coherence, and that would be the function that I would hope would be incorporated both throughout and certainly at the steering level as well.

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

Thank you. So we have Wes Rishel, who is virtually – oh, oh, so Karen, yes.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Can I cut to the front of the line? This is, for those on the phone, Karen DeSalvo. Speaking on behalf of the Policy Committee, just to follow-up on what Jon Perlin just said, we're really counting on the Standards Committee to keep us straight. So if we come up with a lofty, someone used some language earlier, but a lofty big idea on how to end world hunger, it's really important that you all let us know that that's not ready for prime time in the standards world. So some – not to re-adjudicate but to certainly we're counting on that feedback to be very honest. Thanks.

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

And that's so much appreciated. As has been said, it is not our role to review the appropriateness of the policy recommendations, but we can certainly comment on their maturity, their readiness, the likelihood of success. So, Wes, virtually.

Wes Rishel – Independent Consultant

Thank you, John. I thought your friendly amendments compiled from the comments were good and represented a good way to go forward. I want – I actually, the main topic I wanted to speak about was our necessity to work from two different perspective views along with the daily work we do on the specifics. Okay, one is the perspective of what can be done in a Meaningful Use cycle and therefore, what measurable impact, what – for example, assuming that Stage 2 goes well, we think that 10% of transitions of care will be sent electronically and read with substantial data in a structured format. We – probably, if we get over that hump, getting from 10% to 50% to 90% is easy, it's getting the thing started in the first place that's the issue.

On the other hand we have been focused on the 2-year cycle, which sometimes grows to a 3-year cycle, for so long we have this hopper building up or filling up with things that may take a longer term view. And I would say the same is true from Karen's comments, both about the Policy Committee and about trends in general and from our interest in standards that aren't necessarily replacements for anything that's already being done. To a certain extent, the liaison with the Policy Committee that I think can be most helpful, is one that says, there are no standards of interest that don't relate to a Meaningful Use performance goal. That is an attestation goal, that is we're just not – we're not doing standards for standards, we're doing them knowing that they will have to be implemented in a specific timeframe in order to get an incentive or avoid a disincentive.

And that there be a way to take a policy goal and jointly toss about alternative approaches to that policy goal with appropriate people on the Standards Committee, before it comes down as a hard proposal. I think particularly – the area that has been discussed heavily today is consumerism and there is no disagreement anywhere that – of the value of including the data from the consumer and engagement of the consumer in various ways in the health delivery and the health maintenance processes. But, it is where we set some specific, measurable attestation goal that we have the ability to actually impact change and to be concrete in what we're doing. But it's often fairly hard, I think, for people on the Policy Committee to understand what's implementable in a Meaningful Use cycle. So the extent we can have that level of liaison, here are some ideas, what are the practicality, here's a finalized set of ideas, now let's

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

Well thanks very much, Wes, and I think we've talked in this forum a couple of times about how the idea of certification only criteria actually not a grand idea, from an implementation perspective. That when you start seeing the vendor products including numerous features that no one is actually being measured on using, implementing or adopting that may not achieve our goal. So that is, I would hope that Implementation, Certification and Testing would ensure that the certification process and the features in certification are well aligned with attestation criteria, because implementation adoption is really our measure of success. Jamie.

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

Thank you. Reflecting on the excellent comments around the table here, a couple of things have been mentioned that actually I think are missing. As maybe a layer that's missing from this layer cake currently and that is, standards around workflow and usability. I know that's been mentioned, but it isn't actually captured, I think, explicitly, even in the friendly amendments that have been made so far. So I would make a suggestion in the nature of a friendly amendment, to add a workgroup specifically focused on standards for workflow and usability.

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

And then the question is, in the interest of the smallest number of workgroups, because as we do get more and more workgroups, it will be harder and harder to sustain membership, do we try to put workflow and usability as part of Implementation, Certification and Testing. I mean, because it's related to that.

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

It certainly could be, it's just I wanted to make it explicit.

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

So terms of reference need to be written and it does sound like a positive, friendly amendment. Now Arien, did you have another comment.

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

I did and it's related to the Policy and Standards Committee interplay, and actually related to Wes' comments. In the world of software, there's always a requirements process and there are good requirements and bad requirements. Good requirements are ever green and outcomes driven, they describe states of the world that you like to see. Bad requirements are functional in nature and describe specific implementations. And it would be desirable if the Policy Committee were able to give us more on the order of the ever green goals and as Wes suggested that we collaborate on how to parse those out through Meaningful Use cycles.

We often get a speculation on what would make a good Meaningful Use cycle without being able to back up against the outcome. And related to that, and sometimes I think we need to remind ourselves that there are bigger fish to fry than the Meaningful Use minnow. And that we need to divorce ourselves in many ways, from thinking too much about Meaningful Use attestation requirements and think about standards evolution that supports accountable, value-based care goals. And so there may well be things that we take on, that to John's point, may be grandiose in a Meaningful Use cycle but may be absolutely critical in the context of a value-based care cycle. And we need to have a longer-term perspective oftentimes in the work that we do.

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

And so a couple of comments, which well here, I think today in Dixie's presentation, she describes how modular privacy and security might be a good goal to achieve that as we start thinking of certification and testing of the future, it may not be highly prescriptive, it may not say you must use ADS 256 in every one of your modules or else. It will say instead, demonstrate to us that certain things can be accomplished, and then it gives the industry flexibility, not prescription, but flexibility to achieve an outcome. And certainly I think all of us who have gone through the certification process would like to see some of those characteristics of flexibility rather than prescriptiveness built in. So Cris and Liz, now you're both up, are you going to tag team this?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I don't know.

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

You never know.

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

Okay, well Cris go ahead.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So, I like the friendly amendment, the creation of an Implementation, Certification and Testing workgroup. But to Jamie's point though, it feels as though it sort of becomes the committee of everything else not related to interoperability, and I worry about that a little though, so. To Arien's point about there being bigger fish to fry than the Meaningful Use minnow, holy smokes, that was brilliant. I still – it would help me understand if there was some supporting document that went with this that said sort of who owns usability, workflow, quality, clinical decision support, those kinds of things. And I understand the point that, oh well, Policy Committee really owns those, but when the rubber hits the road around we want to give meaningful direction to vendors and to EPs and EHS about what the heck to I do with that? I think there's still a role here, so, I worry a little bit that this expanded Implementation, Testing, Certification group becomes too – perhaps too broad.

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

So I think one of the things we have to deal with is iteratively improve the structure, I mean, we had to start with some terms of reference. But so when we get to a use case of clinical decision support, I would imagine that we would be able to say, oh, we have to represent a clinical decision support rule and that will fall into Content and Vocabulary, or some such thing. But if we discover it can't, well turning it to you is probably not right either. Then one of the suggestions that was made is, there may be certain circumstances where we assemble a Task Force, a Tiger Team, an assembly of people on a particular issue, and certainly as I think about the Arien did with Direct, right. I mean that was a unique one-time event to solve a unique problem. It wasn't a singular committee we may do that.

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

The only other comment – this is Liz, I would like to make is as we – as the charters are formed for these groups, that while we're looking forward, we're also still evaluating what standard we have out there today and is it working? Because that's one of the challenges that we often hear. Everybody wants to go to the better standards because there's a reason why they get balloted and they're better, but we are still living with those, so have that as part of the – group, not just have it as part of the charter to pay attention to current state.

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

I think you'll see in some of the NPRM reviews today, that flavor will be transmitted, that we selected certain standards in Meaningful Use Stage 2, oh, and some aren't working as perfectly as they should, so I agree. Floyd, last word and then we will move on to hear about the Implementation Workgroup NPRM.

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

Thank you. So, just to follow up on implementation issues and trying to achieve outcomes, one of the things that I think is really important is to connect the groups. So one example on the quality side, and not that it's all quality, but if you look at the terminology, there are good terminology – proper way to use the underlying terminologies. But if the structure, which is a different group, doesn't allow that to work well, it causes an implementation issue. One of the issues came up on, if the measure says not to – I didn't order this or do this procedure for a reason, the standard QRDA makes you say which of the meds of that big list do you use. And while there's a little improvement in that, you still have to say, what didn't I do at that level of precision, because of the documentation. So we have to be careful that those two groups don't become new silos and as we look through them all, there does have to be a way and it's all about implementation to make sure we don't cause extra problems by having everything right, but not connected.

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

Okay.

Wes Rishel – Independent Consultant

John, this is Wes.

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

So yes, Wes.

Wes Rishel – Independent Consultant

I just want to triply emphasize what was just said here. I think the biggest single learning we've had in all of semantic interoperability in the last 15 years is the inseparability of structure and vocabulary.

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

And, very true, they are certainly interrelated concepts. Now I think Andy, did you signal that you also had a c –

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

I'm a little confused. Have we formally supported the going forward with this structure?

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

Well, so I – now that all –

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

Should we do that?

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

Well, what I was going to summarize is as follows. That it seems to me that we have some amendments to refine the titles of these, but importantly, we have terms of reference that are going to be key. And so I guess the question I would ask the group is, based on all the comments you've heard today, if we move forward with a next step, and that is writing a scope document, the terms of reference of the groups that would be a Steering Committee including perspective of our multiple stakeholders. It would also serve as an interface to the Policy Committee. The Vocabulary and Information Models would stay as described. Document and Data Structure, as described, Transport and Security as described, Services and APIs would add Architecture and Certification and Testing would add Implementation with an understanding that it is not a dumping ground for everything that doesn't fit in all the other committees. And then, as we go forward with this structure we also agree that it is going to be mutable. I mean, it may require the addition of selected Task Forces where multiple groups come together to tackle a specific problem if we find that we can't tease them into these categories.

And that's, in effect, what I've heard and I don't know if there are any other amendments to that? So I guess feedback to Doug and ONC would be, well done. I hope you take our comments as helpful suggestions and then terms of reference will appear and we will probably add a few edits to those and then move forward.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Thank you everyone for the discussion and I think it was really, really helpful as we move forward.

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

Good. Well, thanks. So Jon, again, you know, you're still with us here, so –

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

Actually, I'll put in a comment, and actually wade back into the discussion. And John, you're so instrumental that I will turn to you, but – so fabulous discussion, really very, very thoughtful. And I'm pleased that we had consensus in terms of the recommendations and the ability to support ONC in a way that's helpful to move forward. What really struck me, excuse me, during this past conversation was that – how responsive the proposed structure, the evolution was, to many of the comments that were reflected across all the recommendations or comments on the NPRM from the various and sundry workgroups.

And I think that the remainder of today's discussions, as we go through the responses to the proposed NPRM, will be helpful in terms of further contemplating that sort of evolution of the model. And Doug and team, I hope that is helpful in terms of really thinking about some of the overarching themes of response and obviously the great support and consensus for support, but also some of the areas that require some potential further consideration in terms of assuring the coherence of the overall and overarching goals. So with that, John, let me turn back to you and we will dive into the specifics and the more granular of those comments. Again, extraordinary amount of work in responding to those, so let me just again say thanks to all who participated in that.

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

So now we begin the marathon of NPRM review. So we start with Liz Johnson and Cris Ross, due to Liz's scheduling constraint, and then we'll move on to Marjorie and Danny before lunch and then Dixie, you have us all after lunch. So, Liz and Cris, please.

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

Thank you, we're going to go ahead and get started, we're not going to – for those in the room, we're not going to change chairs if it's okay with everybody.

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

Okay.

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

Is that okay?

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

That's fine. I'm just going to come around and grab lunch then, as we transition. So, sorry about that.

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

So we'll go ahead and get started while they gather that. We're going to – first, I want to recognize Mike Lipinski's on the phone, he has been a tremendous help from the ONC in helping us understand this, along with Steve here, so we can use him also as a resource kind of going forward as we've gone through these measures. We're going to talk about the process, some general overall comments and we'll stop at that point to get your comments as well. And then we'll go into the specific recommendations following that. At the end of the presentation, you'll see a number of slides where we didn't have time, as many times as we met, to talk about all of the final comments. But we wanted you to see all that were submitted, because even when we weren't able to meet, our members were very diligent in getting us additional comments that we will submit. So, want to follow it in that way. Okay.

So what we were asked to comment on, certainly not just us, but everyone was on the Voluntary 2015 edition for the EHR certification criteria. And those comments are actually due on the 28th of this month, so we have a PowerPoint here that obviously has significant amounts of comments in it and that will be submitted by the ONC on our behalf into the entire comment section.

Excuse me. So we really did want to make sure that there was also an understanding here that this was an ONC new approach around overall policies with a 2015 edition. And that this was incremental rulemaking, this is not tied directly to Meaningful Use and that this is an opportunity for them to leverage the op – to go and look at new ideas and new kinds of proposals related to that. And there are some very – I think you'll find some very good ideas that were incorporated, but also some concerns that we have about those recommendations. We also were charged with, if we had time, to look at the 2017 edition and that was very ambitious and it didn't happen. But we will now take that as our next task, as well as looking at the Meaningful Use Stage 3 measures.

So the way we divided the work, and we hope this will help structure the form that we're going to talk about and where you will see things that were not brought to necessarily a great deal of discussion, because there was general agreement. But we took each one of the parts of the edition and we assigned them to a date. And then we have indicated for you, on the chart, whether there was general agreement on what was recommended or whether it became a discussion item. And where there are discussion items, we will give you the content related to that discussion. So, as you can see, we had a lot of meetings, a lot of content and as one would expect, there were some meetings that didn't quite make the agenda and so it went over to the next agenda. I'm sure you've all been through that. But the team really did a tremendous job and I again really would like to also recognize the membership, lots of loyal people spent many hours discussing this at length. And that takes – these people all have other jobs so we were very appreciative of that input.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Um hmm.

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

So that's – this next slide, slide 2 goes ahead and talks about where we went for – went from there. And like you can see, on April 23rd we made the decision to go through all the previous comments, create this presentation for you, but we have also created those member inputs for you. And with that we'll move into the actual comment section. And like I said, we'll start with some overall comments, not specifically related to any part of what was being recommended, but to the overall concept of a 2015 edition. And then we'll stop and pause to get comments from the Standards Committee, because it's very important that as we give these comments back to ONC, that it's not just representative of our workgroup, but of all of our input into this.

So the first thing we wanted to comment on, is that – and this is something that cannot be avoided. ONC cannot guarantee that what we would make changes for related to 2015, will be included in 2017. That's not a criticism of ONC, they cannot – it's not plausible for them to do that. But for those of us who are implementing or would consider implementing this, or the vendor that would build it, we have to take that into consideration. I'm going to simplify that for you and say, if you implement a new recommendation, you're going to then have new code out there for all of us that work with this on a daily basis, and we would be making potentially a change in workflow that may or may not be sustained through Stage 3. So you need to think about that as we go forward. Again, not a criticism, just a reality that we need to be aware of.

The second thing is, there – it was unclear about the benefits to the provider community, and this is somewhat a build on my first comment of implementing an incremental update while continuing to gather data during a current attestation period. So what that means is, we all are – or many of us are attesting now on the 2014 edition, and it doesn't matter what stage you're in, that's the edition that you are attesting against. If you incrementally put in 2015, you now are in an edition that you're not testing against, and so you need to think about that as we go forward.

Frankly, a large percentage of our group would really prefer that the vendors start to focus on optimizing current code and begin their preparation for Stage 3. Now there's almost, as one might say, talking out of both sides of your mouth when you say that. Part of the purpose of this 2015 edition is to introduce a concept that may be needed in Stage 3, and we recognize that. So that that puts us at sort of a competing priorities here, but we want to think about that going forward. All of us – you've heard many expressions not only in this group, but also through our hearings, of some of the struggles we've had as the vendors have tried to keep up with the code releases and what's going on and what's required. All of us on the provider side of the world are still dealing with that, and we would like some time to catch up, because we really are interested in making the care better. I think many people have said the value – that this whole MU Initiative has brought tremendous value to this country and we'd like you really begin to translate that more and more into patient value. Did you want make a comment?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

You'll see this comment repeated in a couple of the domains as we walk through specific items, where the issue was raised of the challenges of optionality, as one vendor moves to the 2015, how do we handle forward and backward compatibility sort of generally. And I think it would probably be useful for us to identify that when we walk through some of the specific issues, because it's a bigger issue some places and a lesser issue in other instances, it's not a one-size-fits-all.

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

Right. And then the final kind of overall comment, and looking for yours as well, is the cost burden. There is not – we want to be very realistic here and regardless of where you may be, and John obviously lives with this every day, when you are introducing a new version of anything, you are talking about workflow changes, training cost, vendor cost, all those sort of things. And again, we've tried to be very representative of the feet on the ground for this committee, bringing back that sort of pragmatic view of, while some of these things are introduced here. And you're going to see, we have some very supportive statements of some of the changes they are recommending, they are still a burden to those who we would be asking to engage in this. It's voluntary but if you make that decision, you will be engaging in it. And with that, we'd like to open it up because we know that many of you have studied this edition and may have additional comments and we'd like to reflect those in our final comments.

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

Arien.

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

Thank you. So I'd like to completely endorse these high-level comments. There are – that being said, there are some, Steve bats 900, but there are some regulatory bugs that probably should get addressed. Separation of content and transport is probably one of those urgent bugs that needs to get addressed. And again, I would separate out the fixing of regulatory bugs or incremental improvements standards bugs, incremental improvements of standards from doing new stuff.

I have seen very lately a – through the work that we've been doing in CommonWell and through some of our own work, that the state of the HIT union with respect to incorporating electronic data with the standards we currently have is very, very uneven. And I would completely endorse your comment that if vendors had to do one thing it would be to improve the workflow for the capabilities that are already supported in Meaningful Use Stage 2 and that asking them to do something new actually impedes rather than helps the policy aims that we all have. So, just with those two comments, I completely endorse this.

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

I think Arien that's very wise, that an email I received this morning from one of our clinicians was, thanks so much for all of the improvements you made to the EHR, I can no longer find anything. Because we've got interoperability here and interoperability there and this kind here and we've got VDT and we've got – yes to highly functional but not completely usable system. So, do need to spend more time on that.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Just to reflect back to Arien, I think your comments are exactly right. And what we tried to do in every instance here was to figure out how do we best make it work so that the 2015 edition would be successful as opposed to getting caught up in saying, well here are all of the reasons why it couldn't possibly work and let's suggest that it's a bad idea. We were trying to come from the standpoint that this is a really good idea, and how could we distinguish between those classes of issues.

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

Other comments? So much rich material on the PowerPoint, I – for 2 minutes, I expected significant discussion. Yes, was that a Wes I heard on the phone?

Wes Rishel – Independent Consultant

Yes. That was a Wes.

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

Yes Wes, please go ahead.

Wes Rishel – Independent Consultant

So, I just want to pile on to what's being said here. Many of the advantages of the 2015 edition come from vendors going through certification. There are no advantages to implementing that certified version for the end users to the extent that if the change relates to Meaningful Use attestation, but not interoperability, it screws up the counting. If it involves a change in how one interoperates, it creates a bilateral asynchronous cut-over issue with whoever you're communicating with. And in general, I think, it would be really helpful to have some regulation writers sit down with some people at Liz's level and just talk through what it means to implement a new version of an EHR in a large institution. What is the planning that happens? What is the training? What is the rollout? What is the time it takes? Just throwing out a new version for some incremental good, and I am using fairly strong words here is fairly insensitive to the needs of the hospital stakeholders. Thanks.

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

So Wes, to that point, yesterday I met with the CEO of one of the larger EHR vendors in our country. And we described some issues of code quality, stability, reliability, not usability even, just basic functionality. And that person told me the timeframe of getting through the certification process and the complexity of the certification process, meant that there just wasn't time for the kind of iterative improvement that would normally be associated with a new release. And so, I happened to in my organization, use some of this vendor's product. We upgraded 28 sites and we are going to now re-implement 28 sites because we, in fact, installed a version, though it seemed appropriate, was actually not quite ready for a release.

And so I think, Wes, your comments are very well taken, that there is a point at which change is your enemy. And it's in effect like changing the wings on 747 while it's flying. We have to land at some point and do maintenance. And so I had made a very quick comment to Steve Posnack that he was going to hear today some mixed reviews. We love some of fixes in the 2015 NPRM, such things as saying, oh we never realized that HISPs might want to be certified and therefore want to decouple the generation of content from the transporter kind – these are great. But then when you add new stuff, then implies that certification is going to create change and it's yet another version control problem for our vendors that are struggling to keep their 2014 versions on a singular release.

Wes Rishel – Independent Consultant

Hey John, if I could just build on that.

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

– Wes.

Wes Rishel – Independent Consultant

We're in a program here, the Meaningful Use Program is about putting dynamite under the tails of a lot of people to get EHRs implemented. And therefore, we are inclined to think more is better, but what we really have to do is think, what have we learned since 2009 in terms of the appropriate pace of regulated change, as opposed to voluntarily adopted change. And anything, even a voluntary standard issued through a regulation carries all the weight of a regulated change, whether it's voluntary or not. So, I just want to emphasize, or re-emphasize or redundantly reiteratively re-emphasize my point.

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

So Karen, what we were debating as you walked in was the fact that in many ways having these interim, voluntary NPRM phases is good. But there are also unintended consequences in that it creates change and change itself is causing issues of reliability and that some of the vendors aren't able to keep pace, just because of the sheer number of moving parts that are happening in such a quick timeframe.

So yesterday, and Jeremy, I'll get to you in just a second, Ashish Jha posted on the healthcare blog, a very nice piece, which Wes to your point, illustrated that despite all of the politics that we have accomplished in our country with healthcare this or that over the last couple of years. It is absolutely the case that we have seen adoption of EHRs in EPs and hospitals skyrocket and we want to proudly celebrate that success. And so to the point you've made Wes, how do we keep this momentum but set the paces of the momentum in a sustainable fashion so we don't see Meaningful Use burnout and hospitals and physicians exiting the program because the pace of change is too great?

Wes Rishel – Independent Consultant

Yeah –

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

Jeremy?

Wes Rishel – Independent Consultant

John, so I'm going – I'm sorry to keep interacting this way, but –

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

Oh no, it's totally fine.

Wes Rishel – Independent Consultant

– I just want to re-emphasize that it's not only the impact on the vendors, it's the impact on the hospital corporations that have to plan out implementations across hundreds of facilities or at least dozens of facilities involving waves of implementation. That anything in the regulation that implies a new release implies a tremendous preponderance. And just to the same way that vendors say, well doing the standard stuff keeps us from putting resources on doing innovative new things. One of the most important lessons of the EHR is that implementation is never done. It's an ongoing job of tuning and improving and interacting changes your EHR with changes in your process. When the staff is busy implementing a new version for the sake of a new version, they don't have the time to support those interactions with their clinical user community. So I think us achieving this balance is – a great sensitivity to the cost of implying the need for a release of a new system is – really is an important bit of feedback we can give to ONC.

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

As Wes points out, there is the iron triangle of time, scope and resources. That if we increase scope and we fix resources, well, then we have to lengthen time. But if we shorten time, we then have to increase resources, and alas, I'm not sure what you're organizations look like, but I'm not seeing resource increases any time soon and time just seems to be moving pretty fast. So Wes, to your point, my only choice is to adjust scope and that means less interaction with the users, less incremental improvement, less workflow redesign because resources are fixed and time is fast. So thank you. Jeremy?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.

So, I hope I don't take us on a tangent and I will desperately try not to, but just to offer a quick vendor perspective on this one. The approach that we'll take to this is to see if there's demand, right? So if it becomes clear that people who want to adopt or people who are current clients value this, then this is something that we would then prioritize doing. But I think that this touches on my single greatest fear for the Meaningful Use Program moving forward, which is this sense of provider organizations feeling held hostage by their EHR vendor. Which that they've sunk a lot of money into an implementation and they're then – the hitch – they made a decision to hitch their wagon and then they're hoping that their vendor is going to be able to keep on meeting their needs.

And then the opportunity to switch and to fire their vendor who can't meet these requirements, it's becoming one where one would have to thread the needle to accomplish that, because in the second year of Stage 2, it's going to be a full year reporting requirement and how could you possibly swap out and do something different. And I wonder whether we need to think about maybe a side or maybe clarify what the hardship exemptions really are, but a way to make it easier for providers to switch when it's the right thing for them to do. Because we should be fired as vendors if we're not supporting. We shouldn't have this sort of halo sort of forever sort of annuity stream of revenue that comes because someone picked us, at some point in the past, to be their Meaningful Use solution. And I worry that this – that it's creating a little bit of lock-in as a result. And so I – maybe that's something to turf back to the Policy Committee about how that switching period could be made a little bit easier for a provider, so that there isn't this anxiety that I think really came out in these comments.

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

So these are very good points and let me just echo a few of them. So, what is the hardship exemption? I'm sure everyone recognizes that it is a mechanism by which you can apply to not to get stimulus funds, in effect. It's saying you won't have that – ,Steve Posnack's here so he can en – and Jodi, you can give us the chapter and verse. But in effect, what it says is, we will not penalize you in 2016 if your vendor couldn't deliver because of certification delays. But buddy, you cannot both have a hardship exemption and continue to collect stimulus funds for the period of that hardship exemption. Is that a fair description?

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Sorry, this is Steve. Yeah, I mean, yeah, that's the general take on it.

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

And so, I have no idea, but I do see many of my Boston-based colleagues in the middle of new vendor implementations for which they cannot achieve Meaningful Use attestation, a switch in vendor, I see – perhaps even thought that delay has occurred, it actually doesn't really remove our work, because we have, as hospitals, nearly completed our ICD-10 projects. So at least in Massachusetts as a state, we decided to just complete the ICD-10 body of work on the original timeframe, and just not go live. So, work isn't going to change, in fact the extent will be more, because we now have to wrap it up in a bow and let it sit of some period of time before we bring it out, regression test it and then go live in the future. So, we sort of have this interesting challenge, as you say, of so much happening so fast, that then, when we are seeing our vendors or our product not meeting our business needs, we then raise the specter, do we add a switch into the mix of work that's in process? I wrote a PowerPoint a couple of days ago for my Board that said, changing vendors in the middle of Meaningful Use timeframes is high risk behavior. You just need 18 months minimum to freeze the organizations attention span on a vendor switch, but you can't do Meaningful Use while you're in the middle of that freeze. So I think – the quandary that you have raised of many moving parts on tight timeframes, a lot of hardship out there and vendor lock-in is a reality.

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

And John the one thing I would add is, recently we had an opportunity to speak to Marilyn – CMS and one of the things we suggested that might help with this, so we could keep going forward, would be to go to quarterly reporting rather than 365 days. We were just looking for practical answers that wouldn't require a – necessarily legislative change. So what I'm suggesting, not just for suggestion purposes, is that in lieu of going then to 365 days, that the attesters would be able to do a quarter each federal fiscal year. Because if you think about going forward, we will – I think the plan is, I mean the way I understand it is, you will be attesting into infinity every year and that's fine. But if you only had to attest for a quarter, then you have time on the other three-quarters to do upgrades, to do optimization and yet you're still moving forward in a Meaningful Use process; just a suggestion for consideration.

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

Sure. And Jon Perlin, you have a question?

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

Yeah, I have a question for you Liz and Chris. Terrific work and terrific feedback, I'm just contemplating on John Halamka's, as always, very important observation that it's so difficult to switch vendors. But as I look forward, one of the threads of discussion we had earlier was a sort of re-imagination of the architecture from less of the sort of monolithic to more service oriented. In that approach, particularly if one thinks about the work of the SMART Program, Substitutable Medical Applications Reusable Technologies, one envisions an ecosystem that's a little bit different, particularly as you get out to 16-17 and beyond, periods of time that we're contemplating now. And so if one has an image of architecture that includes robust transactional systems, foundationally system BUS, APIs and then applications on top, how are we – are we anticipating the certification and implementation needs in this model or does that suggest, and what you heard – hearing and feedback, etcetera, any modifications for thinking not about the sort of switch from horse to horse, but the evolution from horse to different vehicle?

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

Maybe even a rocket ship.

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

Maybe even.

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

I would say that's a very good thought and I think what we're trying to do is balance where the world exists today and how we get through the next couple of years against. We absolutely, Jon, should be doing what you're suggesting, which is thinking about the EHR of the future and the types of mechanisms we're going to be able to use, that aren't here today. So, in all candor, we would be back kind of to the practical stage of how do we deal with the next two or three years? Because we are hearing – so we have this opportunity at Tenet through a recent acquisition, going from a single vendor to now four vendors. And so, as he smiles at me, he understands completely what I'm talking about, and so we have literally got an update to one – for one of our vendors, last week, to make a 2014 edition changes. And it's a reality that we have to deal with. That's not our issue here, today, it's my issue, but it is one that we want to bring up and raise up, how do we get through the next three years, keep advancing four years, whatever it takes to make those architectural API changes for the future?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So if I could comment on that, I think those are fantastic points, Jon. I would add a couple of things, one is, some of the 2015 regulations I think are intended to both lubricate and goad the industry to do some of those things in some positive ways. And so when we walk through these things, I think we'll see some of that power. Second, I'd say I'm not sure that the embedded vendor community has quite yet decoupled their products to be able to do that, in part because they're struggling to do a lot around Meaningful Use. And I don't mean that in a disrespectful way of the vendors, they're just really trying to push along.

By the Halamka test, my organization is now engaged in what is it, dangerous behavior, as we look – risky, as we look to move to a consolidated EHR across our environment, right at the cusp of Meaningful Use 3 coming along, and we just don't have a choice around that. I think we may want to – these were intended to be sort of an overall view of the flavor and general policy issues associated with a 2015 edition and what our thoughts were about it. But I think we may want to transition into walking through the specific elements, in part just to keep on time. Does that make sense?

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

Absolutely.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So if it makes sense, if we could go to the next slide, I'm going to start these and we're going to do these collaboratively. So on each of these, I know it's hard to see on the screen, so perhaps people will look at their paper version as well, because there's some color-coding here.

What we have listed is, in terms of chronological order, how we went through these items. We've not listed what is the standard and what is the response, because we literally just couldn't get it on the screen in a clear way. What we've listed here are issues that have been raised questions, comments or concerns, which gives an overall sort of sense of negativity that we're hoping to not convey, as we walk through this. I think our intent was to say, we like a lot of these things, but please take into account these issues as we go through. So, let me just highlight the ones related to transition of care.

So the items that were listed by the group, and we've only listed in these slides for instance, those issues where we felt that discussion was appropriate. If you go back in your paper version, you see a number of these that were green, where we basically said, it's fine as is, please proceed. So on transition of care, here are a couple of the issues that were raised. One was the question about whether EHRs would be able to distinguish between the two different versions of C-CDA, the 2014 and the 2015 version. We recognize that the 2015 edition certified technologies would need to be able to receive both types, but how do you handle that issue of optionality when there are two different records required. We've been sort of through this before to a – in a slightly different flavor, in Meaningful Use Stage 1 when we were dealing with both CCR and CCD. It's not perhaps that profound, but it's still an issue.

The second was EHR technology certified to the 2014 edition, would they be able to receive and process a transition of care using the C-CDA 2.0, which leads to a general comment, the third one of, this is a Wes Rishel trademark comment, but we actually have to get his language right. I think we did it an injustice, I think Wes' phrase was bilateral asynchronous cut-over, and it's the issue of all the profound issues you need to deal with as we think about forward and backward compatibility. So, on an asynchronous basis, can one party change without affecting the others? The bilateral component being, it's always easy to do forward or backward compatibility when you're only reading in one direction, but in this instance, especially around transition of care, I'd say bilateral issue and so on.

So that's a cluster of issues that had to deal with vocabulary for consumption and production. We had further comments around the Direct EDGE protocol implementation guide, great idea, but at this point, probably too ambiguous and not sufficiently constrained so as to deal with the issues around optionality. Some comments around the performance standards, great idea to have a performance standard, but the quest – around, can these vendors actually perform in their ability to produce and consume records. That's going to be a key issue, we're in the early stages of that. Will it work and is there a nice way to measure it so that the customers of the vendors understand what they're working with. But based on it as now, we've noted that it would be difficult to understand how we could test that from a certification standpoint. And then finally, comments with respect to patient matching, suggesting that we use year rather than month, day and year as a purpose for patient matching. I think we should just com – pause on this slide to see if there are comments. The next slide is somewhat related, but I think it's separable enough we could talk just about this slide if there's feedback.

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

Sure, so any comments on transitions of care? So as I read through each one of your slides, I mean I, just from an implementation standpoint in my own organization agree with basically everything you had said. So, I think silence is concurrence. Oh yes, Arien.

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

I just have one additional comment, which is that – this is Arien, which is that if the consolidated CDA certification testing process were rigorous enough, you wouldn't need the consume large bodies of Consolidated CDAs. I think we're in a quandary now because the testing process isn't rigorous enough and isn't clinically constrained enough, it's focused on the structure of the document, but not on the clinical interoperability of the content. We've had issues with people who have sent only active medications without an active-inactive indicator versus people who have sent every medication the patients ever been on and the variability right now and the clinical meaning of that variability has not yet been tested against.

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

And Doug, did you have a response to that?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

Yeah, I think it's important to raise the issue of testing, because I think it is one of the ways that we change the definition of success from conformance to the standards to demonstration of interoperability. I think the issue though isn't the rigorous nature of the testing, it's the way the standard defines optionality so that if the definition of success is conformance to the standard and any of its wide variability, then, in fact, we still can get highly granular and sophisticated testing that doesn't lead to interoperability. And so I think part of what we need to think about is what is the way that we can change the definition of success around standards from being one of conformance to a specification to demonstration of interoperability. Because I think then you can have the conversation at the beginning of the standards process rather than at the end. It says, if everyone is accountable to being able to interpret version A and B and C, then the standards group has to say, we're not willing to accept the burden of that. And so the hard conversation about a reduction in optionality occurs at the front rather than at the end.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yes.

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

This is Arien. Surescripts faced this issue in their EHR certifi – in their ePrescribing certification program and they found a need to do certification not just at the standards compliance level but also inclusive of the clinical and workflow meaning of accepting various messages. And I think that's the piece that's missing currently with respect to Consolidated CDA .

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

And Cris?

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

Oh Cris, go ahead, sorry. Well, I was just going to make the point on the similar exact parallel arguments applied to the addition of an EDGE protocol, if we go that route, is that it really should be highly constrained, not a smorgasbord of possible APIs, but something very concrete and testable and implementable. Citing Halamka's law that "or" means "and" to the vendors and so if you "and" together a bunch of protocols that you could choose from, the chances of interoperability emerging from four poorly understood specifications is near zero, whereas one really well-defined implementation guide would ensure, or would increase the probability that we get what you intend. So, constrain it, please.

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

So to that point, I see two options here, don't mean to offer two, but either highly constrain it, so there's only one way for an EDGE to connect, or don't constrain it at all. And in fact, what we've done in Massachusetts, as part of our Mass HIway is we've said, we will at the HISP level, create a singular transaction that will go HISP-to-HISP. But if you want to get to the HISP with smoke signals, Morse code, FAX machine, you know, that's sort of an implementation detail that it's up to you, the vendor. And we've actually seen – not EHR vendors, but third-party offerings, connect to the HISP in somewhat novel fashion, because it blinds the user of the HIway from whatever complexity is occurring in the EDGE – should leave the HIway.

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

And this is David again, that was the original design of Direct that was a conscious decision to leave it that way so that the notion of introducing a new EDGE protocol is a new idea. And a case can be made for why there is some value in doing that, but it has to be done really carefully and really precisely. Otherwise it'll set us even further back in what we thought was going to be a pretty easy connectivity problem that has turned out to not be so easy, albeit due to the trust issues more than the API issues at this point.

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

For Arien, because you were in the thick of this whole initial debate, here's what we're seeing the implementation reality in Massachusetts is that every EHR vendor is using XDR, not a single EHR vendor, at least in our instantiation, is using SMTP/SMIME as an EHR-to-HISP protocol. Now all the HISP-to-HISP transactions are going SMIME/SMTP, so a constrained version would be, thou shalt use SOAP from your EHR using this narrow implementation guide to the HISP. The HISP, thou shalt use SMTP/SMIME HISP-to-HISP, then suddenly we don't have any of those "ors" anymore.

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

Yeah, we would agree with that choice as well, the XDR, of the ones that were listed.

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

– better double down on David's comment, if I would fix one problem and just put a stake through its heart, I would fix the trust issues and leave the EDGE protocol alone. It's the trust issues and certificate interoperability that impede the larger ecosystem much more than the lack of a standardized EDGE protocol.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So I would say, please – this is Cris, I would say please keep that powder dry for about three slides from now, both of you will have things to say. But I think the issue that was just raised, I think by Doug and John around how do we go after this, I have to raise the issue of it has the implication of where does the burden lie to be able to prove that it's working well? So a highly constrained technical option, the vendor does it once, maybe imperfectly. Because the process is imperfect, but gosh you know it's going to happen, because it's tightly constrained and it's easy to test. Whereas the better outcome that Doug's talking about probably puts a little bit more burden on the EDGE. So, I think we've got to be thoughtful around who is best to carry that burden, admitting that the way that Doug recommended is clearly the superior way to do so. So how do we do it in a way that doesn't disproportionately burden? I wonder, we should go to the next slide.

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

Sure.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Can you forward one more? So next deals with transmission certification criteria, begins to touch on the issues just being discussed. We raised this in the form of a question rather than a recommendation. The question was, how would testing and certification ensure that a C-CDA could be exchanged using the transport standards besides Direct? And as that begs the question, would this not require multiple EDGE protocols and an EHR to be certified against all of them in order to ensure widespread exchange. And we have two examples associated with that. So maybe we could pause for comments here.

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

Yeah.

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

Okay, non-controversial.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So let's go to the next one please, around view, download and transmit. So a positive comment to note at the beginning, it's good to push EDGE – Direct EDGE protocol requirement once the constraints issue is resolved, but it's only a small part towards HISP neutrality that this is necessary but not sufficient to get to HISP neutrality. Then we're going to talk about trust here. It was the recommendation of this group, and I would say that there's actually some controversy in the group, not necessarily unanimity on this use amongst our workgroup. We should not be required to send or receive health information from any Direct address without an established trust relationship, and that certification should follow the approach used for the 2014 certification of transition of care summary transmission; in other words, to prove the capability to establish a trust relationship during testing, for the purpose of testing and certification.

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

Just to be clear, this is the transmit – the consumer transmit portion of the requirement.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Correct.

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

That's correct. Right.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Correct.

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

Agree?

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

So, just a quick comment on what we've done.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Um hmm.

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

And, let me just – as everybody knows, I'm totally vendor neutral, have absolutely no stake in any vendor, but what we've seen is let's say eClinicalWorks, as a company, said we are going to be the HISP for all of our users. And we, Beth Israel Deaconess want to interact with eClinicalWorks users, so automatically by exchanging trust anchors, we trust every eClinicalWorks user. And we've said, well Joe's Endoscopy Shack may very well be an eClinicalWorks user, but we actually don't think that they are a good actor. And so what we have chosen to do is yes, trust anchor, that's one problem, but then we have a participation agreement and we say, we actually will not transact with individual members of that HISP until they secondarily sign our participation agreement and agree to certain behaviors. Now that doesn't scale perfectly, but it illustrates this problem is that we are just not going to blindly send stuff to somebody because a certificate exists.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

And I should have said at the beginning, too, which is, I think the workgroup, even though we had some differences around the exact approach. I think there was strong unanimity amongst our workgroup that solving the trust problem is enormous, and if there is any right-of-way issue, that would be it in this area, of how do we get that settled.

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

Yeah, I think the proof of identity issue and who does it and who's responsible and where does it occur, it came up over and over. We've all dealt with it in different mechanisms to get some trust relationships in place to be able to do the things we want to do, but it is far from perfect.

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

Well I think Arien and David have some comments in this regard.

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

Oddly enough.

M

Surprise.

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

So the nature of trust in directed exchange, I will take this out of the actual implementation of Direct in – after numerous discussions resolved down to the notion not do I – not do the two – trust each other to do appropriate things with the data. The data holder has made the decision to – already made the decision to disclose the data to the data receiver. So we don't have an issue of inadvertent disclosure that we might have in a query-based case, the issue at question is whether having made the decision to send – to disclose the data under HIPAA appropriate terms. Do I have a level of assurance that it is indeed going to that data – that receiver and only that receiver and/or BAs of that receiver? And so the trust framework and trust mechanism for Direct is designed only to solve for that problem. And the point of Joe's Endoscopy Shack is, if Joe's Endoscopy Shack is indeed a legitimate provider, who has made a decision to send data that the trust pre-conditions should be for the receiver, did it really come from Joe's Endoscopy Shack.

The secondary considerations of, is Joe a good doctor? Are they a good actor? Those in many ways are secondary to the trust issues of directed exchange. So we're taking, I just want to also note, this is why I was trying to be precise about the transmit portion of view, download and transmit, is consumer transmit to any third party, and there are different trust considerations with regard to transmit to any third party. With respect to provider-to-provider transmit, again I would editorially comment that if we solve one problem, it would be the trust issues related to provider-to-provider transmit. And I'd also note that DirectTrust has done really excellent work in this area by providing a strong trust framework for identity as well as a strong trust framework for HISP actors with an accreditation process that drives towards a level of assurance for privacy and security for those actors.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So I would – those comments are really helpful, I just want to note that in our discussions, one of the things that we did note was an observation that despite the work that DirectTrust has done, which I think there's good consensus that it's been extremely positive. There are competing trust regimes and that that is a public policy challenge for us.

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

That's absolutely right.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

And if there were ways that ONC in its guidance and regulatory role could help resolve some of those trust issues, it would be extraordinarily helpful. But there are political, jurisdictional economic issues that are layered. And I'm trying to be respectful to all parties who are involved in these disputes as we see it, but we observed that it's a challenge.

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

And just to put a very fine point on it –

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Was that diplomatic enough?

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

It's worthwhile just putting a fine point on it because John has made, I think, probably incredibly business appropriate and mission appropriate decisions for the state of Massachusetts. The state of Rhode Island has made business and mission decisions with respect to the state of Rhode Island. Rhode Island has paired up with DirectTrust, Mass HIway has not, and the real world consequence of that is that, depending on what side of the border you sit, you may or may not be able to exchange information and that's – that doesn't fit the policy goal that we're trying to get to.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Correct.

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

So Lisa seems very energetic, please.

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

This is Lisa Gallagher from HIMSS. ON the point of inter-trust framework trust, there is – we had a briefing at the Privacy and Security Workgroup from the NSTIC, but I don't think it covered the fact that one of their pilots is with GTRI, Georgia Tech Research Institute, to look at trust marks. And they're actually defining requirements, and there's an, I don't know, 8 or 10 different trust marks. So – and they're going to be piloted in some other pilots. I would say that it would be good for all of us, ONC, all of us here, to pay attention to that initiative and get involved and connect to it. Because it is this very problem that they're trying to solve. And when it comes to use of those trust marks in healthcare, it's going to be us that needs to facilitate that. So, and anyone who needs information on that, I can point you to the GTRI website on that pilot. But it is an important initiative to follow and engage in. So thank you.

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

We have David, Wes, Leslie and Dixie. David.

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

So I want to concur with what Arien said and with what Cris said, but maybe less politically adept and just say that, we have, with Direct, converted a technical problem into a policy problem.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Correct.

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

And we have a perfectly adequate technical solution for trust and we have now devolved that into a policy problem for how we get entities that have built up trust networks to bridge to each other. It is not a technical problem in any way, shape or form, it is strictly a policy problem, a business problem. So, we've gone from islands of incompatible protocols to islands of incompatible trust. But that's a step in the right direction, because policy things can be solved without writing code, and that's always an easier way to go, at least to those of us who write code. Thank you.

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

Wes?

Wes Rishel – Independent Consultant

In the race towards being more – of less and less delicate, when we talk about the various means that ONC might have to help the industry allow people to exchange messages with a doctor across a state border, most of the resistance – the localization of trust is coming from state HIEs. And many of them are still somehow beholding to ONC for policy guidance. So, I think it is actually more in the bailiwick of ONC to deal with this than might be obvious with most policy issues. Thanks.

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

We have many cards that are coming up here, so let's try – because we have limited time for our group, Leslie, quick comment and then we have Dixie. I think we have Jeremy and we have Andy. Yes, go ahead.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would just echo the comments about trust being the big issue to resolve first, and also note that as we have patients and their designees integrated into this ecosystem in relatively near term, that this problem will be exacerbated if we haven't resolved it in a more national framework versus a localized framework. Because our patients move, the average Medicare patient has 14 physicians. We have people moving and wanting to be able to interact with many different providers and this isn't going to be something easily understood to the provider world, let alone to the patient world. So this takes strong commitment and a national framework for trust.

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

Thank you. Dixie?

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Two points, number one is, following on to Lisa's, the NSTIC work that we'll report this afternoon is undoubtedly very, very important, but it's not really applicable to this particular problem because it's at the individual level of identity and not organizational. But the second thing is that, about a year, year and a half, David can correct me, the NWHIN Power Team looked at – or I guess, this whole committee looked at the governance RFI and a decision was made not to have governance. And I think, personally, it's time to revisit that whole question, with respect to Direct.

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

Thank you, and then we have, I think, let's see, Andy and Jeremy.

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

Well at the risk of seeming like as a cycle of – I actually think the market is going to solve this, because with the secular trends toward consolidation of healthcare delivery systems that cross boundaries, all kinds of boundaries, they have business needs to make this work and make it work well. Jon, I'm looking at you, you take another 6 or 7 big systems like HCA, they'll sit down and crack this nut. And I don't know how long it's going to take, but it actually isn't going to be that long, and I'm old enough to remember that there was AT&T and ITT when I was a kid, and somehow, phone calls got through. And then the systems developed common switching protocols and nobody needed to make rules about it across state boundaries.

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

Jeremy?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.

And at the risk of belaboring it, I'll try to be quick. I – this one feels like a broken windows issue to me, the theory that, if this industry can't solve something as seemingly simple as loading a directory, where we know that the people in the directory are correct. I don't want to work in this industry, and this one is worth pushing through because it is – we will never achieve other solutions to bigger problems if we can't do something as simple as this.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Exactly right.

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

Well, we certainly have had a lot of commentary and emotion on that topic. So Liz and Cris, thanks for raising it and now I think implantable devices are next.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, we think this one – what we just talked about is probably the majority of the controversial comments, I think we can move a lot quicker. Implantable devices, the main comment here was that the HL7 product instance template associated with C-CDA does not fully align with the FDA UDI requirements. So we would look to HHS broadly to figure out how could we get to conformance between those two requirements. We didn't have a recommendation about what the heck to do if we couldn't get them conformed, but it's clearly required that we do.

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

If they're not conformed, yeah.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So unless there are any comments on that, we'd move to the next one on clinical summary. Can you keep advancing –

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

Yup.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So the issues – here we were asked the question around codes associated with vaccinations, CDX is the code that had been recommended, has been used in 2014, and there were questions around the use of NDC, RxNorm. It was our conclusion that the use of CDX code, which was recommended, was the right thing to do for immunization and vaccinations. With respect to LOINC, the real issue here had to do with the use of LOINC in an ordering context. And we issued three items here around the clinician order not being sufficiently precise, especially around future scheduled tests, that they could be completely LOINC encoded. Second issue was about LOINC not covering all orders and the last was again, a future issue – future order issue around specificity of those LOINC codes versus the indefinite nature of future orders. And we believe that needs to be resolved in the future.

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

I think there was one friendly amendment, I think it should be CVX codes, not CDX codes, so – before you tell me that.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Sorry, CDX, I'm just reading along blindly.

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

David.

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

David McCallie with a comment about the LOINC codes and it's a broader comment that we're running into serious problems in Stage 2 attestation around the requirement that the problem list be 100% coded in SNOMED, discovering that that's just not possible. In the real world, SNOMED will never keep up with medicine, it's a lagging vocabulary, so same thing goes here, LOINC will never keep up with the evolution of medicine. It may catch up, but it won't keep up. So, all these requirements, wherever you see language like 100% or entirely in or things like that, I think will lead to just problems and they should be restructured as when available or majority or some kind of best effort. But not a 100% target, it's just not good medicine to say that you can't talk about it if it's not in SNOMED, it's just bad medicine.

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

Perfection enemy of the good situation, absolutely, understood.

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

We're going to go ahead and continue on with family health history. Again, we're, actually that was included in Stage 2, we're in favor of that. However, there's no evidence that the HL7 pedigree and the new implementation guide are in wide use yet. So, our – I'll list our concern as, you remember one of our principles has been that we look for market penetration and how widely is it used and is it effective, before we make it a requirement. And then again, kind of converging to just HL7 from SNOMED will be complicated and burdensome. We're just pointing that out in terms of just – both for the vendor side of the house, just like David just said, and we are definitely fighting some issues around SNOMED diagnosis problem list and so on, and this is another place where that will be an issue for you. Any comment there?

Okay, we're going to move on to safety enhanced design. We didn't spend a great deal of time on this. There are four questions that were asked and those four questions are indicated here for you. Obviously should it be expanded, should there be more criteria? Should there be usability tests actually during certification? How explicit should they be to summative testing? And should there be a minimum number of test subjects. All good questions about the process but I'll tell you how we actually responded to that. If you look at it, certainly we feel like it is the responsibility of the – from a safety enhanced design, at the certification level, that's the vendor's responsibility. Now I want to say in very clear terms, as another patient advocate, as are many of us at the table, that is not to say that we don't think safety enhanced design shouldn't be part of the vendor's job. There is no question that what they deliver to us should be focused on that design that is not what we were asked to look at. We were asked to look at, should we put more into the certification process. I'm not sure how many of you, certainly John knows, I have that opportunity to understand, what actually goes on during the certification process and it's not real – I just want to be real clear that it replicates what the criteria said and whether or not you can demonstrate that. But it is not taking a case study and backing that vendor functionality against it, it is simply not. And so when you talk about safety enhanced design, I think our eyes should still be on this, we – others may have a better idea of where we might go with that. We didn't spend time, based on our time, it's a right concept, we don't think it belongs in certification as an expanded concept.

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

Our experience with the safety enhanced design was that we had to document for CCHIT, the processes we used to engage our customers in continuous improvement and feedback.

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

Right.

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

And so it wasn't that they said, oh, you must use this NIST methodology or whatever, it was just that there was awareness of the need to do it and documentation of a methodology that seemed appropriate and formal.

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

Right.

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

So we liked that, and we thought it was good.

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

Absolutely.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

I would – a friendly amendment. Our expectation is more than just that there's a continuous feedback loop, right, our expectation expressed in the 2014 certification, and this is Jacob Reider speaking, for those in radio land. Our expectation is that there be a formal testing process and so for 2014, we expected developers of certified EHR technology to submit the results of their summative testing process. And one of the questions that we asked here was actually, maybe formative testing, because we've gotten feedback from vendors, maybe even the guy to my left, that formative testing might actually be more meaningful, to use an important word, that summative testing in some situations. And so that was one of the questions that we posed in the proposed 2015.

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

Well, for others that may be around the room that know more about what might be included in that, it might be – I mean, Jacob, I'm not disagreeing with you at all, I think we had focused and in hearing after hearing we've heard about usability in general and safety enhanced design over and over, the criticality that is. Because these systems that are now proliferated in a very wide spanse, which is absolutely what we wanted, now they really need to be designed to deliver safety. No question.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So if there was an underlying comment that came through these – through our discussions it was a thread that went through it, that was very, very helpful, Jacob, is that third bullet under RFC 1-3 Response around the issue around being prescriptive in the design of HIT. And in our conversations not to give it short-shrift, but it was important, was is there a risk that the regulations are now being prescriptive that a vendor must act particularly in this way, and their screens must look just like this and so on. That are the requirements having a de facto result of being highly prescriptive around design.

Then there's the secondary question is, has the implementation of the certification process made things too prescriptive, even above and beyond what was the intent of the regulation?

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

Right, right.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Frankly we have a hard time teasing that apart, but I would say that the work that the Implementation Workgroup, and Liz I'm sure will say this better, but over the last year we've looked at things like clinical-based scenarios for certification. We've looked at the kind of outcome versus process measures that Doug was talking about with respect to C-CDA and their reuse. And I think the, if I could editorialize for the Implementation Workgroup, I think there was a lot of belief in the idea of outcome-oriented, results-oriented measures were a wonderful thing. It's hard to do that in a regulation and certification environment, we want to recognize that. But I think there was a little bit of an overwhelm – an overall theme throughout our discussion around please take care around the degree of prescriptiveness of both the regulation and then the echo of regulation as it appears in the certification process. And I think we were probably more critical of the certification processes than we were around the policy and regulatory issues.

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

Exactly.

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

This is – .feedback.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

But we heard that throughout.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

And really good feedback and I'm looking at Michelle, when is the certification hearing? May 7, so stay tuned, because I think that's where we will tease out some of those important issues of where the – maybe the prescriptiveness that was absent from the reg, found presence in certification.

Wes Rishel – Independent Consultant

This is –

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

I think I heard Wes' voice?

Wes Rishel – Independent Consultant

Yeah.

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

Yes please, Wes.

Wes Rishel – Independent Consultant

I was involved in at least some of the discussion at the workgroup level and I realize that at least me, if no one else, didn't really distinguish well between certification by examination of work product, if you will, versus certification by testing. And as a result, we may not have given complete credence to opportunities to do things like certify the documented, having gone through a process, rather than certify by testing the product for usability. If others – I don't know whether maybe I just overlooked that and other people are aware of it, but I'm concerned that we have a way to somehow revisit that and still comment, given that comments on the NPRM close on the 28th. Perhaps we have some report we can write to ONC after the May hearing or something like that.

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

Okay, thank you, Wes.

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

We're going to go continue on, we're only going to go through one more, the rest of them we agree with you, we can, trying to keep you to the timeline. But one thing we did want to point out about non-percentage-based measures, those are the yes/no measures, to make it simple for you. We are in support of capturing some audit data to get that. I can tell you, sort of like we were just talking about sort of the, it got into certification, whether it was in the regs, as Jacob described. When you're audited, even though there's a yes/no answer, you are expected to produce audit materials, which is appropriate. What we would like to have is some guidance on what might be appropriate to give them.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Um hmm.

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

Because that is a constant battle that we have and I think it also will be clearer to us what you expect. And so both for the vendor and the providers who really want to get there, many of the non-percentage-based measures are really important measures. I mean, there are things that we really do need to have out there, but again, the evidence is unclear. So again, we support the concept of capturing it, we'd like to know what it is you would like captured for the purposes of development, right. And then again, we certainly will take any questions if you – again, what we found was in many cases in the remaining areas, it was where implementation guides just simply needed to be updated or, for example, they're going to want to split out in CPOE, rather than have a single measure, we have one on labs, one on rad, one on meds, all really good ideas.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Liz –

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

And we note that a number of the things that are listed in green through the rest, were indications where we thought that the 2015 edition could serve in a very powerful role to address some of these transitional and sort of perfecting issues. SO we want to give full credit so the effort of Steven and team and ONC as a whole of trying to use this as a useful stair-step from 2014 to 2017. So –

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

And we may hear Wes.

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

Yeah, I think I heard Wes.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Actually, this is Mike with ONC. Liz and Cris, is it a chance that you can go – I don't think you touched on family health history, where you had some comments, unless I missed that.

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

Yes, we did –

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

That the transition to HL7 pedigree –

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

Yes.

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

– from the combination of HL7 pedigree and SNOMED CT would be hard. So there is one blue comment, and then we're almost out of time for your area. But, on the immunization registry issue, Karen – Karen said our public health community is very sensitive about standards. And when we say things like, oh, we like certain transmission standards that the CDC may not like, that's, in a way we've done this, we think our standards are good, you should really look at them. So if you make a comment like, we think that query-response of immunizations should be optional, I am certain that will be met with significant feedback. So, could you comment on that one?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Well with – specifically with respect to immunization registries, part of the issue here was the desire to be able to query environments that supported it. So there was – this is a little bit of a damned if you do and damned if you don't sort of requirement. You're absolutely right, the public health is exempt from these requirements, to a large degree, are down their own pathway in terms of the standards to be used. But we run into a really practical problem that the Meaningful Use train and the public health train are not on the same tracks and when we get to the issue of if it's one way, it's not a challenge. When it's a query, I want to know, did my patient have this set of immunizations accomplished, it's hard to do that today with that standards impedance problem. And there's a degree to which that's also true with respect to syndromic surveillance, but it's a more pressing issue with respect to immunization.

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

Right.

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

And so I would certainly concur, as Floyd knows because he titled his company this way, I use the term parsimony, what is the smallest number of variations we can have. And when I think in our last meeting, I proposed, hey public health, why don't you just converge on the same standards we're use for transmission of oh, I don't know, transition of care? I think Karen you received 18 different letters, so yes, I concur, there is a parsimonious –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Apparently I'm meeting with Tom tomorrow.

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

The smallest number of standards for both query response and transmission and whether we can get to one, is to be determined.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yup.

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

Well I think that was one of the reasons the suggestion around implementation guide be formulated because that will help people get closer, if ONC produces an implementation guide, it will help.

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, this is Karen DeSalvo. This is not a standards issue so much, but a larger policy issue and I think what public health is saying is, we may not be 100% ready or aligned, but we want to be. And so the more that the Meaningful Use Program or the Certification Program presents an opportunity to drive that alignment and drive the opportunity to improve public health with the HIT infrastructure of this country, they want to be part of that. And so they really want to be at the table and work with us.

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

Very good. I think we have David McCallie and I can't quite see, it's Floyd, do you have – oh, sorry. Kim?

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

Yes – suggestion or thought with the immunization registries, since we didn't have time to go over that because there was some thought about changing the vocabulary for that. And this may actually be a great place for the Vocabulary and Information Model cake layer to review this and look at it because I was speaking with Eric this morning, because as I saw this, I got a little concerned with it because between CVX and RxNorm, there's very simplistic vocabulary to very complex vocabulary. And then when you look at immunizations, they're not really in the typically, except for a few exceptions, they're not in the ePrescribing information model part of the EHR. He was saying you go into the order entry, then you have an immunization, you have different questions that you need to answer. So I think it's very important we understand all of that before we start making recommendations for the vocabulary, and it would be great to dive deeper into that.

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

Yeah, and while we're doing that, being one of those providers, like John, that has the opportunity to provide care in many states and many localities, all of the requirements are completely different and we've now added requirements about opting in with information. I mean, it's gotten incredibly complex, so we need to be very, very careful. You are absolutely right.

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

And then David, last comment and then we will move on to our next group.

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

Yeah, David McCallie, just to pile on the notion of trying to converge on some common reporting requirements for public health, I took part of a presentation or listened to a presentation just last week from a group that's been working to try to use the CDA document template as a way for reportable disease submission. And the presentation started off with complaints about how expensive it was for each new interface that had to be created and couldn't we all just form a common approach around the CDA. And then they proceeded to show the CDA template that they implemented and they were state-specific CDA templates, because every state has different reporting requirements. And that is not going to make the cost of interfaces go down. So, this is a problem that can be fixed at the state level.

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

And I want to add what David is saying, it's not just the state level. Unfortunately, in California, it's at the county level.

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

County level. Yeah, I mean, the vendors are going to charge money for those because they're all different.

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

That's right.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So we heard a little bit about some CDC investments in that space as well, that – we didn't have a chance to know a lot about, maybe Andy knows about it...but it sounded promising

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

I have worked with the CDC, I can tell you all – this is Andy Wiesenthal, they actually don't have any authority to make those changes. They can create examples and sometimes the states and counties follow them, but they too have costs associated with making change to what are now antiquated public health data capture systems. So, I mean the public health infrastructure in this country is a patchwork that isn't going to be solved by federal edict, unfortunately.

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

– Karen's meeting with Tom Frieden tomorrow and so –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

(Indiscernible)

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

– you give us – as we've talked about in Doug's presentation, you give us the constraints and we will work magic within constraints. So I think – thanks so much for the Implementation Workgroup's report and many further discussions, I am sure will occur on some of these topics. And we look forward to ONC parsing the input and turning it into wise regulation. Next we have Clinical Quality Workgroup, and so it would be Marjorie – ah, and I think Karen and Jon must run to the airport, so –

Karen DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Or to HHS.

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

– or – yes. So as Danny and Marjorie join us, I just want to certainly again thank Jon Perlin and we will be in touch physically and virtually.

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

Well and look forward to being back with you as a civilian member of the committee and, I just hope everyone – Karen and I had a brief sidebar. I pulled up the picture of the trajectory of Meaningful Use implementation, and I know there's a lot of distance yet to go, but my goodness, what a lot of distance covered. So thank you all very, very much.

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

Thank you. Okay, Marjorie and Danny, please tell us about the clinical quality NPRM evaluation.

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

Okay, well good morning. Danny and I as Co-Chair of the Clinical Quality Workgroup are very pleased to present the very thoughtful deliberations of the Clinical Quality Workgroup on the 2015 and 2017 edition proposed rule. Oh, I can't see that very well, so I'll just rely on my paper. Our assignments primarily focused on clinical decision support, as well as clinical quality measures for the 2015 edition and the proposed 2017 edition. And we spent most of our time on 2015 edition and that's where we'd like to really gather most of your comments. Danny's going to start on the clinical decision support proposals and comments and then we'll go back and forth on the clinical quality measure proposal issues. Danny.

Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System

Great. Thanks, Marjorie. So, clinical decision support as the sibling, or more like the conjoint twin of quality measurement, the group was asked to sort of comment on two pieces. Number one is on the clinical decision support knowledge artifact implementation guide, which is, how do we say the "if/then" rules of clinical decision support and then the second piece we were asked to comment on was the decision support service implementation guide, which is how do we sort of move around those knowledge artifacts?

The first question we were asked was, the ease with which EHR technology could be developed to consume CDS knowledge artifacts. And before I start going into specifics, the feedback from the group around decision support I can summarize as, keep it simple, keep it directed and keep it connected to existing activities, i.e. leverage what we've already got. And so you'll see that as sort of the theme of simplicity as we go through each of the individual comments. So first wanted to note the ease with which EHR technology could be developed to consume CDS knowledge artifacts. And the group felt that this can be done, but some of the standards are immature and likely to be technically challenging because there are no shared data models or standard data elements for these.

And to add to little bit to this, this is really sort of a binding issue, right, so if, for example a decision support rule is saying "if A, then B," and the thing it's sort of looking for is a maternal history of breast cancer in a primary relative. While the decision support rule can say something like that, how that is bound to the data within your EHR still remains challenging. And we saw a lot of this with the clinical quality measures. So the suggestion from the group, and then a side point to that was that the implementation guide sort of covered three aspects, one was the ECA rules, which was the event condition and action, it covered that. It also covered order sets, representing order sets and also covered structured clinical documentation. So, the workgroup felt that if it was just constrained to start off with, the ECA rules only that would make things sort of easier. So for the first phase, just starting off with ECA rules and starting off with a few ECA rules.

Implementation would probably be easier if it was linked to specific ECQMs, where a lot of the binding work for what data we're looking for has already been defined and worked out by the vendors. And then additionally it would be helpful if there was a CDS artifact repository and implementation guidance for each individual ECA rule. So the comment I was talking about with the binding concerns, how is – how are the data from a single ECA rule bound to the content in the EMR? As a point of order, would you like me to go through all of a-d for the Health eDecisions Proposal, Dr. Halamka, before opening up to comments or – ?

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

I think, David, do you have a comment?

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

Yes, David McCallie, just a concern about the ECA. Because the ECA is not able to account for local workflow variations that are necessary to optimize appropriate delivery of decision support, and because ECA doesn't incorporate any rubrics that allow for Direct data access, because as you say, there's no binding that makes sense. I question whether there's any value in expressing the ECA in a computable form, like an abstract syntax tree of XML, as opposed to just a clear-cut, English language, unambiguous pseudo-code expression of the logic? It can't be really compiled into the EHR, so what's the point in writing it like a compiler's output? Just pet peeve of mine, Jacob and I have discussed this in the past. But I mean it's possible to reverse engineer the ECA logic and convert it into the local rule system, but that's a human translation process, for the most part, because you have to hook it into workflow and bind it to local variables and local data access patterns. The VMR pattern is not adopted by anyone that I am aware of, so I don't think that has a lot of traction either, and would prefer focusing on something like FHIR in the future.

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

Jacob, did you want to make a comment before I turn to Eric and Floyd? Okay, Eric.

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

So, to David's comment, I think it's very valid and in the context of the NPRM, which talked about two Health eDecisions use cases and use case one was the one that encompassed event condition action rules as one CDS knowledge artifact type, and two other CDS knowledge artifact types, order sets and documentation templates. Our feeling was that if that were – if we were to pick one that would make the most sense to try to develop and deploy interoperable decision support content, that the traditional here is an alert that may be relevant to – at this point in the care process, those kinds of rules, would make most sense. And I think, I would certainly agree with you much more strongly if the NPRM were for mandatory certification, but I think that we have an opportunity here to see where the challenges are and how difficult or perhaps even impossible the binding is to – between these Health eDecisions artifacts and a plug and play experience in the EMR. But I certainly agree with you that the challenges are going to be there.

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

A secondary – a second comment on the positive side, I think the notion of an order set standard is to me more tractable. We already have many order set vendors who produce order set content in an XLM form that the EHR vendors can consume, why not get them to standardize on a common format and I think that would imply also, developing some notion of a common order catalog. Because order sets that can't reference a standard order catalog are somewhat problematic, that's a tractable problem that's already being solved in a piecemeal fashion and could be made more efficient by getting standardization around a standard order catalog and standard order sets. Those are static, they can be imported with relative ease. ECA that's embedded in workflow and is dynamic is a much harder problem and it seems you're going about it in a wrong sequence to focus on ECA.

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

Thank you. Floyd?

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

So, while everything that's been said is true, I think the concern is one, the nice thing about ECA rules or artifacts in HeD is they also include some vocabulary bindings. So the value sets really, even if you're doing something manually with the content, at least help you understand exactly what elements you're looking for and what applies, what does not. I think the challenge is, and I wouldn't say it always has to be an event action rule and I don't think we discussed the actual nature that is a pop-up. It could be an event action rule that is related to population-based, all those patients with these characteristics, on whom you need to act and those may actually be simpler, easier to deal with, thinking about the kinds of rules you might want to include. That's a personal comment, that didn't come from the committee. But working in this right now, that's something we're seeing is what's more valuable.

The clinical quality framework, I think is a good place to do this kind of testing and studying. And what David's talking about makes a lot of sense, in that kind of a setting. The concern is, how much can you put in a rule base versus let it evolve in a – in the framework and in the community to allow folks to start doing the implementing and seeing how it affects the workflow. And I think that's the concern I have here, but I do think there's value in the content that's in it, even if you really use it to read the details manually because they're much more clearly expressed.

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

Okay, we have Arien and we have Andy.

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

I just want to double-down on Floyd's comments that population based measures are currently generally decoupled from the EHR and decoupled from the tight workflow that's necessary and may be a more tractable problem. It doesn't necessarily lend itself to Meaningful Use driven certification criteria, but may well lend itself to certification criteria for new classes of HIT that might add some ecosystem value.

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

Thank you. Andy?

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

I worry that we aren't hearing from the end user community, or a big segment of it in relation to some of the more complex forms of CDS. Because I think the specialty societies are busy grinding out guidelines year after year, most of us are – physicians, who are used to seeing them sit on our shelves saying, I really should remember that when that comes up. And if they aren't asking for them or generating requirements for a common process, then we're missing the boat. Because if the obstetric community comes out with guidelines and forms and order sets in a specific form and format, in my own society, the pediatrics community does it differently, we a problem of trying to make it all make sense, especially when the patient actually falls into more than one category. So, is it the role of government and I'm looking at Jacob and others from ONC, to try to convene the specialty societies and get them to feed a requirement space so that we can understand how to move forward as we build standards.

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

Okay.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Thank you. I say thank you because primarily I'm in listening mode for this part of the conversation. I think it's really good input. This is not something that we – oh, I should say it in the positive, this is absolutely something that we have thought about, we've talked with some specialty societies, including yours, about exactly this topic. So, it's really good feedback, keep going.

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

Doug, did you have a comment?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator for Health Information Technology

I just wanted to make one comment as well is that, what you articulate is a value proposition that's different than what we've been talking about so far. It's not about value of being able to sort of suck that information in in an automatic or computable way, it's about getting clarity in terms of how the guidelines are represented in such a way that they can more easily get translated. And I think we have to be – we have to realize that that is a tremendous addition, just trying to translate loose guidelines into something that is computable is a hard task. And having a syntax that the specialty organization and others can use that forces the developers of the guideline to go through the work of figuring out how to make a computable version of that, is probably where the right expertise needs to be. So, I think that's a really interesting point that I'm writing down.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Much of that work in that domain actually comes from pediatrics, as you may know. So Rick Shiffman is probably the leader nationally in helping a specialty organization organize the clinical practice guidance in a logical way, right, and making words like “might,” “could,” “should,” “ought to,” get those out of the guidelines. So that when we – and we did this – the same thing happened, and that's part of why a lot of our focus at ONC in the last whatever, 9 months, has been on thinking about quality measures and decision support as one thing under the umbrella of clinical quality improvement.

Because the same things happened 5 years ago when the quality measure development community came to the health IT development community and said hey, why aren't quality measures in EHRs? And we said, well what do you mean? And we weren't saying what do you mean why aren't they in, we meant, what do you mean when you use ambiguous phrases like, blankity-blank. And so I think the work we've done with CMS and with NQF to clarify the intent of the measure developer is now being done in the clinical practice guideline community and will then make it easier, even if David is right, I submit that that's a possibility. That we don't need to make this computable 100% of the time, I still believe that there's a chance that making it computable will be of value to some. But we can't get there if the choice between the 6 antihypertensives is a choice, right, there's got to be a best choice.

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

All very good comments. Now I know that we have about 8 minutes or so for the next 8 slides, so, please Danny, go ahead, or Marjorie.

Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System

So I'll try to compress some. So the essence of this next slide, the question that we're being asked is, should we distinguish between easy and complex CDS artifacts? And the next question being asked is, please comment on the ability to map the knowledge artifact data to standards in the EHR. We sort of touched on this a little bit on the previous slide. So, should we distinguish between simple and complex? Yes is the simplest way to answer that, and if we can sort of focus on the common, no-brainer areas where we already have good coverage like labs, meds, demographics and vital signs, that'll make implementation easier and less ambiguous. Second point is around mapping to standard data. Do we have the ability? Yes, but it will be made easier if the examples chosen are simple, directed and aligned with previous quality measures.

And on the next slide, the questions were around commenting on the ability to store and auto-configure this knowledge artifact in EHR? And the workgroup wasn't 100% clear on what was meant by the term auto-configure. We took a guess at it and we basically said, if this means to automatically grab and automatically sort of turnkey implementation of a knowledge artifact without having to sort of manually look at a document, then type something in to the EHR. If that was the intent of this, then we would need to have obviously a standard data model, standard logic and lots of implementation guidance to configure these systems, easier said than done.

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

Now, oh, maybe I'll reserve for the end.

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

Okay.

Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System

The last point for the Health eDecisions proposal was – this is the second half, which is now no longer looking at the knowledge artifact itself, but looking at how these knowledge artifacts are exchanged between systems. And the question was, is this feasible? The group felt that it's feasible, but again, it's very challenging to actually do this right, so, the workgroup suggested the likelihood of success for this would be made higher if rather than focusing on all 7 interaction types. And just so that you're aware, the interaction types that were sort of mentioned in the rulemaking were, as examples were, drug dosing calculation, immunization forecasting, disease management, quality measure evaluation, transitions of care, predictive rule evaluation like APACHE and severity of illness things like trials and co-morbidity. The likelihood of success would be higher if we just focused on let's say, two or three of those with specific guidance as opposed to all 7 or any of the 7.

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

Comments? I mean I think the general theme we heard from both Cris and Liz is, let's do less better.

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

Okay, so moving on to the clinical quality measures that we were – proposals that we were asked to comment on. The first dealt with patient population filtering, and specifically whether the EHR should be required to record the structured data so that population groupings can be developed from patient characteristics, such as the practice site and address, the diagnosis perhaps using SNOMED codes or demographics such as age, sex, preferred language, education and socioeconomic status. We were specifically asked to comment on whether the CQM standards such as QRDA Category I and III can collect the metadata for the characteristics that we just discussed so that a report – so that the information can be filtered and then a CQM report can be generated.

And the group felt that for some of the characteristics it's possible, but not for all for QRDA I. For instance, and I believe Floyd this might have come from you is that, there's no standard to collect or exchange education level and socioeconomic status, for example. And I think one of the comments that we spent a lot of time on was – is that the patient characteristic information lives – some is clinical and some is administrative, and because of that, they live in various systems that don't necessarily interoperate. And so having – asking a provider to be able to bring this data together may be challenging. And so, the group felt that perhaps rather than place that effort or burden on the EHR, maybe a data warehouse of some kind of data intermediary may be necessary.

I do have to say, it's not on the slide though, there were some – I think there was one member who felt different in that and felt that asking a provider to bring this type of information from various systems wasn't necessarily challenging. And I apologize that that didn't make it on the slide, but that's also a thought. And if I can finish this one point before we move on to questions, and we also responded to whether there are vocabulary standards that can be used to record the characteristics that we just described? And the answer is, there are standards available for some of the demographic information and some – we need standards or we need to identify standards for other things like the socioeconomic status or the education level. What was really important is that you need more than just the vocabulary, you also need to understand the context of that data element and so that means additional metadata or value sets, etcetera. So, I'll stop there and ask for comments.

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

– thank you.

M

That's good work, what it points out is yet another role for us I think we would all agree on, but I want to make it explicit and that is, we should have a national agreed upon core data model that's extensible. So we can agree how many genders we have and what they are so that they'll trigger the proper rules and all the other 50,000 some-odd elements that are in the model. Because otherwise it becomes a nightmare for the vendors and a nightmare for the people who are trying to write rules and measures, because you're referencing elements that have no common meaning. And so, if we can get that accomplished, I think we will have gone a long way. So this points in that direction and I'm grateful for it. Thank you.

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

Floyd?

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

So, thank you. I think – I just wanted to clarify a couple of things that we talked about in the group and that was, in the September 21, 2011 I believe transmittal letter from this committee, there were certain vocabularies identified for use in clinical quality measures, among them was not education level. And in discussing socioeconomic status with the vocabulary task force at the time, it was clear that that is a variable kind of decision. You might be able to say income level, if there was a standard for income level, and patients were willing to share it. You might be able to say education level, but SES, socioeconomic status was not something that was standard to be able to – or even static to be able to evaluate. So, I just wanted to mention that.

There is work going on today in HL7 to try to standardize some of the data model. Now a ballot which you can still comment until Monday night, called the QI DAM, Domain Analysis Model for quality across decision support and measures. There's also some other work going on this ballot for May and also for September to support some standardization. It's just not all done yet.

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

Arien and then Eric.

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

So this comment was triggered by the – Marjorie, the comment that some members of the workgroup felt that this data would be easy to bring together. I am generally concerned that the net effect of certification criteria across multiple domains is to cut across the vision that Jon Perlin painted of modular EHR components that work across a data backbone. And instead encourage monolithic applications that require tight coupling in order to deliver the level of workflow that we're looking for.

There clearly are some EHR vendors that give extraordinarily good service to customers on a backbone of tight interdependence and non-modular architectures and may well be able to combine data from – that traditionally would be in administrative and in clinical systems to support population-based measures. There are others that specialize in particular areas and particular domains and it would be, I think, bad policy to encourage the development for nonmarket based needs of fully interdependent architectures in favor, I think would be good policy to encourage the development of modularizable components. But let the market decide about whether interdependence or modularization is required. And that begs the question with regard to these questions as to, if you define an EHR – even if you define an EHR module, I mean we have modular certification proposed for 2015 as the only way to do it, which I fully support. If you define modularity without defining the inputs and outputs of that modularity, what you do is again drive people towards interdependence and non-modularity.

So if you don't define how data gets into this from a practice management system or from an EHR, but you only define the means by which the rules get into the system, what you're doing is biasing the markets towards full interdependence in ways that may not meet the policy goals that you're looking for.

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

Thank you. Eric?

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

So one of the things I think we need to be aware of is that there's a – we're going to bump up against a policy issue here that perhaps needs to be – the Policy Committee needs to be aware of. Which is that there may be difficult or infeasible workflows that would be required in order to support the data capture for some of these types of data element, partly because we're talking about types of data that may change over time. A patient's socioeconomic status obviously may be different one year to the next or one month to the next, and do we really need when you check-in for every doctor's visit to be asked whether you're rich, poor or middle class.

The other thing is that I'm a little concerned about the fact Floyd mentioned that there is a paucity of standardization and, what I'd say is that even with standardization, there may be challenges here. The update of the US Extension of SNOMED CT, which the National Library of Medicine controls, that came out in March had concepts for income as percent of poverty level. I don't know – nobody knows where that came from, who suggested it, whatever, I mean it could have come from anyone because the NLM takes suggestions from all comers. But if we're going to have two or three years from now requirements to capture that data, patient's income is between 150 and 200% of the poverty level, the idea that physician practices would be able to determine that, how much do you make? Let's see what the poverty level is today – so I think there may be a need to balance the need for capturing data required to determine health disparities, which is a policy imperative, from not breaking clinical workflows.

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

So requiring FICO score at every transition of care is probably not what you want, okay, I get it. Yes, please continue.

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

Actually I have one – okay, one question.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Steve –

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

Oh, sorry.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

It's – I would just on this one I think what you guys did exactly right was identify the appropriate scope of what an EHR is. And so I think when I think of what clinical quality reporting does in an EHR, it's when you open a patient chart, you see which measures are applicable to a patient and whether they're in or out of compliance and that you have an ability to identify patients who need some kind of care to be filled. And I think you've separated that from sort of advanced analytics and I think that one of the things I listen to in these meetings is, are we talking about an EHR or something else? And I thank you for deliberately tackling that when you were looking at this requirement.

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

And certainly everyone has a different model, our model is, the EHR is for transactional care coordination and quality measures are actually produced from a separate software application that is fed by multiple EHRs and information is consolidated to form the –

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

Good point. Okay, so, moving on. One last thing that we commented on was that with respect to clinical quality measure export and capture and within the – there isn't a change in the proposal between the 2015 and 2014 edition and the groups comment was that the standards have not been evaluated well enough to know whether import can be achieved. And there aren't enough mature enough processes to really determine if capture can be achieved directly from the HQMF and then have a subsequent report out. So I'll stop there before we move on to the 2017 comments. We'll probably move more swiftly through that and ask if you have any specific comments in certain areas, I can go over some, but in the interest of time I wanted to first open it up to complete the 2015 review.

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

Comments? Okay.

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

Okay.

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

2017 and you've got eMeasures coming up I think.

Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System

First a point for 2017 was, question was, what's the usefulness of broadening the export requirements to also include QRDA Category II as opposed to Category I? It is useful, the group felt that resources would probably be better allocated focusing on improving what goes into Category I. And also from a timing perspective, that Category – QRDA Category II is somewhat of a mythical being from a detailed, balloted standard in HL7. One other – a workgroup member felt – had a side comment about QRDA Level III that felt a lot of folks weren't actually using QRDA Level III and that was QRDA Level III was burdensome and perhaps the focus should be on QRDA Level I, which can then be aggregated to Level III.

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

– I think everyone knows what this nomenclature is, but just quickly, the Category I is the single patient report, the Category II is summary report and Category III is calculated reports. Whereas II, as you say, doesn't exist in the real world. Okay. Oh sorry, Floyd.

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

Sorry, so just to add to this, Category II was never balloted in HL7, so it's technically not a standard, it was a concept. And the question about III, one of the things that came up in talking about a calculated measure was some of the things that exist in measures they ask for are considered supplemental data elements, race, ethnicity, you can include preferred language, whatever you'd like. But when they're there, and there's no instruction about how to create the individual cells and report out your results based on those criteria, then it would be really hard for a provider to know how to create a summary report, unless the measure specified that, I want this stratified by these three races, these three ethnicities. And if that were the case, they wouldn't be supplemental and they would be in a Category I.

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

Thank you. Great, back to you.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Let me –

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

Oh yes, please Jacob.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Just have a clarifying question on the sort of additional guidance on III versus I. So you're saying that folks don't use III and therefore so we should abandon III and really focus on I. What about that concern that folks don't want to send individual patient data places, and remember, we're talking about certified EHR technology and in the vein of what Jon Perlin talked about, this isn't a monolithic EHR. Certified EHR technology is a set of potentially interoperable modules, and if I'm using the Halamka model, I have my transactional system that I'm using day-to-day. I throw from my transactional system to my or some entity that I have contracted with to perform my warehouse analytics capabilities, so I'll throw that entity my QRDA I's, granular data, but it's all under my umbrella. And then from there I'll just say to any organization that wants it, maybe it's CMS, maybe it's my payer, maybe it's somebody else, here's how I did. And QRDA III is the answer, here's how I did, it's very simple, it's very clean, it doesn't burden that receiving organization, say the federal government, with granular patient data that we really may not want to be accepting. So, what – where are you on that?

Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System

So, I wouldn't go as far as saying that the workgroup felt that we should abandon the Category III, I think those were the comments of individual, how well Category III is being adopted. Conceptually from a personal level, I agree with your comments, I think the voice of the workgroup was really, I versus II, that the focus – if we had put resources in one of those buckets, focusing on Category I.

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

A couple of minutes, because we do want to get public comment in, and these people are getting glucose levels below 100 right now.

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

Okay. So I think we'll just – these – again, these are early 2017 comments that we may decide to further refine. If we need to move to public comment, we can do that, unless there are other –

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

Any summative comments on eMeasures that you'd make?

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

So I would say that with respect to, I think this is one that we spent a lot of time on, was the industry readiness to adopt the HQMF format to represent the clinical quality measure as an electronic document. And the group essentially felt that the standard wasn't ready yet, that much of the data was – in the measure is unstructured if it exists at all. And that quality measure value sets need – are not ready to support that effort. And they also recommended a centralized authority to create and manage value sets. So that's a quick summary of that particular slide. Comments now?

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

And as I look through the other slides, was there a functions and standard certification final slide you wanted to cover?

Marjorie Rallins, DPM – Director, Measures Specifications, Standards and Informatics – American Medical Association

Yeah, definitely...Danny?

Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System

Um, yes. Floyd was actually touching on this a little bit and the response from the workgroup was really focusing on this notion of supplemental data and how does it sort of fit into things. And just to sort of paraphrase what Floyd was saying, if the measure is saying, we need to stratify by a certain variable that it depends who's doing the stratification. And if the stratification is intended to happen locally, at the practice or at the hospital site, then instructions need to be explicit for how that stratification happens? And so then it's no longer supplemental data, it's actually core data that's important to calculating the measure. If, on the other hand, the aggregation is intended to happen somewhere else, then those can in fact be supplemental data and just included as another data point in Category I. Preliminary comments, of course, for 2017.

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

Floyd.

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

This is Floyd, I'm just going to answer that. I think one of the problems with supplemental data is on a population basis, they may be very valuable. But at a local practice site, you're getting into small cell analysis and you might actually end up with incorrect assumptions being made. Because you only have one or two people in one cell and it comes out 100% negative, and it looks like you have a disparity when, in fact, you don't or, you might but we don't know that. So, we have to be very careful on some of those supplemental data elements and how they get used at a local, small practice level.

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

Thank you, Floyd. Any closing comments on quality, QRDA, HQMF? Very good point on the issue of what data we want exported from our EHRs and how much patient-identified line-item data we want to send out of the firewall. Well, I have been told by Michelle, that Dr. Posnack is going to be extraordinarily quick this afternoon, so lest you think we're really behind schedule, we're not. So Michelle, let us open it up to public comment and then we will break for lunch.

Public Comment

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

Okay. Operator, can you please open up the lines? And while we do that, if there's anybody in the room who would like to make a public comment, if you could please come up to the table to make a comment. Also, as a reminder, public comment is – there's a maximum of 3 minutes for public comment.

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute

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

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

So Gary, I didn't recognize the beard and I thought it was Sean Connery, so please, go ahead.

Gary Dickinson – Director, Healthcare Standards – CentriHealth

Well, watch out, my wife isn't in agreement with that. In any case, my name is Gary Dickerson, I'm Director of Healthcare Standards at CentriHealth. I'm also Co-Chair of the HL7 EHR Workgroup. My comments, I've long been baffled by the statement, don't let the perfect be the enemy of the good. I've heard that expression in standards circles since I joined in 1989 and 25 years later, what is perfect, what is good? We have no metric for either so – meanwhile, it's become routine to declare almost anything, any form of standards-based record information exchange good or at least good enough. I witness ONC and others declaring achievement of interoperability in Meaningful Use Stage 2 exchange. Citing the 1990 IEEE definition of exchange and use, at first – this sounds perfect, but maybe it's only good. How do we know?

I think the key is whether interoperability, per the axiom of exchange and use actually produces health records and information that is fit for use. First consider fitness for primary use where authenticity is vital. Clinical care interventions and decision making maybe perfect equates to exchanged health information that is fit for primary use. Then consider fitness for secondary use, most every other purpose where transformation and approximation may be okay. Maybe good equates to exchanged health information that is fit for secondary use. So maybe that's our metric, or maybe we could take another perspective. The paper health record as the source document is clearly fit for primary use. As such, it has characteristics, which convey both truth and trust, authenticity and insurance if you please, to anyone who views that record.

So let's reference that IEEE definition again, noting that the paper health record can also be exchanged and used. Exchange typically starts with reproduction via FAX or scan or photocopy of the original paper record. Next we should consider whether the copy exchange process retains vital characteristics of the original source document, such that truth and trust remain evident and thus that the resulting copy remains fit for primary use. Ah, maybe we found another metric, so maybe perfect in this case is the metric that establishes exchange of electronic health records and information as fit for primary use at each downstream point of receipt and process and access.

Thus whether we have a paper source health record or its electronic health record counterpart, truth and trust, authenticity and assurance are equally conveyed. So maybe good is really the enemy of the perfect. Maybe after 25 years it deserves a closer look. Maybe we're too focused on the good that we ignore the perfect, what it is and how we might achieve it. Fitness for primary use cannot be considered just good or good enough, it must be much closer to perfect or at least as good as the paper record and reproduction methods it replaces. It is our recommendation that the HIT Standards Committee take a close look at the electronic health records and information exchange such that truth and trust are both measured and ensured end-to-end.

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

Thank you very much. Profoundly said.

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

I'm sorry, is there anyone else in the room? On the phone we have Allison. Please go ahead.

Allison Chi, MPH - Program Director - American Immunization Registry Association

Thank you. My name is Allison Chi, I'm Program Director for the American Immunization Registry Association, also known as AIRA, and I wanted to thank the workgroup for the comments – the brief discussion on CVX codes and support of CVX codes, and also to respond to an online NPRM comment that was made about CVX codes in NPRM versus – NDC versus RxNorm. And so from the IAS perspective, IAS will support inventory management for federally funded vaccines and RxNorm does not allow inventory management or decrementing based on HL7 messages. Also NDCs support inventory – and in addition to supporting the inventory management, NDC is granular so it includes product strengths, description, presentation and components. Bar coding can accurately identify administered vaccines, but it doesn't support all of this important functionality related to inventory management and also integration of 2-D barcoding and so systems can map from NDC to RxNorm as – percent of the NDC codes in HL7 messages and do the translation on the application side as needed. So just to say that AIRA is really – is strongly in support of ongoing use of CVX codes for vaccine identification, especially when the specific product is not known. And we also strongly support the use of NDC codes for reporting administered doses of vaccines. Thank you.

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

Any other public comment?

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

That's it.

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

Okay, so we are going to officially take a lunch break. Wanted to thank all of the morning presenters, great discussion, great questions. We will return at 1:45 PM for the afternoon of Dixie and then comments and Steve Posnack, so, thanks again.

Okay. So Michelle, do we have to bridge in the public and that sort of stuff?

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

We're actually already open for the public.

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

Oh, okay.

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

So we can just get started. I was just talking to Dixie, we think – we originally had talked about doing the NSTIC update first, but I think it would make sense to do the NPRM discussion first so that it flows with what we just discussed this morning and then we'll shift to the NPRM discussion – I'm sorry, to the NSTIC discussion.

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

Very good. So, we will – I feel like we're having a little bit of a video issue at the moment with some slides, but hopefully folks who have the electronic copies and paper copies of Dixie's material –

Multiple speakers

(Indiscernible)

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

So, do we have a cabling problem? I think there was a –

(Indiscernible)

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

Sure. Today I think there was a little tripping incident that occurred over here and no doubt there has been a physical disruption of connectivity. So, we have our afternoon of Dixie now, we're going to begin with the 2015 edition NPRM comments from the Privacy and Security Workgroup. And particular interesting discussion about what we do in a modular EHR world to ensure privacy, security and data integrity are protected. I will need to step out for 5 minutes at 2:00 o'clock to talk to a group of folks in Massachusetts about the importance of recording consent and Jacob will be, in those few minutes I am gone, your official leader.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Okay.

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

Dixie, go ahead.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Okay. Good. Thank you. So in the interest of continuity, we're starting with our NPRM comments from the Privacy and Security Workgroup. So, do we have the slides at all or is he still –

M

He does have them online –

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Okay, well you guys have the handout anyway so we can start. I wanted to start by introducing my new Co-Chair, Lisa Gallagher and so she – beginning – you'll see that Walter's going to present with me the NSTIC presentation and Lisa is the new Co-Chair. The primary reason we did this is that my tenure with the Standards Committee will end in – next May, like a lot of you guys as well, and Lisa came a little later, so for continuity, she'll be able to take over the leadership at that point. So, I'm going to teach her, on-the-job training. So, with that, we were assigned – the Privacy and Security Workgroup was assigned several issues to look at in the NPRM and so we've addressed all of those that were assigned to us. And in addition, our ONC support suggested that we look at a couple of other issues as well, and so we're going to give you feedback on both the ones that were explicitly assigned to our workgroup and those that we chose to address apart from that.

The first topic is a very important issue is the certification of EHR modules. What has been – as has been already talked about is that the new NPRM or the proposed method – I've got some notes here that aren't here – the proposed method that's proposed in the NPRM is to drop the certification of complete EHR technology so that EHR technology, all EHR technology, will be certified as modules. So that's the first topic we're going to talk about. The NPRM request – oops, I hit the wrong thing, of course. Oh, this is the wrong presentation, we reversed these two; we want the NPRM one, this is the NSTIC one. So – at any rate, the NPRM has a specific request and it relates to the 2017 edition of the certification criteria and they seek comment on four options for certifying EHR modules.

The first option that they list is to readopt the approach in the 2011 edition – thank you. And the 2011 edition requires that all EHR modules be certified against all privacy and security criteria. The option two is to maintain the 2014 edition approach, which is to not explicitly require modules to be certified against any privacy and security criteria, unless the vendor requests that it be certified against those criteria. The option three is to adopt the Standards Committee recommendation that we presented in 2013, which is to certify EHR modules against all privacy and security criteria, but we proposed three paths, and we'll go over that in a minute. And then the fourth is to adopt a limited applicability approach, which would establish a limited set of privacy and security functionality that every EHR module would need to address.

In March 2013, this committee transmitted to the ONC a recommendation that modules be required to be certified against all the privacy and security criteria, but that they be given three paths to be certified against any particular criterion. One path would be to implement the required functionality and then prove through testing that that functionality had been implemented. The second method would be to demonstrate and document a service interface that would enable them to obtain that service from an external module. And then the third is to demonstrate why the criterion isn't applicable at all.

The Privacy and Security Workgroup totally agrees that to achieve the strongest security protection in any enterprise, each EHR module would ideally use a common set of enterprise-wide security functionality. And path two of our recommendation would allow that, it plays right into that idea that you would have one module that does privacy and security services and the other modules – the 2014 approach for certifying EHR modules against privacy and security criteria, only at the vendor request really presents two concerns that are significant for us. One is that a provider could purchase one or more certified EHR modules that would not be able to provide the protection that's needed to counter the risks that are presented by the certified functionality itself.

And then the second concern is that by not certifying a module against the privacy and security criteria places the onus completely on the provider organization to determine whether the certified EHR module will protect them against both the security risk presented by the certified technology and against HIPAA certification – compliance risks. We believe that a provider should be able to assume that a certified EHR product that they have purchased provides the functionality they need to protect health information and to comply with HIPAA. Until now, when a provider acquired a certified complete EHR, until the NPRM proposal that is, they could be confident that the product had been certified against all of the privacy and security criteria. Because in order to be certified as a complete EHR, you had to be certified against all of the functionality included in what was called the base EHR definition.

But now, as we move to certification of EHR, everything is EHR modules, no module is required to meet the base EHR definition, so, the privacy – so we leave a gap there. The Privacy and Security Workgroup believes that a provider organization should be able to assume that any certified EHR product that they purchase, provides the necessary privacy and security functionality they need to both protect the functionality provided and that was certified, and that will enable the organization to conform to HIPAA – comply with HIPAA. But we do recognize that the privacy and security criteria are not equally useful or applicable to every criterion in the other functional areas, like care coordination, and public health and consumer engagement. And as you'll see, the recommendation we're presenting today recognizes this reality while still providing the multiple paths that we proposed in 2013 and that we believe are very essential.

So this is our proposal and it has two parts. It – I want to go on to the next slide. This presents the – what we recommend is that each privacy and security criterion be explicitly specify the conditions under which that criterion is applicable. This is similar to how the end user encryption – end user device encryption criterion is written. And then that each criterion be – to be met – and allow each criterion to be met using one of the three paths, either implement the functionality, document the interface that shows how you're going to get that functionality from an external service or to document why it's not applicable.

We see that this could be accomplished, the first part of this, revising the criteria. Either you could revise the criteria in the regulation itself or you could provide conditions as guidance and in either case, the conditions and the paths would need to be incorporated in the test procedure. And if this approach is acceptable, the Privacy and Security Workgroup would be happy to work with ONC and the Transport and Security Workgroup would be equally eager to work, correct. So, to show you an example of this, one example is the current end-user device encryption does exactly what we're proposing to do. It says that EHR technology that is designed to locally store electronic health information on end user devices, must encrypt that information. So if a module doesn't store information on end-user devices, then it doesn't have to meet it.

And the next criteria – the next slide shows a criteri – one of the examples of what we've worked out. You'll see at the – in your handout, there is a spreadsheet that shows a number of security applicability statements that we really worked through as the Privacy and Security Workgroup just to demonstrate to ourselves that this would work and would you like to say something about that?

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

Okay. So in order to see if this concept would work for us, we went through the exercise of creating examples of what applicability statements could be. So Dixie mentioned that the encryption requirement sort of already had that embedded in the requirement text, but the rest of them didn't. So here's an example, emergency access - permit and identify a set of users to access electronic health information during an emergency.

We – when looking at whether this would apply to a particular module and thus require it to be certified against this criterion, we created the following statements that are here in bold. If the module allows human user access to electronic health information and if the module performs functions supporting the purpose of delivering patient care, then demonstrate how the module supports emergency access by an identified set of users. So this allows – when anyone is presenting a module, they could determine the applicability of each of the security criterion by going through the applicability statement.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

And they would have the three paths available to them, they still could either implement the functionality, call an external service or document why it still isn't applicable. So moving on to the rest of our –

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

Do you want to pause for questions?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah, do we want to pause for question here?

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

– and I have to run out for just this quick call, but I've got one question for you, because I know in your dialogue with Steve last night, this came up. If there are other regulations in force, like the HIPAA Omnibus Rule, one of the questions I think we should ask is, how much we should put into a certification and testing or Meaningful Use regulation versus how much should be inherited from other regulations that exist? And so Steve, any comment you'd make?

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Well, from the beginning, I mean, we've advo – we've included in our regulations privacy and security certification criteria to be a mechanism or vector to serve as tools that are part of certification that would be available to assist with compliance. Our certification obviously cannot guarantee HIPAA Security Rule compliance, but in a lot of cases, we've included, many I think would argue relatively simple and industry standard kind of functionality that could be part of EHR technology as a whole. The question I think you're raising John, which I had dialogue with Dixie about is, where certification either becomes redundant or overly specified or unnecessary because there are other paradigms or impetuses, if I'm saying that right, for providers and the market to deliver EHR technology with those security capabilities, without the forcing factor of certification as the construct that in order for the product to get certified, it needs to address these things. And Dixie and I have had a good intellectual dialogue about what the case is and how best to have certification support some of these things where I completely agree, the inherent potential either vulnerabilities or functionality that could present security risk. And whether or not there is a happy medium between the extra effort that an EHR technology developer would have to go through in getting certified for these extra – the privacy and security functionality relative to the context that's appropriate to the product. So –

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

Well, good answer and let me just give you one example of, so Dixie, I absolutely really like what you've done and you just sort of wonder how practically we can implement it in a modular world. The Massachusetts HIway offers the Direct protocol to any user who comes knocking at our door. An EHR. by certification must emit a C-CDA. The Mass HIway said, I want to certify my capacity to deliver payloads and ONC said, well I'm sorry, the way the certification criteria is written is, a certified electronic health record technology must emit content and deliver a payload. So there was actually no way to separately certify the module for the criteria of delivering the payload generated by software. And so we have to be very careful in the way that we word these things, allowing sort of, oh I as a doctor am going to go buy five different modules and the whole will then do what I want and I can be assured it is certified.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

That's right, that's right. I think there are two things I'd like to say. First to respond to Steve, I think that most of us here would agree that most EHR vendors would also make sure that their product recorded demographic information and physician notes, because the market drives that. So I don't think that's a – if we – maybe we were arguing that we shouldn't certify technology at all, but I think even more importantly is the expectation of the provider organization. Provider organizations should be able to assume that when they buy certified EHR technology, it protects health information and will help them meet the HI – comply with HIPAA. Healthcare provider organizations are very compliance-driven and they, I'm sure, will expect their certified EHR technology to help them do that. Yeah?

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

And I would say that's the very purpose of the certification is to have the purchaser have some sort of baseline understanding of the functional capabilities of the module that they're buying. And I would also say that the HIPAA requirements are organizational. So, they require the organization to do a risk assessment and manage their risk with all the tools that they have available to them. And the functional capabilities of the EHR around security are a set of those tools. So I do feel that where applicable, they would be benefited by some understanding of the security capabilities of each module.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Good.

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

Comments?

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Oh, now I'm John. David?

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

Yeah, just to – this is David McCallie, just to put a – shine a harsher light on the tension or the dialogue. Because it's been a really good dialogue with Steve as I was on the workgroup with Dixie and Lisa and others is, it really is kind of a policy decision of should security – should privacy and security measures be part of the certification effort or not? That's the high-level, branching decision. If the answer is yes, then I think what we've put together is the least intrusive way to do that because it breaks down each requirement against the functions that would trigger the need for that requirement. But if the answer is no, as Steve has positioned, then it simplifies life for everybody, but you're buying certified technology that hasn't been tested in any way about privacy and security. And I think that's a policy decision. I think we did a – we've done a careful as we know how to do it job at simplifying what it would take to do the certification, but that's a decision to go, no go. If you don't certified around security, then you don't need this.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

If I could – for the record, I wasn't positing the "no." I think that is, at the highest level, that's probably the choice at a policy level. And then – and if you decide yes, then there are further gradations of how you balance what you want to see out of the – what Lisa mentioned, the assurance and the awareness of what the product was tested to and for what it was tested against. Given the three paths that exist that your workgroup has thoughtfully discussed, that will lead to different abilities of products as they go through the certification. And so some that may rely on a service, some that may do it themselves natively, I'm not sure that we would be able to explain the difference to providers. But there would be some assurance that it had been addressed. And so, I think we also need to recognize the limits of what certification can provide and not provide.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

And I think that's what it all boils down to is the expectation of the provider, because the provider is really our ultimate customer here.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Or the patient.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

And the patient, yes, excuse me.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Sorry. I spoke for Leslie. Andy?

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Yeah.

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

So, there are two kinds of providers. There are the larger, more institution-like providers, large systems of hospitals or care delivery systems, who might have a prayer of actually doing some of this themselves if it didn't exist. But then there are tens of thousands of small practices that have to adopt electronic health record technology that can't. And they can't do it at two levels, and I understand that you're addressing with this the one level, but I'm still not getting how you're addressing the other.

The first is individual modules that they choose to go buy modules and put them together as their own package, yes, we will have certain kinds of privacy and security testing and assurances to you as a buyer. You buy that module, it's done. What happens if they put together some previously undefined collection of modules and they have to interface? And data has to move between them and they're using web stuff, does it really – can they count on the fact or how do we help them count on the fact that they can do that? Because we're implying, when we say you can buy modules and they're all certified, we're implying plug and play, we are, whether we like it or not, we are. And they're going to assume plug-and-play and that means nothing I do putting these pieces together is going to compromise the security of the data that I'm collecting about patients. So how do we represent that in a way that 200,000 family physicians and pediatricians and obstetricians are going to understand?

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates
(Indiscernible)

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

Well, I mean, I would say that goes to the issue of certifying only modules and how we're going to communicate what that means to the purchasers. So we were – or the problem we were given is, if we're certifying individual models with varying functionality, how can we apply security requirements. But the issue of how to communicate what they do for any of the criteria –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates
Um hmm.

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

– and how to put them together is a challenge for the next level of certification.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates
Yes.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

I didn't want to engage as much as I have, so I'll try to remain quiet. I think just wanted a kind of factual statement about the certification program and what gets issued. We have a term called EHR Module, capital "M," defined kind of term of art, proper noun, that is what is the certificate and the scope of a certificate that's issued to a product. So in a lot of cases, I think, modularity is discussed with a lower case "m," which is not – is kind of outside the scope of our regulatory construct for EHR Modules with a capital "M," as we've been describing. As today, products get certified and they get issued an EHR module certificate, which is representative of a subset of capabilities that were assessed vis-à-vis the certification criteria that we have.

The certificate is not issued to the entire product, it's issued to the scope of the certification criteria that were evaluated. And so even with a complete EHR certificate, which is one of the reasons why we have proposed to discontinue it, it implied that it was issued to the entire product when in fact, it was only issued to the scope of all certification criteria that we have. And there are other reasons why we described it as well. So, having that ability to communicate makes a tremendous difference and the modularity that some may expect may be different than the actual sticker, as I've been using with Dixie. The EHR module sticker that gets put on the kind of product as what it got certified and the label that it gets issued as opposed to its modularity in a lower case "m" sense.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

David.

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

Yeah, I mean the fact that modules are defined only in that sense of what you bring to the table and you call it a module, it rules out robust testing of security because people can bring any combination they want to the table. So we tried to decompose it down to the functional level as much as possible but it's limited as to what you could do. If you really want to test security, you'd require an incentive measure that relied on penetration testing on and an as deployed system, then we'd actually know something about security.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Right.

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

And I think we'd all – I'd be in favor of switching the whole model to that kind of an approach. If you really want to change security and privacy policies, is demonstrate penetration testing – resistance to penetration testing .

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah, I agree.

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

– because only an as deployed system can be really tested for security.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Those of us who had to get our charge cards changed after we shopped at Target know that one well and for those who don't remember, it was the heating and cooling system that was the Achilles' heel of that implementation.

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

A well-known EHR module.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Yeah, a well-known EHR module. But I think – to me that spoke volumes about the vulnerability of a component of your system that you don't expect to have to test, right? And I think that's what you folks are saying –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

That's right.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

– is that there are pieces that may actually be connected that are an afterthought, right, and maybe it's the glucometer sitting on the desk somewhere, that actually becomes the conduit into a whole system. I think, the trouble is then it begs the question of, who is responsible?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Um hmm.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Right, is it the institution. And Andy's example of one pediatrician in North Dakota 60 miles from the nearest person with an associate's degree in computer science, that's going to be hard for that person to do the full risk assessment and to make sure that all of the stuff had the right seal of approval on it.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Right, right. Now obviously, risk assessment and ultimately the pieces that they glue together, however they glue it together, it is a provider of responsibility to meet HIPAA, it's not a vendor responsibility to meet HIPAA. But I believe very strongly that it is a vendor responsibility to make sure that the product you have there will help them meet the HIPAA – comply with HIPAA. Thank you.

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

And I have solved all consent problems for the state of Massachusetts so let's move on to...

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Thank you.

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

They did, actually.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Okay. Now we were asked to address a number of questions from the NPRM. One is the ONC was requesting comment on two-factor authentication. That means when you login you present your password but you also have to present a second form of proof that you are who you claim to be. And we were asked two questions, whether the HIT Policy Committee's recommendations were appropriate and if not, what would be better? And secondly, should they adopt a general two-factor authentication capability that went beyond just for the prescription of controlled substances, which is – where two-factor is required.

Our response was twofold. One, we didn't dare say that the HIT Policy Committee's recommendation was ba – no, we agreed that it was actionable and it was a reasonable recommendation and it can be tested functionally. So we certainly fully supported the Policy Committee's recommendation. We know – but there are a number of approaches for meeting this recommendation, so we did want to point out that this two-factor authentication testing would need to be functional testing. Because there – you couldn't possibly prescribe one particular – or even two particular standards to be applied to it.

The question about broad adoption of two-factor authentication, we weren't aware of any really driver for this. Because we weren't aware of any Meaningful Use measures or any other healthcare policy that would warrant a more general requirement for two-factor authentication. But we said if the ONC chooses to adopt it anyway, then at least for two-factor authentication for the EHR piece, the clinical piece of it, that ONC should consider using the DEA audit of the two-factor authentication capability as having met that requirement for clinical systems. But not necessarily for remote access, that's the other – the Policy Committee recommended two-factor authentication for remote access. And so that, two-factor for remote access would still need to be tested and again, it would be function testing, not against any particular standard.

We were asked – the 2014 Final Rule allows some users to disable audit logging and the 2015 proposal proposes to remove this functionality. So you couldn't disable audit logging. Our recommendation was, we suggest that it be left like it is, that the ability to disable audit logging not be taken out. Although the current certification criteria don't preclude the audit log from being disabled, they do require access controls restricting that capability to those authorized to manage the audit log. And also, they require that the action be audited. So we think that any change in this would really – could prohibit the audit administrator from performing their job. And we don't think that EHR technology should interfere with how people perform this job. There are situations in which disabling an audit log would be the safe approach in terms of clinical care. So we think that the current capability of restricting it through access control and auditing any action to disable it or – would – is the appropriate approach.

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

Maybe this is actually a Steve or ONC question is, why would anyone want to ever turn off an audit log? I just – I don't even understand that concept.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Are you serious?

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

I really am.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Well there has been – not everybody sizes their systems correctly and there are certainly lots of organizations that would give you examples where their audit log fills up all of their storage and the system just grinds to a halt, comes to a halt, you can't even use it because the audit log. If you audit every single thing that's auditable and collect every data element – for everything that can be audited, it can happen.

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

And the reason I ask this is that, I mean Dixie's point well taken. If we looked at it as an audit log of a router, I mean yeah, sure. You're gathering two million transactions per hour and maybe that's going to be used in forensics because of – service attack or malfeasance or something. But in a clinical information system, the amount of space that an EHR log fills up is just de minimis. It's Joe looked at Sally's lab test, date/timestamp, right, it's 20 bytes per entry and storage is so cheap, I just – I can't imagine an EHR causing such a problem. And that's why –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah.

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

I am sure that there are others who have comments here, just so I understand this one. David?

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

Well I – this is David McCallie. I think it was more along the lines of routine maintenance, even if for something like installing an upgrade of the software requires that you shut the service down while you swap out the components. So, it – the thought was just to avoid a silly, one of these absolute requirements in regulation that just doesn't match the way the real world works. And given that audit logs audit when they were turned off and who turned them off, you are still keeping track of something that could have gone wrong. It's an auditable event, the fact that somebody turned it off and it was off for 15 minutes is now auditable. So, we just thought that any time you go absolute and say "shall never be turned off," you're just asking for trouble.

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

Got it, and really what I was making sure of is that there was a good policy reason to enable such a function. And Arien or –

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

I had a question related back on two factor authentication. Did you define remote access for the purposes of looking at the applicability of the security requirements? I'm not aware – I think it's a bad security policy in general to assume that some access is remote and some is non-remote. There are factors that could include location and there need to be controls in place to make that sure you verified that location that warrant foregoing certain measures. The classic example is an OR environments where only authorized personnel are admitted, may not have any password requirement. But to assume that there is something called remote access and non-remote access seems to me to be, in general, bad security policy. So I just wondered what your thoughts were relative to the actual requirement in the first place.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

The requirement came out of the Privacy and Security Tiger Team as a policy requirement. So this workgroup didn't really address that. And David and I are both – and Wes, are all on the Tiger team and I don't recall how remote or whether or how remote access was defined. But I understand what you're saying, yeah.

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

Yeah, I think the general working assumption was remote means you are coming from outside the firewall of the entity, but that's obviously a tricky –

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

Good, that's a definition that assumes a certain software configuration.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Um hmm.

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

It would mean that every software is a service application, all access would be considered non-remote. I'd note that there are ways – so even if you're hosting your own EHR, you typically have different firewall configurations for the – behind the E – in front of the EHR and in front of your users and you need some means for determining whether that user is accessing that EHR capability from within your network. So in that case, all access almost by definition is to some degree or other, remote, that requires some proof of location in a facility that allows lower access requirements. So I just think the very definition of remote probably should be removed in favor of a security – a set of security requirements that give some guidance to factors that would permit password-based authentication, factors that would permit no password-based – you don't open it to anybody who uses it.

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

I think you make some very good points, Arien. If you look at what we were responding to, for the purposes of this question, I think what we were trying to say is that with regard to the audit that's done for the DEA requirement, if the organization has had that done, that should be considered part of – or it should be a path for certification. And perhaps what we should have said here is, all other types of accesses, we don't see a requirement for two-factor here. So I think the use of remote was just an example and a term we didn't really define.

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

General comment, which is, the way we have thought about this, and I think it's exactly as you say, security policy driven, what is the nature of the access, by whom, from where, using what device? Now you could have brought a personal laptop inside the firewall and require two-factor authentication.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Yeah.

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

Or you could be using a known registered device from Shanghai and using username and password; I mean, it really just depends on we call it, adaptive authentication based on a set of rules.

M

That's right.

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

Well and, as Dixie points, that term remote came from the Tiger Team, we inherited it, we weren't asked to redefine it. I know – and we punted it back then because it was so slippery to define and I think this question is kind of a downstream fallout of, is this something that we should require. And I think our answer is –

M

Is no.

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

– it's no. You have to make this situational and get NSTIC moving so that you only have to carry one of these tokens around in your pocket –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah.

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

– instead of 50 of them, but we're not holding our breath about that either.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

What I would suggest, I mean, one – part of our – of the request from ONC was to say whether the policy recommendation was actionable and we said, yeah, it was. But I think that with respect to the policy recommendation, that this committee should make that comment, because I think it's a very valid comment.

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

And John's framework is exactly right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah.

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

Who, where, what access and what device.

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

Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah.

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

Something that would be very hard to certify, per se, you just can't –

M

– situational.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Okay, I'm making myself a note.

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

So, Andy, do you have a comment?

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

I'll go back to audit for a second. I've been on these workgroups long enough to know that the charge has a lot to do with how the response is. But the question I have is, why would we keep it just – keep that ability to turn off audit in there without some qualification? I mean, was that part of the charge to not look at it any more broadly. Because I would say that keep the audit on for business, but for administrative purposes – only administrator purposes or some kind of qualification be allowed to turn it off.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah, if you –

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

I mean, it looks to me like you're just opening a big wide door to allow if we turn it off or as it is –

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

It just – what it says now is that selected users are able to disable audit.

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

Oh.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

And the proposal was to remove that entirely and say nobody can disable the audit.

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

And I would say, selected users are only allowed to remove audit for the purposes of technical mechanical failure or whatever.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

That's not a product thing though, the product is what we're certifying and product doesn't know reasons why you're –

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

Oh, okay.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

And there's no way to measure reasons why you would disable. And our response is very consistent with what you're saying.

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

Okay.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

You've hired this person to manage the audit, let them do their job.

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

Yes. Then I'm fine. Thanks.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Okay. Maybe that's how we should have worded it actually.

W

I really like that, straightforward.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

The next request was comments about the sufficiency of ASTM E1247 and this standard – it's actually 2147, I think that's a typo in our response. But ASTM E2147 is about – has two things in it, it has auditing and it has accounting of disclosures. And right now it's a requirement in the 2014 edition, but the requirements are enumerated, from section 7 of E2147, the statements are enumerated. So we were asked number one, is the query action in section 7.6 of this document is not a defined term, so we asked whether that was a problem, whether that creates ambiguity. The second thing was whether ONC should establish a minimum baseline of actions that the EHR technology must always be capable of for the purpose of audit. And the third question was whether there are other actions that ONC should consider specifying in an updated standard. And then finally, are there any alternative standards to 2147.

So our response was ASTM 2147 was updated about a year ago and we're not aware of any need that was – anyone ever expressed to define query or any problems that developers had encountered regarding query, so we didn't see any need to add a definition to it. We recognize that there's a lot of confusion in the marketplace about audit and section 5 of ASTM 2147 does a good job of explaining the audit – security auditing – audit logging concept. Also I should point out that ASTM E2147 is specifically for – related to healthcare, it's audit for healthcare. So we recommended that the reference to 2147 be expanded to include all of section 5, because it helps with understanding what healthcare auditing is all about. And we also recommended that section 7 be referenced in its entirety instead of quoting the statements in section 7 in the regulation, because it would make it easier to handle – to manage and the only statements that are not already in the regulation are those that are labeled optional, so they'd still be optional for the regulations as well.

Section 7, by the way, includes – is a discussion that specifies the data elements that must be collected for each auditable event and those are right now enumerated in the regulation itself. So we suggested we just replace it with collect the elements as specified in 2147 section 7. The minimum baseline for the – the question of whether they should add functionality so that it could be audited, we thought that was kind of a strange question. Typically one audits security relevant actions by – with perf – associated with performing the required functions, you don't require functions so that you can audit them. So we say no, don't add functionality just so you can audit it, it didn't make much sense to us.

The third question was consider other actions that we might consider being audited. And we think that – we would reiterate that we think it's very feasible to certify EHRs against E2147 audit log standard and we don't recommend any other actions to the auditable, any other data elements to be collected, but we do recommend including sections 5 and 7. And that was the end of our recommendation. We're still supportive – we remain still supportive of E2147 is the right standard to conform to.

The next question had to do with that ONC plans to adopt certification requirement that's the same text as E2147, this has to do with accounting of disclosures. But given that with the 2015 they are proposing to discontinue the complete EHR concept, they're – ONCs proposing that the accounting of disclosures optional requirement be dropped. And we agree that since the Office of Civil Rights hasn't issued its final rule on accounting of disclosure, we think it is premature to include it in regulation.

The next one has to do with Blue Button Plus, we were asked, is there a market need for Blue Button Plus certification, which elements of the Blue Button Plus Direct specifications would be most important to reference in the criteria and how they would be tested? And third, what elements of Blue Button Plus REST specifications would be the most important to reference and what use cases it would apply to. We're – Privacy and Security Workgroup is very supportive of Blue Button Plus, you've probably heard us talk about this before. And we are very supportive of further piloting of Blue Button Plus and we're supportive of the direction that the standard's taking. But we think at this point, prescribing specific standards that Blue Button Plus must use could potentially constrain the momentum that Blue Button Plus already has developed. And so we think we should just continue to support Blue Button Plus development and piloting, but not really put it in regulation at this time.

Disaster preparedness, I think you guys talked a bit about disaster preparedness before. There were a number of questions about requirements for disaster preparedness, standardized naming conventions, how you collect data. And the Privacy and Security Workgroup felt that the solicitation for comments on standards relating to disaster preparedness may be premature because they unresolved policy issues that must be addressed first, before we have standards and technology to support disaster preparedness situations. Any further questions?

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

Comments?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Comments?

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

Thoughts, audit trails – response. Steve Posnack.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

I think, I don't know if we go back a couple –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Um hmm.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

One more, one more, sorry, one more. One more. There, you're good. On number two there, I think there may have been a misunderstanding or interpretation of the question that we asked. So in section 7.6 of the ASTM standards, there are six actions that the standard says need to be captured. We've been – we had gotten questions from developers saying, we don't permit one of these actions to occur ever, it's not part of our system, so do we have to audit an event that we never allow to occur and we said, that doesn't make any sense. So when you start to pursue that slippery slope, then you get to, of the six actions that are currently required, which ones should always be there? And that was really what we were getting at with that second question in terms of the baseline set of actions to audit.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Well section 7 doesn't specify the actions to audit, it specifies the data elements to collect per action. In the regulation, the events to audit are hard coded into the regulation, they aren't in 2167.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

We actually changed that in the 2014 edition and we only point to the ASTM standard. So we reference section 7.6 which is the type of action and that's where it specifies – I can show you because I have the standard. So we had pivoted based on that recommendation from the Standards Committee the last time around to just reference the standard and not enumerate anything explicitly.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

So what you were asking is, are there additional events in 7.6 that sh – okay. Well, we'll recommend –

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

That's why we – and that's why we asked about transmission, because if there's a di – if the industry is making a distinction between query, which we indicated is somewhat ambiguous. Is there a distinction between query and transmission that should also be an action that doesn't fit in additions, deletions, changes, queries, prints or copies, and is that an action that should be considered for...

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Okay, we'll go back and look at the events specified in 7.6. Okay.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

And then the other, and this is obviously one thing that we take care of in the regulatory process as well, so we also point to section 7.7, which is designated as optional. So in that case, we would trump the standard, essentially. We could reference section 7 in its entirety, as you mentioned, those things that would be optional would remain. The other on the accounting disclosures, I think just to be clear, and this gets to an interplay between the complete EHR certificate and the certification criteria that we have in the 2014 edition. We designated that criterion as optional so that developers that were seeking to get the complete EHR certification didn't have to do that if they didn't want to. Going to an EHR module certificate world only means that we don't need to designate criteria as optional or mandatory, so we just proposed to remove the optional designation, not to remove the criterion as a whole.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Oh, I see. Okay.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Because then developers would still have the choice whether or not they'd get certified to it, it just – they wouldn't be compelled in order to get the complete EHR certificate.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

I think that's fine. That's fine. Yeah.

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

That's fine.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

I just wanted to give that clarification.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah, yeah.

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

And we should say that –

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

In case anyone from OCR just had a heart attack.

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

– good to say, Michelle, is that because Joy Pritts wants to make a comment or she's just joining the meeting, very good.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

I'm just joining you fresh from, speaking of OCR, Sue McAndrew's retirement.

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

Ah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Oh really?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Yeah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Huh.

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

But of course, as you all saw, the OCR announcement yesterday, the two million dollars in fines levied for two stolen laptops.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

I read that, yes.

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

So Dixie, we need more work here, you know?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

I know, I know. Use full disk encryption on your laptops.

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

Okay. So, other comments. Okay, well Dixie, thank you very much for that feedback. And I think we can now move on to NSTIC. And in this next presentation, the thing that I found particularly useful was that Dixie and Walter enumerated a number of different technologies and approaches and looked at their applicability and their maturity, their scalability, their longevity. So I really like that table you put together, I thought it was quite inspiring in this next presentation you're going to deliver.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Okay, thank you. And we've had a switchover. First of all, before we start this, I want to thank Walter for serving as my Co-Chair for three or four years I'm sure by this time. He's just been a joy to work with and one of the most reliable people and conscientious people I've ever worked with, so I sincerely appreciate the help you've given me on this workgroup. I also want to thank you for agreeing to continue to participate on the workgroup, as a member of the workgroup. We really will – really value you're input. And then finally I want to thank him for agreeing to lead the planning of the NSTIC hearing. And so I – so most of this presentation I'm going to, as his last hurrah as Co-Chair, he'll be presenting our NSTIC feedback. I also wanted to thank – did Julie leave?

W

She had to leave.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Well, we've had just great support from Julie Chua and also from Debbie Bucci on this NSTIC planning and on this NSTIC hearing. So, it's just been wonderful working with both of them, we really appreciate it. All right.

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

Great, thank you. Thanks so much Dixie for those words, it has been a pleasure to work with you, along with the rest of the workgroup and look forward to continuing to work with the workgroup and now under the Co-Chair leadership of Lisa, so, it's just great to see the group continuing to work on all these important topics, I think. So, as Dixie mentioned, yes, this was a hearing that we organized to focus on NSTIC, primarily to allow the workgroup to receive some current status and where things are with NSTIC and consider what might be some recommending points that might be applicable to the healthcare industry.

So you see in this slide basically our purpose and our objectives, which actually we try to follow into the agenda itself. So our primary objectives were to review and discuss where things are with NSTIC, where are things with respect to the standards involved in deploying NSTIC and the NSTIC ecosystem. And then hear about the experience and the findings and lessons learned from the NSTIC pilots, particularly and we were lucky to hear from pilots related to healthcare. And then invited a number of organ – healthcare organizations to provide their perspectives with respect to NSTIC, even though they might not have a direct experience with respect to implementing some of the basic elements of NSTIC, there were some very important points that they brought up.

So, in the next slide I think we list here the organization of the agenda. And again, you see here how we really brought together a group of people to talk about these four major areas. I wanted to emphasize actually the importance of the international perspective into this hearing, we heard from Nat Sakimura, who is the OpenID Foundation lead and he was actually coming, or joining us from Japan. And really a lot of this work has major international perspectives and involvement, so we were very fortunate to have him join us as well.

So, in the next slide, just covering basically what we heard from our first group. We had the fortune of having representatives from NSTIC and from IDESG to talk about where things are. And I will try to decode most of these acronyms that you will be hearing throughout this presentation, I am glad it's coming way after lunch so you won't get too much indigestion with all these acronyms. So it's interesting this month actually represents the third year of the creation of NSTIC, the passage really and Executive action of the President to establish this a national initiative and a national priority. And in that Executive action, the President called for formation of a public-private partnership really to lead the efforts and to create an identity ecosystem in the country, that applies to basically everything that consumers and all of us do online, including certainly healthcare.

And so that's what NSTIC is really, is a national strategic initiative that is intended to foster competitive development of stronger identity and identity proofing standards. It is not, as we say in the slide, not a standard development effort. It is not an attempt to create a national identity identification or ID of individuals. It covers a wide range of options and identity possibilities from anonymity all the way to full identity. And it has different, it does have really different settings or applies to different settings and context, where these require identity levels of assurance are needed. It is intended to leverage existing credentials and credentialing systems across different sectors, including healthcare.

And what's interesting is, if you think about what we do today, which is, we all have probably an average of 20, 25, maybe 30 passwords, the expectation is that we would be able to, in the future, use credentials. But the difference would be that instead of having 30 different credentials that are siloed and not interoperable or not connected, you would have a set of credentials that can be ported across different applications and different entities and organizations. So you can, sort of the way that some systems do today, which is applicable to NSTIC really, when you log in or you go to a website they ask you if you have a Facebook or a Google password, and they can take that. And that kind of interoperability across identity systems is what this NSTIC Initiative is looking for.

It calls for the federal government to be the early adopter and the federal government actually started a federal credentialing cloud exchange or FCCX, which actually uses and is built on the US Postal Service technology that they have to cross-validate, if you will, the identity within federal agencies. So if a consumer goes to one federal agency, they can use the same credential to go to other federal agencies and do online business. It does – NSTIC does have currently a number of collaborating pilots, 12 of them, six of which are healthcare related and again we heard from three of them. And then about 20 months ago, an organization, this public-private entity was formed, called the Identity Ecosystem Steering Group, or IDESG, which is a voluntary public-private enterprise organization formed really to help develop and advance the adoption of the national identity ecosystem framework. It does have an international coordination committee, which helps align the work that NSTIC is doing with the international efforts.

In this slide, yup, I think this is the next one. So we heard that background and it was very helpful to understand the background about NSTIC. We also heard about what are the standards and what are the components of the ecosystem. And this table really simplifies the review of the various technologies and standards. The good news, of course, is that we have a robust set of standards that help identify and support really an NSTIC ecosystem. And so I think that's the starting point, we wanted to hear, where are those standards? And these are the various standards that were identified and looked at as the key underlying standards.

The first one, the first row is really a group of standards built around Open ID Connect and OAuth and the JSON web token or JWT or J-W-T, sort of an application of the Open ID standards. And these are identified as an immediate high central key elements, the core elements of the standards being used in this NSTIC approach or framework. Some of the comments, as you can see, these provide really the backbone of security and portability and the identity capability. We also talked about the User Managed Access, or UMA, which is also identified as a high central value in the medium term of the evolution of the NSTIC framework. Really, UMA is seen as a profile of the OAuth application. And then we also heard of the Security Assertion Markup Language, or SAML, which is seen also as a moderate central value, and you can see some of the comments there, friendlier to large IT shops and web browsers than to smaller organizations. So it reached – it's reach really has some limitations. And it's commonly used for the kind of single sign-on capability that people look for in systems.

We also heard about X.509, extremely valuable as security mechanisms, but really struggling with respect to the issues in the identity platform. Something else called FIDO or FIDO, depending on how you pronounce it, the Fast Identity Online technology developed by – or promoted – being promoted by the FIDO Alliance, is still sort of an evolving technology and as it points out there in the notes, authentication specifications that are not yet really built on open standards. And the last one was the XACML technology, which we thought had low peripheral value to it.

All right, so with some additional points or comments on the standards themselves and the ecosystem, I think we have here really some of the critical parts are the ability to locate patient data and maintain an accounting of disclosures are some of the specific challenges in the healthcare industry. And UMA profile, based on the IDESG Health IT record location service use case, has and could provide and could demonstrate some of the usefulness in both of these areas, the location of the patient data and the accounting of disclosures. IDESG is also going to be promoting adopting – or calling for adoption in the industry of standards that are truly beneficial to NSTIC, so that's really the vehicle that is being used to advance the adoption of the standards of IDESG. And there are – there is an ongoing call for increased participation from the healthcare industry in the IDESG structure.

As is pointed out there, two of the majority of large, off-the-shelf software providers support OpenID Connect. This one and OAuth 2.0 are some of the more robust and supported off-the-shelf software standards. Major companies choose to use OpenID Connect because of its ease and flexibility over some of the other standards like SAML. So really, those two are again critical components of this framework.

Now we heard in the next session about the pilots and again we were fortunate to have representatives from three different pilots related to healthcare. The first one, very quickly, advancing commercial participation in NSTIC ecosystem was primarily a use case of access to AARP Health. And the organizations involved, NIST and DAON. And the status, as you can see, is first phase just moving along expected to go live in the AARP by the middle of this year. And the standards being tested there are SAML, OpenID Connect and the Kantara-certified LOA, level of assurance 1, 2, 3. So those – that was one of the first pilots. I'll mention a few of the lessons learned in the next slide.

But very briefly, the second pilot Cross Sector Visual ID Initiative, the CSDII. The use case there was the patient and provider access to hospital portal and EHR. And the organizations involved included the American Association of Motor Vehicle Administrators, Biometric Signature ID, the Commonwealth of Virginia, Microsoft, Binary Structures. And currently they are preparing for the marketplace, really their pilot launched in – this month, and they're also looking at the same type of standards that we mentioned already.

And then the last one was the FCCH or FCCX for the Federal Cloud Credential Exchange, which connects FICAM exchange multiple government relying parties to a single identity hub. And this is the one I mentioned the USPS, the US Post Office Postal Service is involved and NIST is also involved and the Government Services Administration. And this is in really early stages and is within the federal agency structure to allow cross-agency access through common credentials. Again, the same type of standards were being tested.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

And you'll hear that referred to as F6, I've heard Joy talk about it a number of times as F6,

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

All right, so what were some of the lessons learned that we heard from these pilots? I think a couple of very significant things, one is really that they have really demonstrated some of the key benefits and value that this capability of cross-organization, interoperable credentialing identity system will provide is that – and it has identified a number of challenges as well relating to the interoperability of the systems. It also pointed out a few other interesting things. For example, the concept of the trust framework that were being considered and that may be actually widely adopted in the private sector, may not necessarily be compatible with the government sectors type of frameworks, like the ones promoted by NIST 863, the electronic authentication guidelines, the LOA – the Level of Assurance 1-4 type of guideline. So there's that possibility that the trust framework that has been or could be adopted and widely used within the private sector may not be compatible with the government's one.

The concept of a central identity hub, while it might be convenient in the case of the federal government, may create some constraints on innovation. And also some single point of failure risk in a larger applicability or application of these in the private sector. So that was another issue or concern raised in the lessons learned. The use of EHR demographic data to identity proof individuals within healthcare may present some HIPAA privacy challenges when on is attempting to use the information outside of the healthcare system.

And then there are some policy questions that are unique in some ways to the healthcare industry. For example, is really the ability to use a healthcare credential so significantly valuable or desirable to be using other credentials? So the credential that I use to access personal health record, should I be able to use to buy things at Amazon.com or Target or something like that? That's an important question. The other question is, the scope covers everything from anonymous all the way to fully identified and there's a question about the value or the usefulness of having anonymous or pseudonymous identities in healthcare.

So that's another important question. And then, what is the need to make third-party credentials – what is needed, not what is the need, but what is needed to make third-party credentials trustworthy?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Can I say something here?

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

Yeah, go ahead.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

One idea that was proposed is that you might, by a number of our testifiers, in fact, was that you might use an existing credential that was issued under low assurance conditions and then add the identity proofing to it. So they come to the doctor's office with a low assurance identity that they bought, but they've never been identity proofed. The doctor performs the identity proofing and it would increase its level of assurance, which is an interesting idea. But at the same time that's when the question about whether you can use HIPAA – under HIPAA, whether you can use identity information in that way.

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

Okay, so I think the last part of the hearing was focused really on listening to some perspectives from healthcare representatives. And we also looked at some of the readiness of the healthcare indus – of this applications to the healthcare industry. So the pilots that have moved really into production at this point are some of the better candidates really to be used for our healthcare industry. And again, some of these pilots are actually in the healthcare sector, so it's going to be very important to continue to monitor and evaluate their performance as they move into production.

Pilots should involve interoperability across a number of comparable stakeholders, so that's another very important element with respect to the readiness of these activities to healthcare. And then the pilot report should include some instrument for evaluating the experience of the users and the assurance that their needs are being addressed. So in some respects, it wasn't necessarily very well described or perhaps documented how the experience of the users and the assurance that their needs are being addressed was actually being achieved.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

I wanted to mention for Lisa's – there was another – there is another, I just learned today, in fact, that there's another pilot that we didn't hear about that really it seems to be directly applicable to the DirectTrust problem that was brought up this morning. And Lisa, I hope during discussion you'll talk more about this. But this is something called the NIST GTRI problem, or GTRI pilot, that really addresses this whole, how do you ident – how you positively identify someone within your trust bundle that you may not trust as much the rest. So I hope you'll say a little bit about that later.

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

Okay.

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

Okay. And then last couple of points here, the healthcare perspectives, we heard from four organizations about their views of this healthcare groups. The first one was HIMSS and at that portion we heard about HIMSS launching the new Identity Management Task Force and Lisa could probably talk a little more about it as well. But there's this new Task Force involving multiple stakeholders, it has a liaison to a national initiatives such as NSTIC, it really serves to socializes into HIMSS membership and provides tools and resources. So, it has again a new opportunity to bring healthcare industry sector organizations into this concept of identity management and connect them with the NIST – NSTIC framework.

The second one we heard with CommonWell Health Alliance. And from CommonWell we heard actually a couple of interesting things, one was, it's always important, of course, and critical to have identity for individuals, consumers and other individuals involved, particularly in the healthcare sector, all the individuals involved in the care and management of the patient's services. But there's always the important aspect of having an organizational identity as well. In some cases, in some ways it's more important to have that for provider-level information exchange, to really have the organizational identity established and proofed, if you will. Higher assurance identifiers would be very useful for patient identity matching and linking, so the identifiers will be critical, certainly in achieving a much more reliable patient match. And then recommend – they recommended higher assurance identifiers be constructed from third-party credentials such as driver license ID.

We also heard from Kaiser Permanente, my own organization, and we heard something very similar to what we heard CommonWell with respect to matching. Matching a patient across providers is really a critical step and it's critical in the sense of patient safety, in many other ways, but especially patient safety. They cited recent studies showing identity matching between only 40% and 60%, which is really, really amazing. Verified and portable patient identity would enhance matching outcomes on a much broader scale. So this concept of having a patient identity that can be ported across organizations and that will enhance matching will be really critical. And then security provisions should be usability tested by target populations to make sure that they do not really widen the digital divide, so that was an important point as well.

And then we heard finally from the Department of Veteran Affairs pilot. They're implementing a third-party credential, used to generate an authorized request to the VAs authentication federal portal. So they describe the project as a NIST compliant, of course, initiative. It includes remote identity proofing as well as a password authentication with security questions and device authentication and verification. So it's a very elaborate pilot, if you will, with respect to the use of third-party credentials.

So just to finish up, some of the conclusions that we gleaned from this hearing. The first one really the hearing helped us certainly understand where things are with respect to NSTIC and how significant and important it is for healthcare to be an active participant and have a very active role in the NSTIC framework and ecosystem being developed. Other I guess conclusion was, NSTIC should be viewed not as a set of new standards, but really as an effort to provide a framework. This concept of a collaboration and a set of guidelines, if you will, on identified standards that help achieve and leverage existing standards that are already in wide use, and are in fact, really standard use things in the project like Blue Button Plus standard and others. So NSTIC is really a unique opportunity for healthcare to be much more engaged and active.

The use of high assurance patient identities can improve the matching of patient records, thereby enhancing patient safety and the quality of patient care. It's clear that among the many uses of the NSTIC capabilities in healthcare, it will provide some very concrete benefits to ultimately improving the quality and safety of patient care. Active healthcare industry involvement is being called for and is needed. Increased collaboration among government healthcare related federal agencies like FDA, DEA, CMS, ONC and others is needed in order to uniformly implement NSTIC in the federal healthcare related initiatives.

And then standards should be evaluated for maturity and adoptability using our own Health IT Standards Committee evaluation criteria. I think that's something we really didn't get into during this hearing, we certainly wanted to first listen about where things are with respect to the standards. But it's going to be critical to understand each of these core standards that are foundational to the NSTIC framework, what's the status of respect to maturity and adoptability. So I think with that, that's all we had. We had a number of other materials available and these are all posted in the hearing website. So, Dixie, I don't know if you have any other concluding comments or we can go to –

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

No, nice job. It certainly was a very, very interesting hearing. Seeing that this was not really a set of standards in itself, but rather using existing standards to achieve the NSTIC objectives was probably my principal take away. Because I had, up to that point, really thought that they were developing standards.

And the scope of it, the worldwide scope was – .and public-private sector. Those were the real new learnings I took away that hearing.

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

Thank you very much. So start with a couple social political comments then turn it over to questions. So Harvard, it turns out, loves SAML. And it turns out that all the hospitals associated with Harvard have Harvard faculty, but we have different identity management and authentication systems. And so Harvard had said, well simple, use your native hospital identity management system and through a SAML assertion, we will then let you into the Harvard's system. Everyone's really comfortable with that idea. If you were to propose across hospitals and Harvard OAuth or OpenID, they'd say, oh, those are some sort of comme – retail consumer grade you know, we would never go there.

So fascinating when you look at slide five, which actually says OpenID and OAuth are agile, they're high-value, they're universal across platforms, they don't require complex active directory federation services and all the rest of that. So you wonder if socially, politically how do we get institutions to think of OpenID and OAuth as industrial-strength tools. I mean is NSTIC going to help us with that.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

Well they aren't industrial strength unless you have strong identity proofing to go with them.

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

Right, well as another political comment, this is probably a Leslie Kelly Hall comment. I was just thinking about the inventory of RFID on my body right now. So I have this one, I have this –

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

He's holding up his passport.

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

I have this, which is by global entry TSA pre-check, I get in line in any airport and I just walk right through. And I have this one, my smart-trip card, which is RFID, which is totally anonymous and just has money. And so the question is, Leslie, as a patient would I use this as my healthcare identifier, would I use this as my healthcare identifier, or this has money on it, why not use this as my healthcare identifier.

You also sort of wonder as we think of not wanting to have 30 different kinds of identifiers for different purposes, what are our patient's tolerance of levels of assurity and identification for the provision of health care.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

My answer is, perhaps is pick one so we know where to go and get it because the confusion is what causes most of the hassle. I do know how to go get my GOES card and I did get that. I did go get my passport and I do – I also have another one, this, that helps to uniquely identify me, I'm holding up my phone. So – in fact, I just got a notice saying I could pay something with my fingerprint, with just a touch of a fingerprint on my iPhone or on my phone yesterday. So I think the answer is let's picked one –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Or maybe two.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

– or maybe two, but something that allows us, that's easy, that uses existing framework. Actually we had someone in our team in the patient group, Lisa Gallagher who went – not Lisa Gallagher, Lisa Nelson, who went to get a Direct address with an LOA 3 and said, how do I go about doing that? Went to a – took her passport and her ID, went to someone at the bank who could go ahead and attest that she was who she said she was, went over to a HISP and presented them to get an ID.

So I think that all of us have ID fatigue, all of us have security and privacy fatigue and concerns equally. So let's get some and get it done, because we – patients will enter the ecosystem, do want to do it securely, do want to do it in a way that's trusted. A provider asked me, well I'm not going to trust anything the patient gives me. And I said, you do it every day, all their family histories, everything that they tell you, in addition, their VISA card, you're very, very apt to accept and –

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

Right. Well Lisa, I think you had a related –

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

Well David had his hand up first. But I think I do have some reaction to –

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

Well why don't we just go in the order in which cards were put up then. We have David, Arien, Cris and Lisa. Go ahead.

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

Yeah, David McCallie, thanks. I mean I think has ceased to be a technology problem and now it's a business problem and it's just a question of how are you going to get these issuers of trust to agree to trust each other. And it's not a technology problem, we have multiple ways of doing that that are now robust enough so that people aren't arguing about the technology anymore. So it's directly analogous but much more complex than the DirectTrust problem that we talked about earlier today where we have certain states that won't trust DirectTrust and it's a purely political and business problem, because the technology would allow the trust in a heartbeat with the installation of a single root certificate.

So with NSTIC, we just have that same problem on steroids. We have dozens if not hundreds of people who want to be the source of the trust. And dozens if not hundreds of people who would be happy to consume that trust, but right now there's a one-to-one business relationships in there. And the technology is there to make it interoperable, but it's the governance and business problems.

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

So. can I go next?

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

Sure.

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

Sorry, okay. So I want to comment on both the issue of the patient and also the trust issue. So what NSTIC is doing at a national level is defining an ecosystem in which an individual citizen of the United States would have one digital identity, multifactor, multilevel of assurance and can be asserted at multiple levels of assurance. And so picture in two years, your patient coming in the door and having their cell phone and saying on this cell phone is my identity, my method of payment and my PHR, could you please update it. I think that we aren't there yet but the day may come where our patients walk in with that.

What INOVA did, it – in their NSTIC pilot, knowing that their patients may not have already had this is they, when they walked in the door for their next encounter and they – or they were logging into their portal, they were offered the opportunity to create that digital identity right there. And then INOVA leveraged third-party credentials such as their DMV records in Virginia, to augment, to make that a multifactor identity. And then, going forward, the patient could use that that identity in that system.

When we had them speak at the HIMSS conference, INOVA, I asked them to speak about the business value and the CMIO was the speaker. And among other things he said, we're going to see a significant reduction in our intake process because we are going to already know who this person is. And so that's the structure that NSTIC is trying to put in place. It's also important to note that NSTIC is defining an entire ecosystem so it's not just individual identities, but the work they're doing in this trust framework through the pilot with Georgia Tech Research Institute, is to define components of trust that can be communicated across federations.

So if you take the individual federation or a community of interest and say, they're operating on some trust framework, each of them. And if we could break that into components and express those components in terms of trust marks that are universally accepted, then we can establish trust across the ecosystem, across those individual communities of interest. The research at Georgia Tech is fairly far along, so they've defined an example set of componentized trust marks, they include identity assurance policy, privacy policy, technical interoperability, security policy, organizational integrity and bona fides usability. And so those are componentized elements of trust that could be universally recognized and communicated. Now, it is research, and it is being put out there for use across all sectors, so the question for us would be, is there a way that we can start to use that.

They've also recognized, though, that there are over 100 that they could catalog, already existing trust marks that are used across the nation in finance and other areas. And so what they're trying to do is define a structure for that so perhaps the ones that already exist might map to one of the componentized trust marks, and that we all start to describe them in a similar manner. And they actually do have sample description documents and they also have a sample process that could be used to create trust marks, get them approved etcetera – proved against the requirements, etcetera. So the work of NSTIC is not just the eco – the identity for individuals, but it's all those pieces that would make the national ecosystem work.

So that I think there's more for us to look at there, perhaps we want to hear from Georgia Tech on that. We're looking at it at HIMSS and some of the other pilots that are coming up are attempting to use some of the trust marks to prove both that they are usable, but also to make interoperable identity happen.

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

Thank you. Arien, Cris and Joy, I think.

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

Yeah, I'm incredibly pleased to hear about that GTRI work. ONC convened through NeHC, I believe, some work to look at trust frameworks. And there was a team that was kind of reinventing the wheel and it would have been great to actually incorporate that GTRI work into the process, because it sounds like it was trying to aim at the exactly the same thing.

My comments on organizational versus individual are reflected here. One thing that I always like to remind us when we have these discussions about identity assurance in healthcare, on the patient side. NSTIC is an absolutely clear win to the extent that we solve this problem – well, it solves a ton of problems, it solves the ridiculous password problem that we currently have that is probably the leading cause of insecurity and compromise globally. In the healthcare provider sector, we also need to address, if we do go down to the individual level of assurance, we also need to address all of the on-behalf-of relationships that exist in healthcare. A little while ago, CMS was thinking about claims signing and the process by which claims would be signed and the direction they were going down seemed to imply that providers would be signing claims. If you don't take into account all of the proxy and extender roles that occur in healthcare and make it clear who's doing what on behalf of whom. You can often drive the healthcare system into inappropriate workflow where MDs are doing administrative work that's not operating the top of their license, so it's another thing just to always keep in mind.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

– can say for the patient as well, there are always on behalf of relationships for any stakeholder in healthcare.

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

Good point, that's right.

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

– potential pilot, I believe, that's going to be looking at the staff being able to prescribe on behalf of, and so that – at least that problem is recognized.

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

Cris?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

From the geopolitical to the absolutely mundane sublime to ridiculous, I think. But Lisa's comments around where this is going are extremely useful and it's nice to get kind of an update on that, as well as the rest of the report. So my sort of micro tactical question is, a lot of us are wrestling with issues about bring your device. And so when you talked about multiple use of the certificate, you gave the target of Amazon example, which is fine, but do you see, as we're headed in sort of a broader direction, any near-term opportunities where we could think about using a regime like that to deal with bringing your own device kinds of issues. I think I'm asking for some free consulting help here, but –

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

Yeah, I mean, why not.

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

Because there are standards for that.

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

Yeah.

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

There are emerging standards for credentialing a device that just essentially put a certificate that establishes mutual TLS.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Right. I'm just wondering if any of the NSTIC pieces in particular are well – better suited for that than anything else.

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

Human identities, NSTIC not device identities.

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

Right, although to the extent that when we deploy the identity, it could be through a software portal, but it also could be through a chip that's on your phone, and then everything's in one place. But that won't be the only way deployed, but there are – there is some part of it that could be leveraged.

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

It was pointed out, yeah, I mean NSTIC is person level ID, it's really not bring your device type of – or system ID even, for that matter. But it's interesting that yeah, as John was putting his glasses and commenting that a doctor would come in, that type of connection that three levels of security are the kind of security level interfaces that need to be defined for different types of devices. The other thing I wanted to comment is really a key element of all these, of the trust framework is the verification of the individual in the first place, because I mean, what if I steal that glass or glasses and go inside the Department. The glasses are not tied to me as the physician that is supposed to be seeing that or and those kind of things that are really verifying the individual, the actual person that is interacting, or the patient for that matter, too.

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

And really quick on that topic, just so you understand how it actually works. The glasses themselves on the WPA enterprise network are a registered known device. A physician who is in an identity management system logs in and once authenticated, prints a one-time token QR code, which they look at wearing the glasses and authenticates the glasses to being on their face. And then they walk into the room with the patient where there is a QR code that is specific to the bed they are looking at.

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

How do they sanitize that?

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

Well, but these are mounted, and so that's the level of B, we call it the BYOG security. Joy?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

I just wanted to clarify one point, which is that there have been a couple of mentions about NSTIC being used to create a single ID for patients – or for individuals, right. But that's not the case at all, because it can create one ID for an individual, it could create a number, hopefully less than what people have now. So for example, in the healthcare context, you could have a single federated ID, just for health. And then you could have one for all your banking. So there are ways of – there's a little bit of mixing and matching here that you can do so that it's just not one level of assurance that you have across everything.

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

This is David again. The issue is getting people to agree to join and use and participate in those ecosystems, which is not a technology problem, it's a business problem. So what's to say that a particular IDN agrees to trust a particular set of identity issuers for patients. Well, they have to be a part of some ecosystems where they've agree to do that. So it's a trust framework that's based on agreements and contracts that will be the limiting rate, not the technology.

We know how to do that today, the technology is pretty easy, but I just see very little movement towards the creation of any kind of national scale healthcare identity ecosystem. There are too many vested interests that don't want to give up their inside track to that space. So we just – we're stuck with what we've got, no longer limited by technology, I think technology was a limit five years ago, it's not anymore.

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

Single healthcare identifier issued by the government, single-payer system, it's going to be great. Well thanks so much Dixie and Walter, very helpful education for us all. Unlike you, Dixie, now that I know that NSTIC isn't an SCO, so to speak, it's not creating standards, it's very hopeful.

Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente

If I may, should mention just of a, not a commercial or anything like that, but the 9th IDESG plenary is actually happening here at NIST June 17 and 19, so anybody interested in attending.

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

– wanted to add that NIST has approached HIMSS and others to work with them on a half-day healthcare focused meeting associated with that plenary. And in that it's in DC, it's in Gaithersburg, we're hoping that we can get a lot of folks there. More information to come.

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

Thank you. So Steve, you have a few moments to tell us about FDASIA and Michelle, we will get our last public comment and get these folks to their planes.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Thanks John and I promised Michelle I would end on time. So, I will do my best. So I'm here to just give a brief update on FDASIA, and if you want to say it fancy, then you can say FDASIA. So ONC, FDA and FCC were charged through section 618 of FDASIA to publish a report on a risk-based regulatory framework for – that included a proposed strategy and recommendations for health IT safety, to promote innovation and avoid regulatory duplication. We've since done that in the beginning of this month, in April. The report is open for 90-days of public comment and feedback. So I would encourage everyone to take a look if you haven't already. It's available on all three of the agencies websites, as required by statute. I believe we have a short URL so you can go to healthit.gov/fdasia if you want to get through ONC's website.

A few important points, just to call out some of the main policy components, this is a draft report. We intend to go through a process after public comments to issue a final one. The report lays out three categories of health IT, administrative health IT, health management health IT which would be an ONC coordinated and led category of health IT, and then medical device health IT, which would more traditionally fit under FDA's current rubric.

Under the health management health IT proposed framework, there are four pillars of activity and principles that we are interested in focusing on, one being quality management principles. The next being the development in the option of standards and practices, which includes also interoperability practices, security as well as implementation. The third being conformity assessment, which includes a large bucket of certification, testing, accreditation, many of the different activities under that large term. And then fourth being the creation of an environment of learning and continual improvement.

Kind of undergirding those and supporting all four of those principles is a proposal that we've made as well to have ONC lead the creation of what we're calling the HIT Safety Center as an avenue and a vehicle through which education, evidence and engagement related to health IT safety could occur. And so this all will lead to another public service announcement about an event shortly approaching. May 13, 14 and 15, we're having a 3-day public workshop, at NIST – thank you to the NIST people for hosting us – with ONC, FDA and FCC. And we're going to have a number of panels where there's going to be a lot of dialogue going on about each of these categories that I talked about before. And I would encourage those of you that can attend to listen in, it's going to be webcast and there are details available on the web.

And that is basically, I think, all that I wanted to cover with my brief announcement of FDASIA's comings and goings, and keeping in mind May 13, 14 and 15, as it's coming up.

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

Great. Well Michelle, you are right it was brief and topical. Thank you very much.

Public Comment

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

Just quickly before we go to public comment, I also want to just make an announcement about a few hearings and listening sessions that are coming up in May. So, as Jacob mentioned earlier today, on May 7th we're having a certification hearing to talk about the Certification Program. That's an in-person hearing and it's the day after the Policy Committee meeting.

And then on May 13, there is going to be a listening session around LTPAC and Behavioral Health recommendations. And then on May 20 and May 27, there will be two listening sessions held by the Meaningful Use Workgroup to hear about experiences with Meaningful Use to better inform how they respond to the Meaningful Use Stage 3 NPRM. So a lot's happening in May.

And with that we'll open up to public comment. If there's anyone in the room, come to the table. As a reminder public comment is limited to 3 minutes.

Alan Merritt – Altarum Institute

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

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

So it looks like there's no one in the room, and checking on the phone; no one on the phone. So, thank you everyone.

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

Well folks a lot discussed today. The NPRM, I know, has got a lot of rich material and certainly I hope for the ONC folks that our feedback was helpful today. And our next meeting is going to be virtual, on May 21. I will be in Shanghai. There is a 12-hour time delay and I will join Jacob because I wouldn't want your first meeting as Chair to be a trial by fire. There's only one problem and that is that I will have to fly that night near North Korea, and so I may be lost or undiscoverable for a few hours.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Please bring your black box.

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

So it is a small chance that I will not be on the phone for some of that, but I am sure you will do fine job just a case.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

All right, well thank you John and thanks everybody on behalf of ONC and Karen. And we will see you in June and we will speak with you May.

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

Safe travels.

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

Thank you everyone.

Public Comment Received

1. I strongly support the creation of a new workflow and usability workgroup. As a person in charge of implementing and usability of clinical quality measures in a large healthcare system, it is very difficult to get the enduser to use, much less enter quality data, into a system that they don't agree with the logic behind the computer code. It is of the utmost importance that the enduser clinicians accept the logic behind what is being asked of them to document. If they don't, you will not get them to enter the correct data.

2. Audit requirements are not just that 'XYZ looked at Patient ABC's lab results'. The system must keep the before and after data and a pointer to that previous data of the changed data. The fact that a record was viewed, changed, deleted, printed, faxed, sent electronically, etc. Many of these actions can happen in one short encounter with a medical record and on many different parts of the medical record under review. So, yes, in our experience the audit log can become huge and this situation has been exacerbated by the 2014 Edition Meaningful Use audit requirements.