

**HIT Standards Committee  
Transcript  
May 24, 2012**

**Roll Call**

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

Good morning. This is Mary Jo Deering in the Office of the National Coordinator for Health IT and this is a meeting of the HIT Standards Committee. This is the 36<sup>th</sup> meeting of the HIT Standards Committee, welcome to all. It is a public meeting, a public call and there will be an opportunity for public comments at the end, and we do ask the members to identify themselves when they are speaking for the transcript. I will begin by taking the roll. Jonathan Perlin?

**Jonathan Perlin – Hospital Corporation of America**

Present.

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

John Halamka?

**John Halamka, MD, MS – Harvard Medical School**

Here.

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

Farzad Mostashari?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Here.

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

Dixie Baker?

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

I'm here.

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

Anne Castro?

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

I'm here.

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

Chris Chute?

**Christopher Chute – Mayo Foundation for Medical Education and Research**

Present.

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

Tim Cromwell?

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

I'm here.

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

John Derr?

**John Derr – Golden Living, LLC**

Here.

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

Carol Diamond? Lorraine Doo?

**Lorraine Doo – Senior Advisor – Centers for Medicare & Medicaid Services**

Here.

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

Floyd Eisenberg? Jaime Ferguson?

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

Here.

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

Leslie Kelly Hall?

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

Here.

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

Martin Harris? Stan Huff?

**Stanley M. Huff – Intermountain Healthcare**

Present.

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

Kevin Hutchinson?

**David Kates – Senior Vice President Clinical Strategy – NaviNet**

Dave Kates for Kevin Hutchinson.

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

Liz Johnson?

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

I'm here.

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

Becky Kush? Arien Malec? David McCallie?

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

Good morning.

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

Nancy Orvis? Marc Overhage? Wes Rishel?

**Wes Rishel – Gartner, Incorporated**

Here.

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

Chuck Romine?

**Charles Romine – National Institute of Standards and Technology**

I'm here.

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

Cris Ross?

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

I'm here.

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

Walter Suarez?

**Walter Suarez, MD, MPH – Kaiser Permanente**

I am here, too.

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

Sharon Terry?

**Sharon Terry – President and CEO - Genetic Alliance**

I'm here.

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

Jim Walker? And would staff who are on the phone please identify themselves?

**MacKenzie Robertson – Office of the National Coordinator**

MacKenzie Robertson, ONC.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Steve Posnack, ONC.

**John Feikema - Office of the National Coordinator**

John Feikema, ONC.

**Lauren Richie – Office of the National Coordinator**

Lauren Richie, ONC.

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

Anyone else on the phone who has not been introduced yet?

**Rich Elmore - Office of the National Coordinator**

Rich Elmore, ONC

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

I'm sorry, would you repeat that?

**Rich Elmore – Office of the National Coordinator**

Rich Elmore, ONC.

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

Thank you Rich.

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

Floyd Eisenberg, NQS.

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

Thank you Floyd.

**Marc Overhage – Siemens Healthcare**

And this is Marc Overhage, I joined late, sorry.

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

Thank you Marc. Okay, back to you Jon.

**Jonathan Perlin – Hospital Corporation of America**

Good morning everybody and thank you very much for joining today's virtual meeting. We've heard generally affirmation that people are pleased not to be traveling this close to Memorial Day weekend, an affirmation that some people are enjoying their relatively cooler climates than the mid to Eastern reaches of the country, particularly in the South, where it's getting fairly warm. So, I'm glad we could accommodate. I know it's early for our West Coast colleagues, so Wes, we'll try to speak softly. But really do appreciate everybody joining. Before I offer some introductory comments, I want to welcome and express continuing appreciation for the terrific leadership of Dr. Farzad Mostashari and I want to welcome Farzad's introductory comments first, then I'll have some comments on the state of play in today's agenda with, of course, our co-chair, John Halamka. Farzad.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Thank you Jon and thank you to the members of the Standards Committee. As I was looking over today's agenda, it strikes me that we are focusing increasingly and appropriately on how not only to technically support interoperability in exchange, but to do so in a way that makes it easy, that makes it scalable, to move from, in a way hand-coding automation to actually automating automation in so many of the areas that we're engaged with, whether it's around the work with the vocabulary mapping that you will be talking about, the concept of having value set repositories that are maintained so that every developer

does not have to find their own set of codes and develop their own set of codes to match a concept. Whether it's moving from information exchange trust that is based on first name basis trust and resolving point to point trust to a more scalable approach where once conditions for trusted exchange are met, there can be insurance that it just works; that if I'm working with a nationally validated entity and I want to communicate with another provider who is also working with a nationally validated entity, however much time it took us to choose which nationally validated entity we want to work with, it just works, those two I have confidence that there's not going to be the need for negotiation between those two around either the conditions of interoperability or the conditions of trust or the business practices.

That's the goal of our governance and conditions of trusted exchange discussion, or whether we're talking about Query Health, moving from a time when being able to glean knowledge, to distribute queries, to distribute quality measures moves from being something that is yes automated once you do it, but that the very process of coding in those quality measures is anything but automated currently; it is painful, frankly. And so I see a lot of the maturation of the work that we're doing at this stage to be from saying yes, we have now shown that it is technically possible to do so and now it's time to make it easy, now it's time to move from where I think necessarily you have to start with, just getting it done, just..., just doing the brute force to a point where it can be effortless and seamless and automated. That's the vision, that's the dream that we're working towards and I think we are making very good progress in that direction with your leadership.

I also want to highlight one other important success. Many of you heard that we have created... that we had a slight organizational change at ONC and we have created two new offices, the Office for the Chief Medical Officer, reporting to me, that would provide a clinical perspective on all the work that we do, but in particular, around the parts of our activities that are facing clinicians, nurses, doctors and other healthcare providers, bringing the perspective, a clinical perspective, to the work that we do around quality measures, around decision support, around that Meaningful Use policy, around safety and usability, the key points of the human computer interface as it were. We also are creating an Office of Consumer eHealth, recognizing that this which started out as an initiative, as a project, is really matured to the point it's been incubated and now it's time for it to really be somewhat..., and for both of those, we are fortunate to have Jacob Reider as our acting Chief Medical Officer and Lygeia Riccardi as our acting Director of the Consumer eHealth Program, but we are conducting a national search for both of those positions.

In the maturation of the Consumer eHealth Program, the other activity I want to make you aware of is that on June 4<sup>th</sup>, the day before the Health Data Initiative meeting in DC, we are pulling together a half-day meeting, inspired in part by the excellent presentation at our last Standards Committee, the Consumer Power Team and Leslie Kelly-Hall, to say what are some of the priority standard use cases for which standards accelerating consensus around standards could help to unlock, unleash the concept of patient access to their own information. So, whether it's really taking the CTE concepts to scale and having open standards where there is a subscribe and notify model for transmission of patient care summaries, whether it's really digging down deep into understanding exactly how we can make the view, download and transmit using the Consolidated CDA and the direct protocol as effortless as possible; whether it's looking at administrative data; so, taking a look at all the range of standards related issues and prioritizing which ones and bringing in representatives from industry, from the innovators, from the consumer groups, from the vendors, from health plans to say, really that there be lack consensus that could help move this area forward, and we will be reporting back to the Standards Committee from those discussions and findings in HDI week. Thank you, back to you Jon.

### **Jonathan Perlin – Hospital Corporation of America**

Well, thank you very much Dr. Mostashari, very exciting. It really is a great segue to a couple of things I wanted to mention this morning, as well as really to the very robust agenda that we have today. I want to cover four things before I turn it over to John Halamka. First, I want to describe to the group, just take the Chair's prerogative about a use case that's possible by virtue of the work the Standards Committee, the National Coordinator, the meaningful use has achieved, a sizeable contribution, and I'll come back to that in a moment. The second item is, I wanted to just close a loop in part tying with the thread that Farzad Mostashari just identified and that's some of the work that's been identified by the Consumer

Engagement Workgroup, some incomplete areas from Leslie Kelly-Hall's presentation at our last meeting, and just put an asterisk as we complete all of the other work and the use cases, that we need to think about how to be sure that that consumer perspective, patient perspective is represented and really be active and intentional in our mindfulness of assuring that viewpoint in all the other work. Of course the third item is the deliberation of our minutes and approval of our minutes. The fourth will be just a reminder on etiquette when we have a virtual meeting.

I had a number of comments over the past weeks in forums outside where those who listened to our webcast really do appreciate when people identify themselves when they speak, it makes it much easier for many interested individuals to follow. So, maybe we'll just leave the telephone virtual meeting etiquette at that. Please do signal in if you wish to raise the figurative or metaphorical card, but do also identify yourself every time you speak and I would ask that everyone keep their phones on mute when you're not speaking, it makes it much, much easier for everyone else to follow.

So, in the sequence of the items I mentioned, let me just take a minute for a Chair's prerogative, to mention a discussion that would really have been somewhat unimaginable, or at least unimaginable envisioning, in terms that once can conceive realizing, even four years ago, and that was something that occurred in Washington last week. Three members of the Standards Committee attended, including me, Becky Kush and Jim Walker, and this was the Cancer Symposium on creating a learning health system. The basic idea was that the Cancer Foundation supports very much the idea that a health system with interoperable health information, with standards for interoperability, standards for data, is the platform, is the foundation for a world where patient care can really be much more personalized and precision oriented, where policy decisions can be made, where the public health can be improved and where the value and the science are simultaneously pushed. And it was just a remarkable conversation because some years' back, it really would have been an exercise in science fiction and I think, in short, by virtue of the work that I'm very proud of having been a part of, but really want to thank each and every one of you for helping to do. It wasn't a science fiction event, it was an event about looking at what we might foresee in the next era by virtue of interoperable health information, the subject really of a large part of today's deliberations.

Let me ask, I know Becky Kush is traveling and not available today, but let me ask if Jim Walker has joined.

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

Jim was on the... actually, he wasn't, sorry.

**Jonathan Perlin – Hospital Corporation of America**

Okay. We may ask him at the outset of the quality report, if he has any additional comments, because he had mentioned the same enthusiasm and appreciation for all the work that's done. But, I would hope this serves as some form of reinforcement, because I know the work can be difficult in so many dimensions, including not just the time, and thank you for making time available proximate to a holiday weekend, but really the thoughtfulness to envision this work of health information liquidity that allows not only better care in a particular environment, but, creates the environment that Farzad had alluded to, conditions for trusted exchange, really a very... the first part of our discussions today, that allow the higher use of health information. Just take a moment to be celebrated and I hope to re-energize the continuing work.

Let me also take Chair's prerogative on T-ing up, in two or three minutes or less, Leslie Kelly-Hall to just identify some of the open action items and appreciate all of the other members of the workgroup and Chairs, just making mental note of the use cases where the points that Leslie would make would intersect, indeed as Farzad mentioned, upcoming activities to really expand on the consumer patient input into the process, making sure that that perspective informs the use cases that are contemplated. So Leslie.

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

Thanks Jon. Yes, there were several action items, I think from our last meeting, and we have questions about process so that we make sure we're following good process and that the work continues. There

are questions about patient identity to matching to data and also about specifically patient demographic recommendations. The Power Team under the Health Information Technology Policy Committee Meaningful Use, Patient Engagement, sub-team #3 I believe, we did use the documents that were created by our team to help inform and start that process. However, the standards related work is still somewhat doesn't have a home, and that work is largely under the themes of any electronic health record action has a corresponding patient-facing system action, and then also that patient-facing systems should not be encumbered by legacy technology. And so, those themes and work under those themes are still outstanding. So, we would love some direction on how to work on the specific requested items, as well as continuing the work on this team.

It's very important to note that there was agreement at our committee and then also in the Meaningful Use #3 subcommittee that standards can actually inform or invigorate policy; just as policy can inform and invigorate standards. So this work, we feel very strongly that it should continue in parallel and hope for direction in that way.

**Jonathan Perlin – Hospital Corporation of America**

Terrific. Thank you very much for that very thoughtful synthesis. What I would ask is that the ONC staff work with you Leslie to kind of create the threads of integration following this meeting, and certainly come back to report on the progress at our next meeting. Obviously we'll ask that as you identify use cases then, there are elements of today's discussion that have direct interface with some of the concepts you've addressed, please do identify and we'll take note and just maintain those threads through the deliberations and the continuing work. So, please note, it's very much appreciated and we will continue to work to even more effectively formalize the threads of interactivity. So, thank you.

**James Walker – Chief Information Officer – Geisinger Health System**

Jon?

**Jonathan Perlin – Hospital Corporation of America**

Yes.

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim Walker, I was talking to my computer's microphone unaware that I was unconnected, sorry.

**Jonathan Perlin – Hospital Corporation of America**

Let me invite you to just share your impressions, I take it then you heard my comments, but it did seem like a moment that is really a reality for consideration versus something that's sort of fictional or fantasy some years back. Look forward to your perspective.

**James Walker – Chief Information Officer – Geisinger Health System**

Yeah, I agree entirely Jon. I thought there was a really strong sense that with a really remarkably wide set of perspectives, we tried to include everyone that's a significant stakeholder in healthcare in the meeting and got really excellent attendance, that really across that spectrum there was pretty general agreement, and we got, I think, within hailing distance of identifying a set of core principles that would enable all of the stakeholders, whom we obviously have to get all of them engaged to really be effective, would enable all of those stakeholders to feel like this is something that made sense to them, that was worth the effort, and I think we made a really good start.

**Jonathan Perlin – Hospital Corporation of America**

So, thank you Jim for those comments. Certainly if anyone has a quick reaction, I would certainly welcome those, but, I'd hope you'd just take the moment as actually a proof of concept that the work that you're doing is not only meaningful in a theoretical sense, but is giving rise to this sort of entrepreneurialism that characterizes innovation in our country at its best and the substrate is one that we've begun to build, but I think links uniquely with today's discussion because, taking it to the next level is predicated on the ability to realize the interoperability, that all of the elements of today's agenda, from value sets and vocabulary to further elaboration of a Nationwide Health Information Network, are the predicates and the capacity of that sort of foundational level of information structure and information

exchange makes the second order uses for improving care, improving policy, improving science, the work that the quality workgroup will report possible, and that's really exciting. So, I just want to start with that charge.

Let's take care of our first action item. I trust that by now everyone has had sufficient time to review the minutes. Are there any amendments, corrections, amplifications that anyone would like to offer? Okay, hearing none, let's assume consensus on the minutes. Thanks, as always, to ONC for a terrifically thoughtful and sensitive capture of the discussions and again a reminder, when you wish to speak, identify yourself, identify yourself when you begin to speak for the benefit of those online and when one's not speaking, on mute not hold and we'll have a terrific discussion today. Let me then turn to Dr. John Halamka to lead us through the technical dimensions of our agenda today.

### **John Halamka, MD, MS – Harvard Medical School**

Great. Well thanks very much Jon and very thoughtful comments from you and Farzad. All of us work on health information exchange at a national level, regional or state level and local level and certainly I have run into the following problem. We have the technology to interop with you, but, our legal teams are really at this point very backed up, and so the data use agreements, the notion that we would trust you, the business associates agreements, well, I'll tell you what, we'll schedule you for 2013 and we'll get to those, is that okay? And so, our whole morning is going to be spent on a discussion from Steve Posnack, Dixie and Walter on how the government, the Standards Committee, the Policy Committee, we can all work together, as Farzad introduced this morning, so that this trust fabric concept is very straightforward. In an analogous way to the way electronic health records are certified, you as an entity would be certified to be a trusty steward of data, a reasonably acting member of an exchange and at that point, it is no longer the responsibility of state government or local entities to do these binary, bi-directional point one off type of agreements before hospitals can trust each other to share data about patients they share in common. So, I think this will be a very impressive discussion this morning, I certainly look forward to the concrete result being some kind of certification program with very clear standards and criteria, by which an individual organization can join local, regional and national networks.

Now, we'll also hear from Rich Elmore about Query Health, and folks all know about Query Health, I think, the notion of sending questions to the data, rather than sending the data to a central repository and I have offered Rich the two million patient records of Beth Israel Deaconess, using some of the I2B2 clinical translation and science awards infrastructure that we have running in Boston, as a mechanism of receiving queries such as pharmacovigilance queries from the FDA. Imagine that you can discover that Vioxx leads to chest pain and stroke in 30 seconds instead of 2 years, by sending a distributed query to those who are capable of receiving it over the internet. I mean, a very powerful concept, so I look forward to that discussion.

We'll also, of course, as Farzad already introduced here, the great work on the clinical quality workgroup as to making quality measures computable via query as opposed to hard coding them in individual applications and from Betsy on those code sets that are going to be downloadable via National Library of Medicine curated central location, so again, each of us don't have to do the 10,000 dollar lab interface and the six month lab compendium build and all the crosswalks that we are trying to do ourselves manually; a lot of redundant, unnecessary work. So, as Farzad and Jon said, today's agenda is really getting us to a level of richness, to getting us a little maturity, where we're beyond the basics of transport content and vocabulary standards and truly into the operation. So Jon, did you want me to kick off the RFI discussion, or would you like to do that?

### **Jonathan Perlin – Hospital Corporation of America**

That would be terrific, let's keep rolling.

### **John Halamka, MD, MS – Harvard Medical School**

Okay. Well Steve, you know, once again you have done remarkable work in crafting a highly readable RFI that really outlines a set of new functions and features that heretofore hadn't existed and you even gave us a couple of new acronyms. So with that, please, give us the details.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

All right, thanks a lot. And I believe I worked it out with the operators that I'll just say next slide and they will advance them for me. I didn't mean yet. Thank you very much. So recently, and I think most of you hopefully have had time on flights or other time set aside to go through the RFI that we recently published and it is jam-packed, hopefully readable as John mentioned, as he said. And, before I jump into some details, just to go over a few overarching points, the RFI is really the recognition and embodiment of a lot of the collective work that the HIT Standards Committee has done, the HIT Policy Committee has done and numerous efforts prior that ONC has engaged in, to really stitch everything together in a large dialogue discussion about how we can advance nationwide health information exchange and so, consider what we're missing in the RFI, consider how we can make the draft proposals that we've got in there included better and whether we'll get to the outcomes that we have expressed in the RFI that we're seeking to achieve. So, we're going to continue as we did the past two months, to tap into your collective wisdom and go forward over the course of many months further to continue to flesh this out.

Next slide please. So, I usually take things from the top. We have statutory authority to establish a governance mechanism for the Nationwide Health Information Network, that's really our guiding principle from a statute perspective, and as the RFI explains in greater detail, we've approached implementing the statutory language by asking where can ONC uniquely add value. And, in answering this question, we've framed a multifaceted approach in terms of what we think an effective governance mechanism should be, and should include. Another general point that I'd like you to keep in mind is that through the governance mechanism we would establish, we're looking to create the foundational structures and processes that would be necessary to support nationwide health information exchange over the long term. So, we're taking both a what do we need to stand up right in the beginning to get the gears working together, and then how that will play out into the future. At its core, the governance mechanism you see discussed in the RFI is not necessarily about one particular form or method of electronic health information exchange, rather it's about putting in place the policy and technical building blocks that the nation needs to make all forms of electronic health information exchange take place. The RFI picks up, again, on a lot of the conversations that have occurred at the HIT Standards Committee, HIT Policy Committee and stitches them together.

Next slide please. All right, there is a little bit of delay. So, what is the Nationwide Health Information Network? I think Doug's included this in every slide presentation that he's given, a set of standards, services and policies that enable secure health information exchange over the internet; and that's been a concept that's evolved over time and as we've better understood what we've been trying to push forward and accomplish with electronic health information exchange nationwide. The RFI goes through kind of the chronology and the lineage of the evolution of the Nationwide Health Information Network concept and for which now we try to establish a governance mechanism.

Next slide please. So why act now to establish a governance mechanism. Farzad touched on this in his opening remarks, as well as others. Part of what we hope to achieve with this proposed governance mechanism is to shift the trust paradigm that exists today, largely a trust on a first name basis type of paradigm and through the establishment of a governance mechanism, we hope to reach a point where... that there need not be... sorry. We hope to reach a point where that kind of trust on a first name basis need not be the case, where trusted exchange can occur beyond those providers with whom you're not on a first name basis and with any provider at any time that a patient may seek care from. So, part of this RFI lays the groundwork for the mechanism and about how we are going to govern and how we are going to try and to make that shift across the nation. In the interest of time and advancing and since we're not in person, I'm going to kind of skip through some of these and focus on the points that I think matter for the briefing.

Next slide please. So, the establishment of a governance mechanism, we see in terms of one of our objectives, provide the unique opportunity to create new markets and new innovations and to really accelerate electronic health information exchange nationwide, and I think as Dr. Halamka mentioned, also about supporting and establishing an infrastructure that can take some of the burden and some of the weight off of individual actors in the community and stakeholders in the community to apply some type of

governance paradigm that may wind up not having or sharing some consistent goals. So, what we're trying to do in this RFI is to express what we would expect to be a consistent minimum set of rules of the road that would let stakeholders then focus on what matters, which is delivering high quality care. Another thing in terms of overall objectives that I'd mention, we had a brief discussion at the last HIT Standards Committee, when we were going through the comments on the standards and certification criteria proposed rule, about transitions of care and the transport standards involved, and there is mention in the CMSM PRM, in its objectives preamble discussion, about the governance mechanism and how that could be leveraged to support transitions of care so, the outputs and what we're looking for as the output of the governance mechanism would be that it could be leveraged by other programs and be used to help reach other policy goals. So, ONC being able to set up the mechanism, set up the structure, set up the processes that could result in additional value-added to a number of different activities, beyond just the approach to established trusted third parties that would be facilitating electronic health information exchange.

Next slide please. So, if you haven't read the RFI, this will be helpful to you; if you have read the RFI, then you know everything and this has some of the new acronyms that John had mentioned as well. For the RFI, from a bird's eye view focuses, and its scope focuses on entities who facilitate electronic health information exchange and I have another slide that kind of goes into more detail about who those could be. The other thing that I would...is that we've discussed that we intend or expect that this would be a voluntary framework that could then be subsequently leveraged through other programs and policy objectives as I mentioned before. We seek comment on five areas, so, here's where you can jot down some acronyms if you'd like. The establishment of a set of conditions for trusted exchange, so we refer to these as CTEs; these are really the rules of the road. We have a subsequent validation process that would result in entities who seek to demonstrate conformance to these CTEs, would have to go through a vetting process to show that they conform to them and then they would be subsequently designated as a nationwide health information network validated entity, so that's what NVE stands for.

Then we have, as part of the multifaceted approach that I alluded to earlier, we have some other processes and aspects to the RFI and the governance mechanism as a whole, that focus on how we would approach updating and retiring and kind of maturing conditions for trusted exchange over time, as well as, I think, something that's near and dear to the Standards Committee here, establish a process to classify the readiness of technical standards and implementation specifications to then feed into or support the interoperability conditions for trusted exchange and really having a transparent process for the industry at large to follow along and to be part of the classification of technical standards and implementation specifications. The last being how we would approach and envision monitoring and transparent oversight over this ecosystem at large, and the processes in place that we could expect or envision, including as part of the governance mechanisms.

One final point that I'd mention here, the governance mechanism we've laid out again is multifaceted in order to meet the diverse needs of stakeholders out there. One of its facets, the adoption of the conditions of trusted exchange and the NVE validation process would essentially establish the formal existence of these trusted third parties that we call nationwide health information network validated entities, and they would meet these conditions for trusted exchange. This facet anticipates that many healthcare providers will rely on a trusted third party to electronically exchange health information on their behalf; be it a variety of different methods that many of you are intimately familiar with like push and pull and query and all the different flavors involved. In cases where a provider is interested; however, in pursuing an electronic exchange method, without a trusted third party, the other facets of our governance mechanism, specifically the standards and implementation specification process, would continue to enable and engage them in the ability to electronically exchange using nationally accepted and classified standards. And so, it really is trying to be an open and inclusive governance mechanism for a number of different purposes.

Next slide please. So, we have three categories of conditions for trusted exchange. I'm not going to read these in detail, but to square you away, we have safeguards conditions for trusted exchange, interoperability CTEs and business practices CTEs. And, as we were trying to bucket them, this is really where we felt the greatest comfort in how we could express conditions for trusted exchange and what made the most sense in terms of the needs of the industry at large. There are sixteen conditions for

trusted exchange listed in the RFI, 10 safeguards, 3 interoperabilities and 3 business practices. These are not meant to be an exhaustive or comprehensive list; these are the ones we had our minds wrapped around the most that we felt we could push out there to get the best public input and frame them appropriately to get public input. So, if there's something in there that you feel is critical, please make sure that you include it in your public comments; that's my kind of general PSA for the day. I would also note that the CTEs again are just a list as they are right now and we have questions in the RFI regarding how they could be packaged together through the validation process, so, it may make sense that a dozen out of the sixteen that we've included in the RFI, could be packaged together in a logical grouping that an entity could be validated against for a particular method or service of exchange and then, other conditions for trusted exchange would be in play for a different modality or method. So that's another thing to just keep in mind as you work through the conditions for trusted exchange. It may not be the case that a single entity would have to meet all of them, from an all in one perspective.

Next slide please. I'm going to go through these pretty quickly, because I don't feel like we have the time or the detail to step into them, happy to answer any questions. The only thing I would caution you against is the context behind each of these conditions for trusted exchange is spelled out in great detail in the RFI, so, please try not to take them out of context when they're just on a slide. In terms of just another thing for people following along, on the left hand side we usually use the first letter or two of the CTE to categorize them and number them in an order, so S-1 stands for the first safeguards condition for trusted exchange. Again, as we work through these, especially on the safeguard side, we considered that the trusted third party that we would expect to become Nationwide Health Information Network validated entity would be performing a kind of common role and service in the industry and thus, that was the lens through which we looked at how we would structure the conditions for trusted exchange and where we felt greater consistency would be necessary in a number of the different policy proposals that we include.

Next slide please. These are the remaining five out of ten of the safeguard CTEs. Next slide please. There are the three interoperability CTEs which many of you have already been engaged and discussing in the numerous workgroups and subgroups of all the committees. Again, shouldn't be a surprise to you, some of these topics that we've included as conditions for trusted exchange and welcome your feedback again. Next slide please. The business practices is another concept again, as we included in the RFI, and to remind folks, these are conditions for trusted exchange that focus on the operational and financial practices to which the NVEs would need to adhere, in order to support trusted electronic health information exchange. So, this is really about these NVEs, these entities becoming standup good actors, good HIE citizenry in the marketplace at large. Okay folks, a little rambunctious with the next slides.

There you go. There, the eligibility criteria. So, we include a list for public comment of a number of different types of preconditions for eligibility that we would consider, or looking to consider in terms of how we would sort who's ready to become a Nationwide Health Information Network Validated Entity and if those preconditions are met, that entity would continue on the process to be able to seek validation. We've listed here again, an included but not limited to anticipated set of eligible entities that we think would be in scope of the validation process and having to meet the conditions for trusted exchange. It includes EHR technology developers, integrated delivery networks, obviously the third parties out there that are regional, state or local or health information exchanges and other health information service providers.

Next slide please. Validation is a concept that we picked up from the HIT Policy Committee through its Governance Workgroup. It's really meant to be an umbrella term at this point. Because of the different conditions for trusted exchange that we have included in the RFI, and it was discussed previously in the Governance Workgroup's discussions, we anticipate and expect that for different conditions for trusted exchange, there could be or it could be necessary to validate them differently in order to assess an organizations conformance to them, so, some of them may revolve around specific testing and certification, others may look at the people and processes and the business practices that the organization has to help reach that level of trust that we're looking for. In terms of structure and process aspect, we are looking to leverage the same type of structure that we've instituted for the permanent certification program that essentially includes ONC approving an accreditor that would be able to assess the competency of numerous validation bodies who would be authorized by ONC to then go out and

operate in the industry to validate these trusted third parties as Nationwide Health Information Network Validated Entities. So once an eligible entity was to complete this process, they would become an NVE.

Next slide please. So this is one of the other facets of the governance mechanism. You'll see a very familiar classification that we've included in here, and this is one of those things where we thought that a stakeholder inclusive, a transparent process to build and advance and be proactive about what conditions for trusted exchange may be necessary over time, that we would establish some type of classification methodology for this, and we've chosen the emerging, pilot and national classification to assign to different conditions for trusted exchange.

Next slide please. Similarly, with respect to technical standards, we think that it would be helpful to include as part of the governance mechanism, one of those additional facets, a process to annually review technical standards and implementation specifications, discuss the role of the Standards Committee in this regard in the RFI, a way to help transparently show the maturity pathway for standards and specifications, how they could be classified going forward, and where also it would help be able to identify the gaps that would be needed to support nationwide health information exchange; so really trying to roadmap out and include a roadmap as part of the governance mechanism for technical standards and implementation specifications.

Next slide please. So this is the last one here; monitoring and oversight and we include again another discussion in the RFI. Really this is a shared responsibility, we believe, so ONC and the entities that we would delegate some of our authority to act on our behalf, would have responsibilities, as well as in the Venn diagram, the overlapping Venn diagrams of many of the different other regulatory paradigms that are in play with respect to health information and information exchange, that other offices and Federal agencies would have responsibilities that are currently within their authority that could provide some additional oversight and monitoring, beyond what ONC would be able to do on its own. So really figuring out where there are partnerships that we could have, as well as what responsibilities that the industry can take on itself. And I think that's it. If you go to the next slide, happy to try to answer any of your questions, but, I would encourage everyone to comment and get your comments in by the middle of June.

**John Halamka, MD, MS – Harvard Medical School**

Great, thanks very much. And so recognizing that Dixie and Walter will be doing some deep dives in discussing some of their questions and issues; are there other questions or comments from folks on the call?

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

David, I have a question.

**John Halamka, MD, MS – Harvard Medical School**

Please go ahead.

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

Steve, I think I got this right, but the distinction between accrediting and validating keeps tripping me up, I haven't memorized the right terms yet, but, as I understand it, let me see if I got this right, the accrediting body at the top would probably be a government entity that would in turn create validating bodies, multiple, which would I am guessing be private entities that would in turn certify NVEs, which could be a mix of public and private entities. Does that sound right?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

You're 99% close, you're really close and I'll just give you the current paradigm that we have for the permanent certification program. So, today ONC has approved ANSI as the accreditation body. And ANSI then evaluates the different certification bodies to accredit them. And so the relationship that we would see here would be a similar type of relationship on the governance mechanism side where an entity like an ANSI-type of accreditor would be approved by ONC and then they would have the

responsibility to assess the ability of different central validation bodies to perform those duties and to assess the actual eligible entities as NVEs. Does that help?

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

Yeah. So the top level body might... is approved by government, but might not be a government entity itself, that's...

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Correct. Correct.

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

That's very helpful, thank you.

**Alan Merritt – Altarum Institute**

As a reminder, please state your name when asking a question. Thank you.

**Wes Rishel – Gartner, Incorporated**

Wes Rishel.

**John Halamka, MD, MS – Harvard Medical School**

Yes Wes, please go ahead.

**Wes Rishel – Gartner, Incorporated**

So, if I recall correctly, the term accredit is used to apply to two different objects in the RFI. Validating bodies are accredited by the national accrediting organization and then NVEs go through a process that includes both accreditation and certification in order to become NVEs, is that correct?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

That's the working construct that we have. The scopes of the accreditation would be different in terms... but yeah, I mean and that's why we've struggled a little with the... and used the validation concept as more of a global approach, until we...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

This is Farzad. If I may add, for those on the phone, this may seem really Byzantine, with our apologies to the Byzantine Empire, to have the different layers, but we are assured and encouraged by our own experience that having these separations between accrediting bodies and validating bodies actually makes sense. As it was pointed out, there is kind of a term of art here that I'd have to learn around what accreditation pertains to, which is, correct me if I'm wrong Steve, organizational capabilities for the most part and what certification applies to, which can be based on tests of compliance with technical standards for example. So, I think the concepts, and we discussed at length whether those two should be split apart and to have a validation process that is split in two, basically having one group look at the organization, the other group look at another pathway, but I think the proposal that we have is that there is a final common point of validation that incorporates both sides of that equation, both the organizational accreditation as well as the technical certification. Is that fair Steve?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Yeah, and there are purists, that I am not one of, that would have other interpretations of certification and accreditation, but that's generally what we've worked with going forward in the RFI.

**Wes Rishel – Gartner, Incorporated**

Yeah, Wes again. I was not intending to imply any concern about the structure or any disagreement with the notion that there are two distinct forms of accreditation. However, I have been involved in calls where it was not clear that there actually are two distinct forms of accreditation and I want to call that out. I have a question that goes to the degree to which the validation process is a combination of accreditation and certification would mirror the current certification and Meaningful use criteria processes under Meaningful use. In particular, for both certification and for actually demonstrating Meaningful use, there are a set of criteria that are set by regulation. For certification, there's an additional set of criteria that were set by NIST for Stage 1 in the form of certification scripts, and I think will be set by ONC for Stage 2. But, the important thing is that the certification bodies had very little discretion in terms of the criteria they used to certify. Is it the intent that the same would apply here, that the material provided to the bodies that do the various forms of validation would be so specific as to provide very little discussion on the parts of the individual bodies that do validation?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

This is Farzad. I think that obviously, as people say, we're asking for your thoughts on that. I would re-emphasize back to the goal here, and the goal is that there's a national framework such that it makes it easy, and it just works, if you have that sort of a trust anchor, as some have called it. That if you're going for the two validated entities, according to a national process, you have a reasonable assurance that they're following equivalent standards around the interoperability business practices and trust behaviors. Now, one could imagine, Wes' scenario where there are different circles and the trust network is more a function of the certification body; so, you may have the equivalent of like a high trust, right, and that organization has, and then just pull a name of a hat, so there may be a certifying body that has its interpretation, and people all over the country who want to adhere to that temple would be sharing information with each other and then there may be another group that says, oh, we're someone else, we're direct traffic and we have our set and people who want to adhere to that temple would be able to see if we can exchange information with each, but not necessarily across those two organizations. And I think that's part of what we're trying to see comments on there is a tension, policy tension period between having the more specific, more explicit, more standardized at the top level, at the accreditation level and the test scripts and so forth that ensures more of the nationwide interoperability between certifying bodies or do we evolve it more at a lower level in terms of the specifics, which would potentially allow for more innovation, maybe even a tighter conformance, but, have some drawbacks on some of the nationwide cross-interoperabilities.

**Wes Rishel – Gartner, Incorporated**

Wes again. As if you folks didn't have enough tension, I would add another level of tension to that trade-off which is that if this validation becomes a necessary ticket for operation of any organization, commercial or non-profit, adding discretion to the validating bodies has a danger of creating a race to the bottom in terms of interpretation, the easiest one to get a certification or a validation from becomes the most (indiscernible).

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

That's true. That's true.

**Wes Rishel – Gartner, Incorporated**

Thank you.

**David Kates – Senior Vice President Clinical Strategy – NaviNet**

Steve, this is Dave Kates. In this certification process, would you envision either in the near term or in the longer term having different, if you will, classes of service so to the extent as John Halamka had described earlier, you know, some of the Query Health capabilities are available, there may be some entities that participate in health information exchange that can support those types of transactions; likewise, there may be again as trusted stores of data, some that contribute and consume data off of a

health information exchange, others who are trusted stores if you will of data that then source to others, is that contemplated in this, either in the short term or the long term.

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Sure, yeah, a great question. I mean, I think that gets to the packages construct that I was talking about earlier and I think we see that there could be a common and consistent smaller set of conditions for trusted exchange that would apply broadly, for any type of, you know, like a starter set so to speak. But then as you get into different types of services, so if you were to take Query Health for example, maybe there are specific conditions for trusted exchange, some of which that are included now, some of which that we would need to add in, that would allow an entity that was seeking to become an NVE to get the general designation plus some indicator that it has been validated for the Query Health CTEs. Does that make sense?

**David Kates – Senior Vice President Clinical Strategy – NaviNet**

Absolutely, yeah, I think that's consistent.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

We just want to be cognizant of how many extra designations that were out there from a transparency perspective. The other point, this is Farzad, I want to make, a little bit I think may be presaging Dixie's presentation is these... the three types of CTEs are linked in a sense, that if the Nationwide Health Information Network is a set of policies, policy service standards, those go together. So, if you're providing the service that includes a patient matching record locator function, that requires... that then comes with, that service then comes with not only technology protocol for enabling that, but also with different policies and privacy practices that are relevant if you're providing that service, that may not be relevant if you're not. So, I think one of the things that we're looking for is, as Steve mentioned, we've come to these packages or kits where there's a base foundation of the conditions of trusted exchange that everybody needs, but then you may want to have a package of additional policies and technology that go with an additional service that may be provided by a group of intermediaries that you would want to then enable them to be able to talk to each other. Does that make sense?

**David Kates – Senior Vice President Clinical Strategy – NaviNet**

Yeah.

**John Halamka, MD, MS – Harvard Medical School**

And that's a great comment Farzad in that as I look at this ecosystem that we're creating, there are going to be providers or payers, patients, but there are also going to be novel entities that we can't even envision, it might be decision support service providers in the cloud, who knows right, but each of them may have different data exchange types and different degrees of protected health care information and maybe some of them will be actually stewards of anatomized quality measures and maybe based on the nature of their services, there are different levels of certification as you described.

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

This is Leslie and John just hit on, of course, my favorite topic which is patients, and as we look at this design, how do we envision individuals participating through trusted entities, knowing that they exist, talk a little bit about how, as the care team expands to include the patient and the family members and non-traditional caregivers, what we've done in this construct to accommodate that growth.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Steve, you want me to take a crack at it?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Okay.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

So Leslie, it's a great question and I think there's two ways at least that we can think about that... or have been thinking about that. The first is with the DOT subjects, they have information exchange deemed a participant. So, if you want to have your information sent... transmitted as part of say Meaningful use, to a third party; I want that to happen for me, right, my information. Then that third party, I would want to choose a third party that is an NVE, that for the purposes of the transaction, I know that they are making sure that the privacy, security, the interoperability and the business practices are maintained. So, they become... and the person controlled health record vendor becomes the analog to the electronic health record vendor where they could either themselves choose to become an NVE or to develop a relationship, partnership with NVE in deemed members of that information flow.

The other aspect is where we're talking about this being part of what an NVE does, is it engages and depending on the use case, this may be more or less relevant. They hold patient information, then maybe you were discussing the patient should have access to a copy of that information or if it's a scenario where patient consent meaningful choice is in play, where it's not simply... where the carrier as if as it were, actually has access to the information or other services or functions that are provided, we ask whether there should be central management and services pertaining to management of those meaningful choice decisions. So I see this, the subject of the exchange at least in two ways; one, an active participant and two, a highly interested and empowered part of a business decision.

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

This is Dixie Baker, I have a question.

**John Halamka, MD, MS – Harvard Medical School**

Yes Dixie, go ahead.

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

Yeah, my question may be stealing my own thunder, but, it seems appropriate to ask it, particularly following on Wes' interaction earlier. Both, as you'll hear, both the NwHIN Power Team and the Privacy and Security Workgroup noted that some of the CTEs are at a very high level, you know, policy level; while others are very specific, you know, even prescribing specific technology standards. So, I was wondering whether as you deliberated on this RFI, you considered a tiered approach to CTEs wherein you would have some conditions you would have; at the highest level, you would have high level policy conditions that NVEs would be validated against, again using the terms specifically that you validate an NVE and you certify technology. And then, more specific, at the lower tier, more specific conditions against which technology implementations or products would be certified?

**Steve Posnack – Office of the National Coordinator for Health Information Technology - Policy Analyst**

So, this is Steve. I think Dixie, this is part of what we're trying to get out of the comments that we receive from everyone as well, and some of the CTEs reflect just the ongoing maturity and discussion of how we were thinking of framing each of the conditions for trusted exchange. I think we recognize that some of them would require some additional specificity, as you mentioned, as well as where there could be a potential to leverage technology being certified as a way to demonstrate conformance with a particular, say for instance, interoperability condition for trusted exchange, as opposed to some other method.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

This is Farzad. Yeah, one of the things that I'm really interested in is, look at the bottom... at the end of the day, someone, a provider, who chooses and NVE needs to know that it just works, it works; it doesn't just work from a policy point of view, it doesn't just work from a technology point of view, it doesn't work just from the business side, it just has to work. So all of those have to be in place, around a validation entity and yes, there needs to be, as you also I think point out, and have championed, there needs to be a fair degree of specificity on the technical standards from somewhere in order for it to just work. The question is, where does that specificity around technical standards come from; does it come at the, and

this again goes back to Wes' point, is it laid out in... at the top level through rulemaking, is it a combination of rulemaking plus test procedures that are developed, is it at the accreditation body or is it left to the certifying, the validating entities that have been accredited; where does that come in. And I think that's something I'm really interested in in having the group kind of think through and consider some of the side implications. For example, if there's conflict between the specifics of the technical protocols between what one validating entity chooses and another; or, conflicts between what they choose and the certification criteria and standards for electronic health records that are established through rulemaking.

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

Yeah, I think that we have talked through that and we totally agree that there needs to be specifics, but we also think that the variability and the change over time needs to also be incorporated. You know, a governance policy really shouldn't change as often as a specific technical standard might; and even the processes and the types of organizations you would want to validate an organization against... validating an organizations operations would be quite different from the type of organization you would want to test a product or implementation against a technical standard. So, I think that all of those considerations, and this is me talking, all of those considerations suggest to me that there should be two kind of levels involved and whether they both be part of governance or not, is really, I don't care about that, but I think that we do need to make a distinction between the validation that an organization is following a set of governance policies versus the certification that a technical implementation is implemented in conformance with its specification.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Dixie, let me just make sure I understand. We can have... and as was pointed out, there could be... the process could be spread apart where there are... as part of the governance framework, there are conditions that are... policy level conditions that are assessed with some frequency with some organization and one could imagine a skit where other more technical standards are assessed by different organizations. But they're both part of a governance framework. If we want to have at the end of the day, nationally validated entities in which information exchange just works.

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

Yeah, I have no... I...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Okay, I just... so I just wanted to clarify that when you were saying it shouldn't be part of governance, I think what you're saying is....

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

No, I did not say that. I said, it could or... I don't care. I think the processes should be split apart. Now...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Okay, no problem.

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

The process of validating that an organization is following the governance in its operations, you know, its day to day operations its following the policies of the governance organization, that process should be different from, and the people who do it should be different from the process of certifying that a technical implementation conforms to its specifications. They can both be part of governance, that's fine, but they're two different activities.

**Arien Malec – RelayHealth Clinical Solutions**

Yeah, this is Arien and I note that the Governance Workgroup is making proposals along these lines with no accident, because I was on the Power Team and then on the sub-workgroup that discussed the lifecycle and the overall framework for governance on the Governance Workgroup; and just as a note that

we've recommended recognition that there are multiple lifecycles, that is, that there may be an overall policy goal, for example, nationwide directed exchange, that has a set of policy constraints, but recognition that the standards and implementation guidance are likely to change at a much more frequent basis, and so, you need a mechanism that allows for the implementation guidance to evolve more rapidly than the policy level goal and to the point that Wes has been making consistently, you also need a process for retiring them. And so I think the mechanism that Dixie's describing basically is trying to set up that level of framework where you have the high level policy goal, in the same way that Meaningful use sets the high level policy goal for transitions of care. You map those to the standards and implementation guidance in the same way that Standards Committee makes recommendations there, and CMS and ONC enable that in regulation. And then you certify with a set of test procedures and certification criteria, and recognize that the latter are likely to change much more rapidly than the former. So, I think that's just the mechanism that we're overall describing.

**John Halamka, MD, MS – Harvard Medical School**

Well, there certainly has been multiple input on this at recognition that policy may be more constant than the standards and implantation guides. Now, I wonder, as the next step for the group, because we're going to continue this same discussion, Dixie has a rich set of additional material to add and then we should continue with the line of questions, if that...

**James Walker – Chief Information Officer – Geisinger Health System**

John?

**John Halamka, MD, MS – Harvard Medical School**

Yes.

**James Walker – Chief Information Officer – Geisinger Health System**

Jim Walker. Just very quickly, I assume that parsimony is one of our goals for this structure, do we have...one way to operationalize parsimony would say, the target is that a compliant organization would cost them some amount of money to do at least the basic accreditation and validation process. Do we have anything like that, if not, I suggest that we think about it carefully.

**John Halamka, MD, MS – Harvard Medical School**

Right. I mean, that's certainly an interesting question, Steve and Farzad, have you ever in the work you've done to date on standards and certification, had any recommendations for cost or pricing levels of the services provided, I presume not.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Although it's an explicit policy goal that there be market stage competition that should result in higher quality of customer service and lower costs. So, I think we're trusting that if there are multiple such entities, as has occurred with electronic health record certification, that there will be downward pressures on cost.

**James Walker – Chief Information Officer – Geisinger Health System**

Right, just... if we... if our intention is to include many, many relatively small and resource constrained organizations in this environment, in this ecosystem, then if it costs three or four times as much as... if we put so many requirements in that it costs more, we will change that ecosystem from the beginning. And just another caution, we cannot write enough CTEs to guarantee that it just works, what we can do is write enough CTE... if we do a really spectacular job, we could have enough CTEs that at least a customer would be pretty confident the thing isn't just going to blow up and destroy their building.

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

This is Cris Ross. I wanted to comment on that, maybe not in the... as part of the NwHIN Power Team, I think Dixie's represented our conversation pretty well. One of the issues that I guess I was curious about, in that conversation and going forward is... completely understand the goal of what Farzad is saying around "it just works," the question is, just works for what purpose, is kind of the next step, because the

RFI does not include... this is not a single use entity, these NVEs are not just doing one task in a consistent, you know, atomistic way. They could do several different tasks. For example, there's questions about which protocol should they support and so on; and as we discussed it, we looked across other industries and other processes, for instance, ISO certification or receipt of a SAS certificate. You know, if I'm a corporate CIO or a healthcare CIO, I want to know if the data center that my operations are running in has a SAS certification, and perhaps I might want to know if it complies with certain ISO standards. And at that level, that's most of the time sort of foundational for me, but that's not where my inquiry stops, at that point I also want to know, well what particular set of services will that vendor provide and so on, and so it seems like entities entering into relationships with these NVEs are going to want to look for the certification and validation and accreditation, whatever set of badges we want to put on that, but they're also going to want to do their own inquiry to say, does this provider fit my use for these particular purposes that I'm particularly interested in because of my architecture and so on. And to Jim's point, I don't think we can do enough CTEs that can deal with the possible set of combinations that you would want from a commercial standpoint. So, as much as we may want to do this, I'm not sure that this gets to sort of plug and play completeness through a validation process; there still needs to be commercial or business relationship introspection to say, yes, I understand the table stakes are met, but now I need to know about goodness of fit of NVE "A" versus NVE "B" and then I'll pick and I think we should anticipate that.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Let me...this is Farzad. Let me articulate a little bit more clearly. A customer can have a lot of due diligence around which NVE they want to choose, and they have time to do that, and they can bring in the contract aspects to it, fits aspects to it, the technology; that's fine, right? Spend as much time as you want picking your NVE, but for a given use case, for a given package of directed exchange, this is a very real... I mean, this is what we're expecting people to be able to do for Meaningful use, and let's not lose sight of the stakes here, this is what needs to be able to enable Meaningful Use Stage 2 pretty darn quickly, right? This is not some theoretical exercise, this has got to work. So, the aspiration absolutely is that if I do all the thinking I do, and I pick an NVE that supports direct exchange protocol and the direct exchange use case, that I then don't have to wait for my NVE to engage in prolonged negotiations and deliberations and custom hand-fitting with another NVE who has also implemented the direct protocols and the direct set of policies, services and standards. And that is, I really would not back away from that guys.

**M**

Yeah, this is...

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim Farzad, what I was trying to say is that it has to be parsimonious and really carefully designed because there will still be the question of, are these people that I'm looking at as working with as customers, are they reliable, are they expensive, are they going to be here next year. That's all.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Right. I'm talking about the...

**James Walker – Chief Information Officer – Geisinger Health System**

... parsimonious enough that it really is just like you're saying, just that when I plug it in... if I plug this phone in the wall, it will connect to the national phone grid and I don't have to worry about that part of it.

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

This is...

**John Halamka, MD, MS – Harvard Medical School**

Let me put it a slightly different way, is that in the past, sometimes we've had interfaces that take ten thousand dollars' worth of configuration and negotiation and if being an NVE means it's now five hundred

dollars, maybe it's not absolutely flawless and perfect, but it's fine tuning and not some de novo creation of policy or technology.

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

And this is Leslie. And no matter what government's rule is, it is never to take the place of business due diligence. So, we need to be mindful that this is really about making it easy and consistent to provide connectivity in a trusted way and let the market then take over its own response, because it has its own reward. So, I think that this is work that is important to do, it's consistent, it will answer many of our questions, but to expect it to answer all of our questions is, I think, not realistic.

**John Halamka, MD, MS – Harvard Medical School**

Well, shall we...

**Wes Rishel – Gartner, Incorporated**

Wait, this is Wes.

**John Halamka, MD, MS – Harvard Medical School**

Yes, go ahead Wes.

**Wes Rishel – Gartner, Incorporated**

I just want to pile on just a little bit. I think I heard two really important concepts here, okay. One is that the collection of CTEs have specific subsets that are applicable to specific use cases; so, sending referrals via direct may not require all of the CTEs, but certainly will require some and sending lab results via direct would have an overlapping set...that had some overlap with the sending referrals by direct. And that it doesn't seem to be a goal that every NVE handles all of the use cases that all of the NVEs together handle, and I'm not sure that that's clear anywhere in the documentation... in the RFI at this point. The second point is that John Halamka's characterization of this as a multiple orders of magnitude reduction in the cost of achieving interoperability as opposed to talk and pay, is really the more realistic characterization and that among the non-government applied criteria that a given practice or hospital or payer might use are the track record of a given NVE in actually achieving interoperability. Thanks.

**John Halamka, MD, MS – Harvard Medical School**

And so Wes, to your point, a vendor recently sent me an invoice for \$90,000 dollars to create a CCD. Right, and you think...

**Wes Rishel – Gartner, Incorporated**

Hopefully the second CCD was cheaper..

(Laughter)

**John Halamka, MD, MS – Harvard Medical School**

So in fact, in 2012, this shouldn't happen. I mean, it should be plug and play, not plug and pray, I mean I think is what I was getting at.

**Wes Rishel – Gartner, Incorporated**

Well I think that... I would hope that you could get that down substantially in the general case, but, certainly for the cases that are outlined in the 2014 standard edition and, the interpretation of them, which is not that you can completely ingest the entire CCD and every nutrient becomes part of your body; but, that you can get the necessary nutrients out of it. I think, at those levels, you're right, that should go to zero or something close to zero.

**John Halamka, MD, MS – Harvard Medical School**

Well, I know this is...Please, go ahead.

**Marc Overhage – Siemens Healthcare**

Hi, this is Marc Overhage and I think we have to be careful as we have this dialogue about cost for what, because there's one set of costs which is connections and things and the other thing is, I think we are still in a world where the implementation, and this comes up in patient safety, it comes up in health information exchange, it comes up in physician training, the way that institutions and organizations have implemented a particular tool are different and so the cost to create the CCD in this example that you give John, you have the actual code to create a CCD that has the right elements in the right place, I'm guessing isn't very great, since that probably exists and where the real costs are, are in the adaptation; the fact that for lots of good, valid reasons over the years, certain data is put in a different place in implementation A versus implementation B versus implementation C and it's that translation or localization where some substantial chunk of these costs come in. And I think that we've got to remem...it's not just the plug it in, it's the local differences, which are substantial. You know, there are very few vendors that have an absolute "here's how you do it, here's where the data goes and you have no choice."

**Wes Rishel – Gartner, Incorporated**

Marc, this is Wes. I think that there is a longer term ability to reduce the amount of mapping that's necessary and that the mapping should end up being the only variable cost rather than one of the number of labor intensive operations that have to go on. I think that increasingly other requirements will make it clear where in a given implementation of a given product certain data can be found or how an analyst can find that quickly. Some of the stuff that Betsy's going to talk about is going to help with specifically code mapping and that we ought to see software... we ought to see the vendors investing in software that is designed to reduce that cost, as opposed to the policy of some vendors which is effectively to put inexperienced programmers on an interfaces so they can learn how the system works.

**Marc Overhage – Siemens Healthcare**

And just a brief response, I absolutely agree, it's just I think we've got to keep in mind the legacy that is out there is substantial and while I agree completely with the direction of evolution you described, that will take multiple years, not a few months.

**Wes Rishel – Gartner, Incorporated**

I agree, and it will require ongoing pressure from ONC to keep focus on that point, but, I think we need to ask ourselves the question, what do we believe is the direct and immediate impact of this governance; that is, if plug and play is an aspirational goal, is there a two year impact from the time they become mandatory to the time we were to make a measure for the effect that is substantial or are we using medications that are only legal in certain states.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

And... this is Farzad... I think the example of the CCD that John brought up is a good analogic summary, but the focus on content and mapping may be a little bit more than the governance RFI tries to tackle in full.

**Marc Overhage – Siemens Healthcare**

And this is Marc, I understand that completely Farzad, that was my only point there was we were talking about parsimony and costs and barriers that we might be creating for people, I just think it's important for us to tease apart where the barriers exist, and there are vendor practices, I'm sure, that are contributors to that, there are standards issues that are contributors to that, but then there's sort of the Carol Diamond, "we can't shut healthcare down and reboot it on the weekend," challenges of installed base, which I just think we've got to be cognizant of how challenging that installed base can be to evolve, as Wes said.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Agreed, agreed. And I think that, again, to bring it back to the condition of trusted exchange, the focus is on, you know, middleware, which is the time honored way to keep your systems running and evolve the interactions between them.

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

So, this is Cris Ross, and Farzad, I want to be clear that the comments that I made a couple of minutes ago intended to be totally supportive of the idea of “it just works,” and it feels to me as though the thing that’s exciting about the RFI and governance process is it gets rid of the things that stop us, but there are some things, I think, that are needed to get us across the finish line, that regulation can’t do and the market will do. So, a lot of the conversation we’ve been having I think in the various committees and workgroups that I’ve been on, is about do we need to regulate this particular item, is there a market failure here and other kinds of things...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Understood.

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

So, I think we’ve made tremendous strides from before and I just want to keep us from kind of trying to make a perfect enemy of good.

**John Halamka, MD, MS – Harvard Medical School**

Well, let us move on to the comments that Dixie will make, because then we will continue this discussion with the benefit of some of her additional details. So Dixie, if you could launch into your presentation.

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

All right, thank you John. This is the update from the Nationwide Health Information Network Power Team. Let’s see, do I have control... yes, I do have control here. I’m going to start out here by giving you an update, a brief update, on the progress we’ve made since the last meeting, on our fundamental core assignment of defining criteria and metrics for classifying specifications and standards, and then I’ll launch into our review of the RFI. As you’ll hear this morning, there are two workgroup in our Standards Committee that have been assigned responsibility for drafting responses to some of the questions in the RFI and in the NWHIN Power Team is one of those. So, we’ll talk mostly about that.

Just as a reminder, our fundamental scope was to develop objective and quantifiable to the degree possible, criteria for evaluating the readiness of technical specifications for adoption as national standards, and the ONC defined these three classifications for us; pilot or domain specific, which are specifications that need to mature a bit before becoming emerging. And then the second category is emerging and then finally, ready for national adoption. And you will see that these three categories have now made it into the governance RFI that we’ve been discussing. So, the approach that we are taking is that we started with the criteria and the grid approach that we defined in the summer camp exercise last summer, but we constrained the scales to be consistent across all categories, to be consistently low, moderate and high, across all criteria. Then we defined attributes for each criterion and a metric for measuring the attributes. The objective and unambiguous attributes and metrics would be...the idea is to apply them to specifications in a predictable way and that way is starting to be defined in the RFI. And then the idea is to have a common set of criteria, a common set of classifications, common process for evaluation of any potential standard or specification.

So, here we have, as a reminder, these are the five evaluation criteria that we defined during the summer camp, need, maturation of specifications, maturity of underlying technology, translation problem there in the PowerPoint, market adoption and implementation and deployment complexity. What we’ve done, the ONC actually removed need as a criterion because this, the need will actually be a factor that’s considered in assigning the specifications for classification to begin with. So, if there’s not an existing need, the specification won’t even go through the process; so, that one went away. Then, the next thing

we did was, we wanted to make sure that the criterion of maturity of underlying technology is not the technology of the whole, but rather all of the technologies that are incorporated into particular specifications. So, we added components at the end. So, it's maturity of the underlying technology components.

And the next thing we did was, we split this implementation and deployment complexity into deployment and implementation that should say, I guess it didn't come out right in the translation again. What it actually says on your sheet that was distributed is, its implementation deployment complexity and operational complexity and in order for us to really use that low, moderate, high sail, we've actually rephrased both of these in terms of "ease of;" ease of deployment and implementation and ease of operations. And then the final thing that we did was, we added one to address intellectual property, which is how accessible the specification is, and liberal it's intellectual property policy might be.

So, looking at these, okay, we have... these are our criteria. So the next step, once we had our criteria, the next step is to identify attributes for each and then finally to define the metrics for each attribute. And this just gives you a progress report on where we are; we've defined, and agreed upon, attributes for both maturity of specification and maturity of underlying technology components and we've agreed upon metrics for both of those at this point. We have draft of everything else. We have a draft attributes, we have the draft metrics for every category and, appendix A, has all of our work to date, and I'm certainly not going to lead you through all of that, but I am distributing it to you because we would just welcome any comments that you have on our work so far. What happens right now is that we have an interrupt, and I entered our process as we were asked to review the RFI. So this... our progress on this roadmap has been interrupted for the RFI review, which I'll bring you up to date next on.

Okay, the Governance RFI, this slide depicts how our work has made it into the Governance RFI. First of all, in the historical part of the RFI, it refers to the summer camp activity and it talks about the recommendations that came out of that summer camp activity. Then, in section F of the RFI, it's entitled CTE processes and standards and implementation specifications classifications; this is exactly what we're working on. It talks about the interoperability conditions of trusted exchange and the classification process. And the RFI actually proposes to include a process for classifying technical specifications and implementation, technical standards and implementation specifications with respect to their readiness as national standards. It calls for an annual review and assessment process and, as I mentioned earlier, these three categories of specifications are now in the RFI; emerging, pilot and national.

This is the figure V-1 in the RFI and this is an ONC diagram that shows the interaction between maturity of a specification and adoptability. This is a nice and concise diagram that really shows how these attributes interact. In the maturity vertical you would see the maturity of the specifications and the maturity of the technology component and the market adoption; all three of those criteria collectively make up the maturity of the specification and the adoptability really comprises the ease of the implementation and deployment of a specification, the ease of operations and intellectual property. So, this shows how a standard actually can move through time, and as it matures and as it becomes more adoptable, it can move from an emerging standard to a pilot and to a national standard. And then question 63 asks "What is the best way that ONC could help facilitate this progress along the specter from an emerging standard to a national standard?"

In the technical standards and implementation specifications classification criteria section of the RFI, it does call for an annual process to identify, review and assess standards and implementation specification, it calls for objective criteria to assess when a standard or specification should be reclassified and it suggests that the Policy Committee would have a key role in prioritizing the needs; you recall my mentioned that need is no longer a criterion, but rather a sign to the Policy Committee to recommend when a need exists for a standard. And then the Standards Committee, it suggests, would have an integral role in advising ONC about how to classify technical standards and implementation specs. And again, we have two more questions about this: "Would the approach that is suggested here be effective for updating and refreshing interoperability CTEs?" You recall Steve talking about the three types of conditions, interoperability being one of them. And then question 65, "What types of criteria could be used for categorizing the standards and implementation specs for interoperability CTEs?" And obviously we would prefer criteria that are objective and quantifiable, and include metrics.

So, the RFI poses a total of 66 of these questions, similar to those I've given you here, and 22 of these questions have been assigned to the NwHIN Power Team to develop draft responses. So far we've completed 5 and I'll give you our responses to those 5 today. All of the other questions I've included in an appendix to this presentation. There are 7 of the 22 questions address specific technology standards, like transport, certificate discovery; 5 questions address policy and processes around selecting and classifying national standards and 10 of the questions more broadly address NwHIN governance policy. As we begin to discuss these 22 questions, we've come up with a couple of general comments; one of which you've heard me mention already, and the first one, I think, you've heard David mention as well, that it really doesn't effectively convey the overall end point or the overall vision for the NwHIN. It's difficult, you've heard in this dialogue today, it's difficult to really fit the pieces together and one of the reasons is this second point, is that the terminology used is not adequately defined.

The RFI uses three terms, validation, accreditation and certification; but it doesn't in a succinct way, define these terms and then... but it does say, at two different places, it says that validation encompasses both accreditation and certification, but it's not clear what. You heard me, in my comment earlier, in my mind, the validation seems to me to be more like a HIPAA audit, in that it seems to focus more on how you operate an NVE and certification seems to be more specific with respect to technology; but it's not laid out that way, it's not succinctly defined. And then the third thing is that the governance process described mixes both policy level requirements and processes and technical implementation level requirements and processes. We believe... we agree that both are necessary, but, mixing them together, and especially without defining the three different types of processes, really makes it hard to understand. Some CTEs seem to be too specific for governance, like the specific standards, they seem more for certification of implementation and, we think that the validation of NVEs against the governance policies should be separated from the certification of conformance against technical specifications. And as I point out here, we don't say that certification needs to be outside governance, that's not... we really haven't... we don't care; it's just that the processes of the two need to be made distinct.

Okay. The first question... I'm going to show you our five responses so far. The condition... a condition is a CTE, condition of trusted exchange. An NVE must operate it's services with high availability. And the question is: What standard of availability is appropriate? And our response is, that availability really is service specific. So, we don't think it would be realistic to specify a single availability level for everything, for all purposes that the NVEs would use for. And we also questioned whether there's really something that needs to be fixed here. We think, in this case and in others you'll hear me cover, that transparency may be more important than establishing a specific availability floor, because if you do establish a specific availability, it would indeed be a floor, it would need to be a floor, and yet there would be some services that would require much higher availability. So, we think actual publication of the actual measured availability over time would be a more effective CTE than pinpointing an availability number; making it transparent just how available your NVE is would bring us closer to achieving the real objective.

Questions 45 and 46 address condition, interoperability I-1, interoperability condition one, which is, the NVE must be able to facilitate secure electronic health information exchange in two circumstances; when the server and receiver are known and when the exchange occurs at the patient's direction. And the first question has to do with transport specifications and asks "What transport specifications should be adopted?" and the second asks about RESTful. You'll immediately note that both of these were part of our... can be tracked back to our recommendations from last summer. The first Power Team comment really has to do with the condition statement itself. We felt that this statement doesn't address all the reasonable circumstances for exchange and, it doesn't use language that's commonly used in other regulations. So, we think that these conditions, where it's appropriate to exchange health information, are specified elsewhere and really don't need to be specified in the governance regulation.

The second comment is that we feel that the trust fabric needs to be decoupled from the transport mechanisms. The transport standards shouldn't be specified in the governance regulation. As Wes talked about if you model the Governance RFI, the governance model, if you pattern it after what's done with EHR technology, what you would have is high level policy, governance policy, that would then be interpreted into specific criteria for assessing technology to support that policy and ultimately testing criteria... criteria for testing technology against what's needed. We do think that governance regulation should require transparency with respect to transport; in other words, it should say, an NVE should

publish what transport standards it supports and how it supports those protocols, but shouldn't dictate which protocols it supports. In fact we would note that even today there exist current protocols that are active in the health industry and are working quite well, that if they were published and made transparent so that you know what protocols they support and what they're used for, that would provide a real value to our industry.

As a general comment, the NVEs implementation of its transport specs, like direct, like SOAP, like REST we believe that should be certified through a process that is separate from the validation process. We think that certification and validation should be two separate things, and, as you'll notice at the end, even though both may be part of a single governance model, they should be two separate processes and as Arien pointed out, another consideration is that the specifications themselves are likely to be changed... change more often and more quickly than overall governance policy. So, if the two processes were separated, it would be easier to accommodate the different timing and changes between governance policy and technical specifications. The second question is, "If a secure RESTful transport were developed, should it be proposed in our same response?" Is it, the specifications of transport should be at a different level, it should be specified at a different level from overall governance policy. The

The condition, interoperability condition two is that the NVE must follow required standards for establishing and discovering digital certificates and then the question 27 has to do with DNS, Domain Name Service actually, and the Lightweight Directory Access Protocol and are they sufficient? We thought they are appropriate, but they aren't exclusive. There may be other ways to discover certificates and we know there are other ways of discovering certificates. So, we don't think that the governance regulation should be specific on what protocols are used for certificate discovery. We think that questions 45, which is the last one we talked about, 46 and 47 are all at a much more granular level than what we believe is appropriate for a governance regulation.

And then question 48, should the CTE require all participants engaged in the exchange to obtain a digital certificate that's consistent with the Federal Bridge? This question has actually been assigned to the Privacy and Security Tiger Team of the Policy Committee and they've done considerable work on this, so we kind of defer to them on that questions.

Okay, in Appendix A, I would remind you that Appendix A are the criteria and attributes and metrics that we have developed so far and we would welcome any thoughts, any review that you might want to give us on that. And then Appendix B. Appendix B are the RFI questions that we still have to address and I've split them into three topics really; the first topic is technology, and these are specific questions about what technologies should be used for patient discovery, matching queries and these questions have to do with the process for classifying and selecting standards and CTEs, directly related to the work of the Power Team. And then the third category, which these questions on this slide and the next have to do with, overall governance policy. So, the Power Team will be continuing to discuss these questions that have been assigned to us.

### **Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Dixie, it's Farzad. It seems that there are two potential policy thrusts of what you just presented. The first might be don't... not just a part of as governance regulation, but even as part of the governance framework; don't specify the specific protocols or standards whether for directory or for transports, just have transparency around that. That's one take-away someone could get and then I ask, and this is a question not just for you, but for the Standards Committee, whether that would make enough progress in terms of actually being able to have a marketplace where there's an assurance that if I have an NVE and you have an NVE, that they can talk to each other; not if I have a VHS NVE with an LDAP and I have to check to make sure that all those impedance mismatches can be counted. So that's one implication and the question for you, in terms of whether it would meet the goal, if we did it that way.

And the second question, or second implication, might be, okay, part of governance of the standards piece is part of the governance framework, but the level at which it is specified should not be at the regulatory cycle, it should be a function of either the accreditation organization or even the individual validating entities or testing bodies and the question I have there, if that is pursued, how do we make sure

that there is a syncing up between the standards that are developed not as part of the government regulatory process with the government regulatory process that we do have to have for the certification criteria and standards, and how do we make sure that if it's developed at these lower levels, that there won't be so much variability between how one validating entity chooses to do it; where would the point of governance be then, in this governance framework.

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

I don't think that we're saying that it needs to be outside regulation or that the standards should be up to the validation bodies, I don't think anybody is saying that. I think what we're saying is that the... and actually, this comment relates to both parts of your question, to really make progress quickly, it might be easier to validate an organization that comes in with their technology already certified by a certification body. You know the certification of the technology we see as very similar to EHR certification and EHR certification, the standards are in regulation; so, we're not saying it should be outside of regulation. We're saying that the high level governance policy, the real... the specific policies that are necessary to build that trust fabric to enable a nationwide health information exchange, should be at a... that should be specified, those policies should be specified at a higher level than these standards for technology implementations. And I think that if we had standards... let's say we have standards similar to EHRs, we have standards for patient matching, we don't have those yet, right? So we have standards for patient matching, we have different types of bodies that similar to EHR, similar to the organizations that certify EHRs, they would also certify patient matching algorithms and then when the NVE comes in to get validated, it says, oh, here's what I use, I use the direct protocol as specified in, and it cites the specification, and for patient matching, I use this certified implementation of patient matching that is consistent with these standards, and then the validation body has only to look at, you know, checks those off, technical implementation yup, yup, yup and then has only to look at whether that organization's operations are consistent with the policies.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Dixie, I understand the two separate processes, one for certification of standards, the other for accreditation of organizations as part of an overall governance framework, I get that. My question is, if it's not done... it's the standards part, the governance of the standards part, is not done through regulations, at what level and how does the Power Team propose that this be done. So, I think we all agree that we can't rely purely on the certification criteria developed as part of the EHR incentive program.

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

So you're not suggesting that we... well, just to be really clear, we are not saying that the standards piece should not be in part of the regulatory cycle, we're not saying that. But are you saying that?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I'm trying to understand what the... if it's not part of the regulatory cycle, where would it be, how would it be governed?

**Arien Malec – RelayHealth Clinical Solutions**

This is Arien and I think I've got an answer to that, or at least a set of criteria for an answer for that. There are at least two things that we want to happen; thing one, Farzad as you've suggested, is that certification criteria should be and need to be unambiguous and guarantee, at least with respect to the middleware to the transport, plug and play. And I think that's a non-negotiable desiderata, right? Thing two, as I think we're pointing out, is that because the standards, and in particular the implementation guidance, change in response to learnings in the field, in response to changes in technology, in response to innovation; there should be some mechanism that allows those implementation...that implementation guidance and if necessary, the underlying standard, to change or be replaced over time. And that process may need to move faster than the speed of regulation. And so that's really a question for: A. How fast the regulatory process can move and respond to changes on the ground and B. Just the practice of government process for... is it feasible to have a sub-regulatory body or sub-regulatory

organization that can do certification settings that's enforceable and transparent and meets all the other goals of government, and I think the right answer lies somewhere between those two constraints.

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

Farzad, how do you... do you envision, maybe I misunderstand, do you envision EHR standards to continue to be regulated as they are?

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

I don't think any alternative has been proposed in terms of the Meaningful use and certified criteria, that I'm aware of.

**John Halamka, MD, MS – Harvard Medical School**

Now if I could just summarize what ever....

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

But, it should be... I'm sorry.

**John Halamka, MD, MS – Harvard Medical School**

I was going to say, if I could just summarize everybody's concerns and thoughts, I mean, we recognize that for EHRs we have standards and certification which have specific constructs with both accreditation of bodies that do what I'll call standards validation testing and then those that do the certification process. Well one wonders, for these trusted network entities, there are policies, and it's sort of the policies are equivalent to your attestation to Meaningful use.

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

Yeah, yeah.

**John Halamka, MD, MS – Harvard Medical School**

And then there's standards and certification criteria, which are sort of analogous to the certification process, so Farzad, you sort of wonder can a network trusted entity on the one hand go through validators of technology and go through an attestation for trustworthiness in the exact same way that an EHR ends up going through those two processes.

**M**

Yes.

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

Yes, exactly.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

So, I think I understand. I think I understand the proposal that we not smush together, as we have posited validation to include both the policy organizational accreditation aspect as well as the technology standards testing certification aspect and that there should be two separate work screens with probably two separate frequencies or time... lifecycles for those two processes. The question that I'm trying to understand, based on the presentation, is whether... where, if the conditions... some of the conditions of trust are laid out, if we want to have at the end of the day, if it's a non-negotiable desiderata, as Arien said, that a validated entity be validated to interoperability and specific interoperability and even more specific potentially, but yet evolving standards; where should that... at what level in this process is it as a government regulatory or sub-regulatory process? Is it a function of the accreditation organization, is it a function of the testing bodies? How does consensus emerge and be substantiated around the evolving technology specific implementation technology standards? That's what we're struggling with, I think, and would love your...

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

That's...(indiscernible).

**Farzad Mostashari – Health and Human Services – Office of th National Coordinator for Health Information Technology**

... If it's not through the regulatory process, then where?

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

And what I'm suggesting is exactly using... John's analogy was right on target. I'm suggesting we add it to the same regulatory processes that we already have for EHRs, we add these standards to that and the certification of technology in that same mechanism that we have there.

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

Well just to note, those are through government regulations that are actually, have been on a two year frequency, so, just a note that it's not as flexible as may need to be flexible.

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

I think it's flexible enough. I mean when we talk about standards changing, the standards for exchange don't change any more frequently than the standards for EHRs, the frequency would be the same. So, they naturally would go together. The policy, if you look in any organization, the policy really doesn't change... the high level trust policies don't change that much over time.

**Wes Rishel – Gartner, Incorporated**

Yeah, this is Wes. I just want to speak for myself, partly because I've a spotty record of attending any of the particular subcommittee meetings, but, I think that over the history of ONC under the ARRA, ONC has carved out a role of coordination of standards work, filling in through the S&I framework, that which can't be achieved by coordination and a particularly nuanced approach to the regulations that require standards as demonstrated in the 2014 edition, and with regards to the I-CTEs, there's no question that I would like to see the work as it has come out, be carried forward and that's for two reasons. One, because I think it has... I think it will be proven to have been effective when we begin to operate under the 2014 edition; I probably could say that with the right tense in Latin better, but, you get the idea. And also because there is such a tangible interconnection between the interoperability standards for NVEs and for EHRs that it's hard to imagine a different process not creating enormous coordination problems.

For the notion that the validation... the accreditation of NVEs being parallel to the delivery of reports that demonstrate conformance with the meaningful use requirements, I don't think we have such a close parallel at this point. I don't think that the subject of the safeguard or policy CTEs are nearly as subject to quantification as the meaningful use requirements and therefore, I have some concern that we not be too glib about trying to establish a process that's parallel there. Accreditation, I think, does involve a direct examination of an organization, partly through some sort of questionnaire or standards submission and partly through evaluation of third party information about the entity that is seeking to be qualified as an NVE, and I don't know that we have worked out those. I know that there are organizations outside of government that purport to have worked those out, but I think we need to, in the regulation that may stem from this RFI, we need to establish a parallel process in the sense that there is an entity that either is writing regulations or is very tightly coordinated with regulations, that creates the conditions for trusted exchange and there is an entity that translates those into the specific procedures that will be used to examine an organization and that multiple entities be able to follow, be able to be accredited in the other kind of accreditation, to follow those directions to the extent that that process of validating... I'm sorry, of accrediting and NVE can follow the approach of meaningful use, in the sense of establishing criteria that are based on performance and measurable and therefore reportable. I think that would be a great serendipitous opportunity to simplify that process; but I wouldn't be willing to bet right now, based on what we know, that we can be as focused on operational reporting as meaningful use qualification is now. Thank you.

**John Halamka, MD, MS – Harvard Medical School**

And Wes, I was using it by analogy, so, it may very well be that as ONC takes this input, it may not be the same entities and same organizations that are performing the two discrete functions as do it for EHRs, so, it was just this notion that I think they've done a pretty good job in the EHR space, separating tasks and if they could, by analogy...

**Wes Rishel – Gartner, Incorporated**

Yeah, no, I agree and I think that it's absolutely mandatory that they use the same organization and people for the I-CTEs and that they learn... they make use of the lessons they have learned in getting this far with regards to the S and P CTEs.

**John Halamka, MD, MS – Harvard Medical School**

Great. Well...

**James Walker – Chief Information Officer – Geisinger Health System**

This is Jim...

**John Halamka, MD, MS – Harvard Medical School**

Yes Jim.

**James Walker – Chief Information Officer – Geisinger Health System**

Just one quick note about the analogy. Another reason to explore the possibility that structures that have worked for other things could work for this is that the question of face validity to the market and of their ability to understand it and actually do it once they believe it has face validity, will both be enhanced powerfully. If we can say this is similar to, there are differences and where they're appropriate, but this is similar to this process you've already gone through; so, we're not starting all over again, you have to do something completely different here than you have to do over there.

**John Halamka, MD, MS – Harvard Medical School**

Well it makes great sense. If you say, in the past you've worked with such organizations as CCHIT and the Drummond Group, and now there's a very similar process and you're working with ABC Company, and it's going to perform this at an HIE level as opposed to an EHR level, or something of that...

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

And I would also point out that a number of the... referring back to Wes' comment, that a number of the meaningful use criteria are not quantifiable and in fact, the whole 100% of the security one is an attestation.

**John Halamka, MD, MS – Harvard Medical School**

Good point.

**Walter Suarez, MD, MPH – Kaiser Permanente**

John, this is Walter, can I make a comment?

**John Halamka, MD, MS – Harvard Medical School**

Please.

**Walter Suarez, MD, MPH – Kaiser Permanente**

Yeah, it seems to me that we've been sort of going back and forth on a few terms and I wanted to just offer, maybe as a way of organizing a little bit the discussion, or at least the thinking the following: I think we're trying to... we're dealing with two things here, definition of standards and definition of the process by which the validation and verification and accreditation will happen. Let me mention about the definition of standards the following; I think we're dealing with four levels of different things here. The first level is what I call policy standards and implementation specifications and it might sound repetitive but let me just finish and others certainly can jump in; but the policy standards and implementation specifications I think

all of the CTEs are that and there are many others including all the HIPAA standards and implementation specifications there are, for the most part, and probably in all the cases, are policy standards. When you look at a HIPAA security implementation specification, the actual text says implement policies and procedures to do this, it maybe even says using national standards, but it doesn't actually prescribe the technical standard, which is the second level I want to mention. So, the first level, policy standards and implementation specifications.

The second level is what I call technical standards and implementation specifications. That is a separate set of things; the technical standard to do transport is there, the technical standard for the certificate is this. Different from the policy statement of condition I-2 for example, that says NVE must follow required standards for establishing and discovering digital certificate; that seems to be more of a policy standard. The third level is the certification criteria, and that is where, just like with EHRs, we have a defined set of certification criteria against which an EHR product in this case, but in the governance side would be an NVE organization or an organization wanting to become an NVE entity would be tested. That's the third level. And the fourth level is the testing procedures that the validator, the accreditor, the certifier whatever we call it, would be using to confirm, to verify that the entity is meeting the certification criteria using the technical standards and meeting the policy standards defined.

And so, back to the question that Farzad was asking, which things need to, or should go into a regulation which are defined by others... in my mind, certainly there are policy standards and implementation certification that needs to be defined at some level, at high level in regulation; there are certainly technical standards and implementation specifications that are already defined and need to be followed. There is no certification criteria offered in the RFI yet anyway, or at least as an RFI, for any of this and then there are certainly testing procedures that are not yet even thought of or developed necessarily. But, I think, considering those four levels might be helpful; and in some cases, there are only policy standards, there are no technical standards, for example, in the business practices, really there is no way of defining a technical standard to have an NVE meet the S-CTE that says, must send and receive any planned electronic exchange message without imposing financial preconditions; I mean, there's no technical necessarily, perhaps a technical standard. There probably are certification criteria to go along with that condition, VP-1, and there will be testing procedures to do the evaluation of that.

So, I wanted to just talk for that, because I think if we think in those four levels, and then map them against which ones should go in regulation, which ones should be a separate set of requirements defining sub-regulatory instruments or ways, it would be perhaps helpful. So, thank you.

#### **Jonathan Perlin – Hospital Corporation of America**

Okay. Well, I think that's been a very robust discussion and obviously very, very worthwhile and critical. But I think it's important that we move on to the next phase of the presentation and, John, back to you if you're there, otherwise we'll go right back to Dixie.

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

Jon, John probably has his phone muted.

#### **John Halamka, MD, MS – Harvard Medical School**

You're exactly right. I've been talking to air. That was exciting. Sorry about that. Anyway, I have said, so Dixie, did you have any closing comments on this so that we can move on to the Query Health section and recognize that we have given this robust input so far to ONC.

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

I did want to thank Walter for pointing out these four levels and to correct one thing, is that three of the four are in regulation currently; policy, technical standards and certification criteria are all three under regulation, with respect to EHRs.

#### **Walter Suarez, MD, MPH – Kaiser Permanente**

For EHRs yes, absolutely, I agree. Yeah.

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

That was helpful, but I'm ready to move on.

**John Halamka, MD, MS – Harvard Medical School**

Very good, well thank you. And Jon Perlin, you did point out the danger of using a handset for running a meeting like this. This is, in my new location, my speaker phone is still in storage, dangerous. Anyway, so let us move on to Rich Elmore and talk about Query Health, and as I gave that broad introduction this morning...

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

I think our Security one is next, right?

**John Halamka, MD, MS – Harvard Medical School**

Oh, sorry, you are correct. So yes, Dixie, let us go through your security one very briefly and then move on to Query Health, so we give Rich Elmore his time.

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

Yes, okay. A lot of this will be a repeat of the conversations we've had already. Let me see, I bet I have control again. So, this is the Privacy and Security Workgroup and we've already said there were 66 questions, the Privacy and Security Workgroup were not assigned nearly as many questions as the NWHIN Power Team, so, this shouldn't take quite as long. Most of the primary and secondary... although there are ten different CTEs that have to do with privacy and security, but most of them are at the policy level and were assigned to the Privacy and Security Tiger Team of the Policy Committee. And they did, throughout all the questions, they assigned certain as prioritized, which means take these on first and secondary, they said after you finish the prioritized questions, then address those; and in the Privacy and Security Workgroup, assigned one question to ourselves; it was one question that a lot of our work members were particularly interested in discussing, so we have addressed that one as well.

Moving right into our questions, I should point out that we're going to be presenting all of our responses here, but these responses still need to be reviewed by the workgroup members, so they aren't quite... we aren't ready to present them as their final version to the Committee. For each question you'll see to the left a P or an S and that just indicates whether it's a prioritized or a secondary question. Okay, the first one has to do with safeguard CTEs and the first safeguard CTE simply says, I know it looks very complex there, but what it's saying is that the HIPAA Security Rule has a number of implementation specifications and some of which are labeled required and others are labeled addressable. All of the standards in the security rule are required, but the implementation specifications under them are divided into those two categories. The addressable ones are still required, you can't just say no, that's not applicable and I'm not going to do it, but, you can implement them in a different way. So if you present an argument that says, I can implement this... I can meet the objective of this implementation specification in a different way, then you have addressed it. Okay, so they are proposing... this condition proposes to make all of those addressable required for an NVE.

And the question was, are there particularly addressable implementation specifications that should not be made required. And we, the group agreed that making these addressable implementation specs required would build trust and would reduce variability. By that we're just saying that you could... anybody... user of that NVE could automatically assume that that NVE had implemented all of those implementation specs. However, some of the implementation specs themselves...(indiscernible) so, we felt that to reduce the variability, we still may need standards and certification criteria to go along with those specifications. After our initial review of the addressable implementation specs, our workgroup didn't identify any that seemed unreasonable to require for an NVE and, as I say, these are not our final recommendations. We have... and at this point while discussing this particular question, our workgroup members brought up some strong concerns about the voluntary nature of the validation process and so that's the question, there is a question about that, and so that's the one that we assigned to ourselves. Walter, is there anything more you want mention about this?

**Walter Suarez, MD, MPH – Kaiser Permanente**

No, no, that's a good summary.

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

The next two slides, just for your... to make it easier for you, these are... we've listed in these tables all of the addressable implementation specifications; so, at your leisure, look at the descriptions and if you note some of these that you think would be unreasonable to require of an NVE, we would ask that you let us know and we would appreciate your feedback on that.

**Walter Suarez, MD, MPH – Kaiser Permanente**

Maybe just one point and to emphasize the comment I made earlier, you will read this and you will see that all of them are description of a policy type standard and implementation specification and, as Dixie mentioned, we thought, in some cases the statements are very generic and they then need a definition of what is then the technical standard and implementation specification that should be referenced in that policy, and what is the certification criteria; but, all of these are all really ultimately policy type implementation specifications.

**John Halamka, MD, MS – Harvard Medical School**

Very good and any comments that folks have on Dixie and Walter's work?

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

Well, we haven't finished it.

**Walter Suarez, MD, MPH – Kaiser Permanente**

We have a few more slides to share.

**John Halamka, MD, MS – Harvard Medical School**

Sure, go ahead, go ahead.

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

Okay. The second question, promise not to laugh too long here, the second question assigned was, are there other security frameworks or guidance that should be considered for the CTE? And in specific, should they leverage NISTIR 7497 security architecture design process for health information exchanges. If so, please also include the information about how it would be validated. The NISTIR 7497 focuses on the exchange architecture and the specifications, and it was developed before... well, several years ago, before the direct protocol was developed, and also before the exchange specifications had been modularized by the S&I framework. So, we feel that, and a couple of our members do use that document, so, we felt that it's good guidance for organizations that are implementing the exchange specs but we don't think it should be mentioned in (indiscernible). And, we also, as we mentioned in response to another question, we don't believe that governance regulation should be transport specific. But, we do think it's appropriate for ONC to make available, to make references to any applicable guidance that would help NVEs in meeting the CTEs.

Okay. The next condition, this is an interoperability condition, and this will look familiar to you because this one is one that was assigned to the NwHIN Power Team as well, that an NVE must be able to facilitate secure electronic exchange in the two circumstances. And the question was, what types of transport methods and standards should NVEs be able to support; should they support both SMTP and SOAP as well as... or should they also have to meet the translation XDR XDM specifications. Not surprisingly, perhaps because there are a couple of people who are on both the Power Team and the workgroup, this... but there are a number of workgroup members that aren't on the Power Team, and the workgroup members didn't think that it was appropriate for an NVE governance model to dictate the transport protocols that the NVEs should support. But, the governance model should be appropriate, regardless of the transport mechanism supported. In other words, the policies, the governance policies and the governance model should support any transports. And most importantly, the NVEs should be required to publish the protocols they support and the mechanisms they use to implement the protocols. And they also suggested that the governance specify a standard for publishing the protocols supported

and the mechanisms that are used; and we understand that there's some work under the S&I framework that is developing such a standard at this point.

Okay, interoperability condition 2 was then the NVE must follow required standards for establishing and discovering digital certificates and the question was, "Are the technical specifications DNS and L-DAP appropriate and sufficient. Again, this question was assigned to the NwHIN Power Team as a priority and to the Privacy and Security Workgroup for secondary review. The Privacy and Security Workgroup also concluded that the governance regulation should not include this level of detail. The Privacy and Security Workgroup also brought up the fact that the definition and scope and associated roles and responsibilities of validation, accreditation and certification are confusing and need to be clarified. And they ask the specific question of, what role some of the existing bodies, such as direct trust.org, the NwHIN coordinating committee, existing certificate authorities, the existing EHR technology certifiers, play in these activities. And we felt that the governance process needs to capitalize on the existing processes and services and, as Jim Walker mentioned before, the more commonalities, the more linkages we can put on existing processes and existing vocabulary, if you will, or terminology, the easier it will be for people to understand and accept.

Okay. The question here was, which CTEs would you revise or delete and why; and are there other CTEs not listed here that we should also consider. So, these next two slides, you have the safeguard CTEs in the left hand column and the workgroup's recommendations in the right hand column. The first one has to do with the addressability with the security rules, addressable, with making the addressable implementation specifications required; and we've already discussed that one. The second one we've suggested a revision in its wording, to make it clearer what is intended. This is one that it was... we felt that the writers of the RFI were not clear that they meant authenticated versus identity proofing and we felt that this first one, the one that exists, should be limited to authentication and it should be linked to a trusted root or trust anchor. And then we suggested as a new CTE, requiring that NVE implement an appropriate certificate policy that accounts for the identify proofing, the level of assurance it provides and how rights are authorized.

We noted that the third one, the provision of meaningful choice to individuals would not necessarily apply to every NVE, but I think that some of the discussion earlier today kind of helps clarify that, that these are not intended to be applicable to every NVE. The fourth one, we offered some rewording; just to make it clear that the responsibility of the NVE is to make sure that the IIHI is encrypted and whether the IIHI is encrypts it, or its encrypted elsewhere is not relevant, just to make it clear.

#### **Walter Suarez, MD, MPH – Kaiser Permanente**

Yeah, Dixie, very quickly one important point on that. When you read it as the way it's written in the rule, it gives the impression that the only, and the only thing that NVEs can exchange is encrypted IIHI and so we're just turning it into, they exchange a lot of other things, non-IIHI, IIHI and other things, but when the exchange IIHI, the expectation is that it will be exchanged in an encrypted manner. So, it's just a rewording to ensure that the impression is not that the one and only thing that NVEs can exchange is encrypted IIHI.

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

Thank you, thank you Walter. The fifth one says that the NVE must make publically available the notice of its data practices describing why IIHI is collected, how it's used and to whom and for what reason it's disclosed. But the NVE may not have a consumer-facing presence at all, and it may not collect IIHI at all, it just may be a channel from one covered entity to another. And the other recommendation is that the overarching governance authority should make these notices available for every validated NVE. So, we envision that the accreditor or the ONC or somebody will maintain a list of NVE that are validated and at the same place, they would have perhaps a link to their data practices, so that anybody, any consumer or any potential subscriber, could get to that.

#### **Walter Suarez, MD, MPH – Kaiser Permanente**

Dixie, very quickly on S-4, if you don't mind, I just noticed the word only should have also been deleted; otherwise it reads oddly.

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

Oh yeah, you're right. Yes.

**Walter Suarez, MD, MPH – Kaiser Permanente**

Just for the record there.

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

Good point, good point. We'll correct that with the version we distribute to the team for their review. The sixth CTE was that an NVE must not use or disclose de-identified health information to which it has access, for any commercial purpose. And we felt that this requirement goes beyond what the current HIPAA and HITECH policy regarding de-identified information goes, and we felt that the Tiger Team and ONC should discuss this, and I'm sure that they will. We also... it was noted, that having the statement focus only on de-identified information, give the impression that using and disclosing identified information is okay; so, in other words, it sounds like it must not use or disclose de-identified, but it can use or disclose identified just fine. So, that needs to be clarified.

Number seven we suggested revision that the NVE... it said, the NVE must operate its services with high availability and we again, this group thought that transparency of the actual availability was really important and that the NVE should be required to publish its actual availability and describe the method used to measure the availability. Number eight is, if an NVE assembles or aggregates health information that results in a unique set of IIHI, then it must provide individuals with electronic access to their unique set of IIHI. We had two problems with this one; the first had to do with resulting in a unique set of IIHI, we felt that defining a unique set would be nearly impossible and so we suggested just deleting that part of it.

We also had considerable discussion around assembling and aggregating health information, it was brought up that if a doctor gets emails through an NVE, they may choose to leave their... never delete any messages from their email, thereby the NVE would be aggregating health information and how do you clarify that that's not the intent here. But, we had no suggestion on how you clarify that. But the second suggestion is that we wanted to make it clear that the CTE is not requiring that an NVE provide a capability for individuals to directly access their repository of health information, but rather that if they do maintain and aggregate IIHI, then they have to provide individuals with an electronic copy of their unique set of IIHI and access to their IIHI. I think that's all we had to say about that. Number nine, if an NVE assembles or aggregates health information which results in a unique set of IIHI, this is the same comment, we recommend that that unique set be deleted and it should also be deleted from number eight, the second time it's mentioned. And number 10, we didn't get to. So, we didn't discuss number ten.

Okay, the next question was a primary, this is the question about should one or more of the performance and service specs implemented by the participants in the exchange be included in our proposed set of CTEs, if so, which ones and why and indicate your reasons for not including them in one or more CTEs. We had considerable discussion around the DURSA and we felt that the type of tight governance that's described in the DURSA is not likely to work on a national scale, that type of tight governance is really appropriate for closed and controlled community, but not for a national health information exchange, that includes both Federal agencies as well as private entities, and both large entities and small entities. So, we felt that the service level agreements like those contained or referenced by the DURSA may be appropriate within this tightly controlled type exchange, but that level of specificity is inappropriate for a national governance model. And, that we recommend that a governance model that requires NVEs to publish their SLAs and their performance against the SLAs would be what would be desired... yeah, service level agreements I've defined here.

This is the question that our workgroup was really interested in discussing, and so we volunteered our opinion. The question is question four is, "Would a voluntary validation approach as described above, in other words, in the RFI, sufficiently achieve the overall goals of a nationwide health information exchange. And the context is described there, but Steve has already given you the context, you know it's a voluntary... the exchange entities voluntarily subject themselves to being validated and they step up and say, I want to become an NVE, they're not required by regulation to be validated, although they are

required to be validated in order to call themselves an NVE. We felt that the key factor in building... the key factor for the success of a nationwide health information exchange is building a trust fabric to support that exchange and it needs to be very clear to everybody, both the exchange entities as well as their subscribers, that validation contributes to this goal and that the NVE validation is important.

Right now, people in the marketplace don't know, or have never of NVEs, and many, many people don't fully understand what the Nationwide Health Information Network is; and so there's a little bit of a branding challenge there. In order for the Nationwide Health Information Network itself, as well as the NVE branding to be really effective in building this trust fabric, that brand needs to be recognized as well as appreciated as having value. So, we need to make clear that NVE validation enables these exchanging parties to do things that without that validation, they couldn't do; and we think that the Federal partners are key here, and the RFI recognizes this. But the key partners really play a key role in making that happen. For example, if the VA and the CMS and the Military Health System all say that in order to exchange information through us... with us, you have to be using a validated NVE, that would go far in demonstrating the value of NVE validation. And really, the bottom line to it all is that the integrity of the validation process and the ongoing oversight and policy enforcement including the option to get kicked out, are critical to the success of a voluntary approach such as this. So Walter, I think that's the end of our slides.

**Walter Suarez, MD, MPH – Kaiser Permanente**

Yes, that's it.

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

Do you have any more to add?

**Walter Suarez, MD, MPH – Kaiser Permanente**

No, no.

**John Halamka, MD, MS – Harvard Medical School**

Very, very well done; yeoman's work on this. And so Dixie, what I heard in your presentation, over and over was, this notion that as we especially think of the scope of this whole governance process, adding a whole lot of layers of technical specificity in the governance is something that you found was a bit out of scope, but this notion that we talked about in our last section of separating what would be policy and attestation and making that sort of governance; whereas certification and standards which evolve at a different pace and have levels of technical complexity, might solve a lot of your issues.

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

Right.

**John Halamka, MD, MS – Harvard Medical School**

And then, of course, I saw lots of friendly amendments to language, offering appropriate clarifications. Now, I know Wes has a card up. So Wes, your comment.

**Wes Rishel – Gartner, Incorporated**

I just want to, what I hope is clarify a statement, if not, disagree with it. We talk about transport protocols and often what we mean is broadly direct versus exchange. However, those terms have a constellation of related thoughts that go to variations in policy, so that the policy requirements for enabling someone to send some IHI to another, known entity for the purpose of treatment, payment or operations, are quite different than the policy requirements necessary to enable ad hoc look up of IHI and, in fact, that's one of the main drivers for creating direct. I fear that an interpretation of the statement that the transport protocols shouldn't have different policy governance would be to say that the policy governance has to cover both and therefore, no organizations can do direct unless they also have the full policy conformance in order to do exchange. And, I think that would be defeating the purpose of direct. I think it's possible to have parallel policy criteria that can be matched to other CTEs without there being a direct translation to protocol, but if the P-CTEs and the S-CTEs don't have appropriate subsets that reduce the

challenge of implementing direct, when compared to the challenge of implementing exchange; we will have lost most of the benefit of direct.

**John Halamka, MD, MS – Harvard Medical School**

(Indiscernible).

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

I think a policy statement regarding transport really should speak to the trust fabric and not the transport protocol under it, and for both direct and exchange, their security and their trust fabric policy would be the same.

**Wes Rishel – Gartner, Incorporated**

I don't agree with the second. Let me just say, I don't agree with that statement.

**M**

Well Dixie, I'm not... maybe it's a terminology thing, but I thought that in your presentation you actually were pointing out, for example, patient choice, meaningful choice may not be relevant if the NVE is serving merely as a conduit between two covered entities. I think that's the kind of scenario clearly different use cases and I don't know if we can simplify the use cases by talking about their technical protocol, and I think that may be part of the problem here. Different use cases and architectures implicate different policy concerns.

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

Exactly.

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

This is David. I mean, I think it's sort of a modular approach, I hate to bring the modular word into this debate, but, if your capability includes patient look-up, you may have to meet a different set of policy requirements all the way up and down the stack to technical standards. If you also support direct, that might add in a different set of requirements and so forth. So, they are vertical in that each capability may in fact, involve some policy and even business constraints that have to be adhered to. It can't be layered strictly horizontally.

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

Yeah. Yes, it's...

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

This is Leslie, I have a question also, and I wonder if at the end of the... we've made things easier or not by ignoring the technical recommendations. Technology will always change, but the purpose of this governance is really to say, we have made some selections with which the nation can interoperate, and understand that those selections may evolve and therefore our policy can evolve. But, it seems that we could throw the baby out with the bathwater if we make such a distinction. Perhaps I'm not understanding this well enough, but, I am concerned that at the end of the day, have we made the situation better and easier? Or have we simply made it more confusing.

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

So, to clarify. We're not sepa... all we're doing is separating the standards and technologies and the policies into separate processes; we're by no means abandoning the standards here.

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

Right, in fact, we're calling for more. In the Privacy and Security Workgroup recommendations we just briefed, you'll notice that in that question regarding addressable (indiscernible) specifications, we actually recommended more, the need for more standards around those. So, by no means are we recommending fewer standards.

**Walter Suarez, MD, MPH – Kaiser Permanente**

The other part really is, and to Liz's point, the other part is there might be... the market and the standard and the industry might be at a point where choosing one over another is appropriate, but in some instances, it might not be yet at that point or, by choosing one over another might stifle evolutionary options and innovation. And so, one has to be very careful, I would make the statement, that if there is a selection of a particular protocol or particular say transport standard over another, while we don't... with the industry still evolving in this area, it might be more risky... at the point of yes, we might have a simpler solution because everybody now has to do this. Yes, that simplifies things, but then it also risks eliminating other innovative and perhaps even more effective and efficient ways of communicating and benefiting the patient. So, that's the challenge, is there is time when there is a clear maturity level of a standard that calls for yes, this should be the standard and there are times where things are still evolving and it's risky to select a standard over another.

**Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

And Walter, I agree...

**Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology**

This is Farzad. I just want to express that part of the concept that we are presenting in the RFI, with the different maturity levels, is a yes/and; that yes we need to move forward, yes we designated certain standards as part of the EHR certification program, yes we need to have governance that supports scaling both now, we don't want to keep hand-wringing. We're not hand-wringing, we know enough to move forward on some things and we need to pull with courage on those oars and get moving on the things that the die is cast on; but, we also want to be able to have room for innovation and so, one of the things, in terms of having these pilot and emerging and maturing standards around a concept was that the governance framework is not the governance regulations, understand distinction here, and provide an opportunity to mature and to try out and to signal progress around the next generation of standards. But, I think it's important to have a yes/and approach to this, that yes, we move forward on specific standards and make them more specific, where we can, where we know we can move, and yet we continue to explore it and innovate. But I don't think Walter you meant to stay in this gray zone, I think we have to move forward.

**John Halamka, MD, MS – Harvard Medical School**

So let me summarize all this so we do get to Query Health; which is, we've had some very valuable input over the last two hours. Arien just sent a nice, synthesized email to all of us as well, that basically there are a series of recommendations to have come out of our group discussion this morning and from Dixie's group and Walter's comments, that we effectively take this Governance RFI and parse it into two chunks, a policy chunk, which is more sort of like an attestation and a certification chunk, very similar to what we do with EHRs, where we do enforce very specific standards, eliminate gray zones, definitely don't want the ambiguity that we had with Stage 1; it's just by doing this decoupling we then enable the policy and the standards to evolve at different rates. Further, we have I think, common agreement that this may be a modular policy approach where it is going to be a different stack of policies if all you're doing is aggregating de-identified data versus providing a comprehensive pull model of maintaining master patient indices and record locator services so that although as Dixie has used the term trust fabric, certain certificate commonality may be true across all architectures, that there will be different policies, dependent upon the nature of what your module would do. And, I recognize lots of passion around this topic, but I hope that synthesis captured a lot of the ideas and, Steve Posnack and Farzad, you've been listening, so hopefully this provides good grist as you go for the revision of the RFI into, I presume, an NPRM.

**M**

Thank you.

### **John Halamka, MD, MS – Harvard Medical School**

So let us now give Rich Elmore and John Feikema their due on the S&I framework long term care work. So hey Rich Elmore, could you tell us about Query Health.

### **Alan Merritt – Altarum Institute**

Pardon the interruption. Please make sure that everyone has their phones on mute if you're not speaking, we're picking up a lot of background noise. Thank you.

### **Rich Elmore – Office of the National Coordinator**

Thanks John. This is Rich Elmore, I'll be providing an update on Query Health for about forty-five minutes, including discussion. John Feikema will be providing an update, a separate update on long term and post-acute care after that. With me for the Query Health update is Michael Buck, who is the Director for the Primary Care Information Project of the New York City Department of Public Health. He has also been the Query Health Clinical Workgroup leader and a very significant contributor to this project. And we want to give you an update on the proposed standards, the reference implementations and pilot activities that are going on around Distributed Population queries. Next slide please. We'll cover the scope, we're going to go over the standards, our progress in reference implementations; the pilots are going to be kicking off here shortly and kind of the implications for going forward and the potential impact that we see.

Next slide please. So, first of all, I just want to say there's been fantastic work that's been done; we have an amazing community around the Query Health Project, I've listed here. The risk of this is you always know somebody who's been an amazing contributor. So, I apologize in advance to whoever I forgot to list, but, listed here also especially are some folks who have gone above and beyond, in terms of thought leadership and leadership roles associated with the project. It's just been terrific work, as you'll see, as we go through this conversation. And I just wanted to call out all of the contributions we've gotten from the community; it was certainly very much appreciated.

Next slide please. The idea of Query Health is to enable a learning health system to understand aggregate population measures. Those are measures of health performance, disease, quality, all different kinds of aggregate measures, as you can imagine, while respecting patient privacy; so, trying to keep sending questions to the data sources, keeping patient information behind, at the data source, and using that as a foundation to be able to improve patient and population health and to be able to reduce costs. Next slide please. Distributed queries unambiguously define a population from the larger set; whether those questions are being sent to a clinical storefront, whether they're being sent to a complex health system, whether they're being sent to a payer's clinical record or many other clinical data sources, the idea is that a question can be sent, an aggregate result can be returned. The questions can be related to disease outbreaks, prevention activities. If we had good enough penetration of Query Health in data sources throughout the country, maybe even rare diseases, health research, comparative research, quality measures; all of these kinds of applications are potential candidates for use of Query Health.

Next slide please. The notion of this is of Distributed Query Networks that are voluntary, not centrally planned, so that there's voluntary collaboration between folks who want to ask a question and folks who want to be able to respond to that question in the community. You may find yourself as an organization, on the one hand, being a researcher asking a question in one network and a data source in yet another virtual network; so, that's the concept, it's not a top-down. There could be government use of this, but it is not a top-down, it is a virtual kind of approach to those query networks. Next slide please.

So, the Query Health reference... the standards and the reference implementation stack really is focusing on standardizing structure, standardizing on privacy and security aspects, standardizing on meaning and standardizing on the reference implementation services that are in support of those other standards. So we're going to talk about the standards for structure, about how you ask a question and how you send back results. We're going to talk about, from a privacy and security perspective, a standard around a query envelope kind of the pathetics container if you will, for sending a question or a response; the privacy and policy enablement layer tied to that, that has come from a lot of the guidance we got from the Privacy and Security Tiger Team and from the HIT Policy Committee. We're going to talk about meaning

as it relates to our clinical element data dictionary, the data target recommendations for clinical data, the sharing value sets recommendation that we're going to be using for accessing value sets and then the reference implementation services that will enable faster, easier, cheaper implementation of Query Health standards through some of the reference implementation work that's been done across three different established Distribute Query Systems including i2b2, PopMedNet and hQuery.

Next slide please. There are two levels of standards. The first is the Query Envelope and the policy requirements, which are applicable to any distributed Query; so that could be for administrative data, it could be for clinical data or for whatever purpose, and they can apply generally for those purposes. And then there are a second set of standards which we'll talk to, which are more related to a clinical data source in the way in which we fleshed them out thus far. And those are the specifications for the query, the data and the results. It is not to say that they are limited to that, it's certainly extensible through additional work to other areas, but that has been the focus of the project up to now. So what we're going to concentrate on is this first level of standards, which is Query Envelope and policy requirements for the next couple of charts. So, if you could move ahead to the next chart.

The Query Envelope is query agnostic and content agnostic and contains the Metadata that really facilitates the privacy guidance that we received from the HIT Policy Committee. For those of you that are interested in that, it is linked to off of the Query Health.org website. There is a RESTful interface specification to integrate the RI natively for this policy enablement layer and for the Query Envelope, and this policy enablement layer which comes out of some of the work that was done in a Distributed Query Solution called PopMedNet, which is the engine behind FDA Mini-Sentinel and the engine behind the HMO Research network, and the engine behind Massachusetts Department of Public Health, MDPH network, is the foundation for this policy enablement layer, which controls the data sources ability to say, "I will let this query in," or "I trust this person to send in a query," I'll process this query, I will decide whether or not I want to return a result back. And a couple distribute query options can also manage lowering data that is being sent back if there are small sub-considerations to be addressed.

Next slide please. Also related to this kind of general level is policy guidance that we implemented, that we got from the HIT Policy Committee and the Privacy and Security Tiger Team, that we implemented through our operations workgroup into this policy enablement layer, the Query Envelope itself that we talked about and then related parts that the operations workgroup came up with including a data use agreement template, which focuses on distributed queries and gives the foundation for how parties would work together to be able to ask and answer questions and put the appropriate agreements in place, with clarity about what the purposes of the questions that are being asked and answered. And then a guidelines document for many of the operational aspects, and there's a link to that, for those of you have access to the presentation when it's brought online on the HIT Standards Committee website, there's actually a link there that you can click to get to that document. Next slide please. The second level of standards, so then the first level was generic, right, that could apply to just about any kind of distributed query. The next level, as we have gotten so far, is focusing more on clinical data sources; so, EHRs, health information exchanges, personal health records, payer's clinical records, anything of that ilk that would be able to potentially implement these standards and be able to leverage these as a data source.

So, the next slide please. The first standard is the standard about how do you ask a question, and for that, the group made a recommendation and has fleshed out to an implementation guide, what we're calling new HQMF, to distinguish it from the current health quality measure format which is used for many of the quality measures that you may be familiar with. Now, there were some challenges with the health quality measure format we uncovered early in our work that we needed to improve upon. And so this new HQMF has been modified to support the needs of dynamic population queries to make it more executable, substantially simplified, which we'll see in a minute. And there are a lot of advantages for this kind of query approach. First of all, it avoids yet another standard problem, that you're always at risk of with a new standards project, and we're able to leverage work that's already been done for quality measures, we're able to extend it, improve it, simplify it and hopefully bring a broader community forward with this newly recommended, more parsimonious version of HQMF.

It's secure in the sense that you're not sending procedural code from a question to a data source, which has some sort of risk to it, it's declarative, so that a translation is being done at the data source to be able

to take that question into what's the right kind of logic and against the right kind of data targets and all the things you understand about your own system as a vendor, for example, of how you're going to be able to make that translation. So that's the idea, it's going to be able to work across a diverse set of platforms. We've done a lot of proof of concept work on that and are building that out in our reference implementation, and ultimately the idea is that it should significantly improve speed and reduce cost to be able to add data sources to existing Distributed Query Networks.

Next chart is a bit of an eye chart, but if you look, go to the next slide please, you can see on the left the existing HQMF, the example of how you'd describe a measurement period and on the right, how the same measurement period equals one year is described with new HQMFs. So, what we're really trying to say here is that we think that we've made a significant step forward in terms of parsimony, computability, where before there was more that was actually textual, this is what you need to do; now it's much more... much more of it is able to be processed automatically by a program, and it's expressive. What we've found is that there's a lot that we can do with it. There are probably some things we can't, but, it is a very, very powerful tool for the kinds of questions that may want to be asked.

Next chart. You of course need to have some understanding of what your data target is, and the clinical element data dictionary, which is an S&I ONC, standards and interoperability work product is really that data target; we built it as a standards independent dictionary. We've been working very closely with NQF and with Floyd, to make sure that it's aligned with QDM. We also are making sure that it's been built for a flexible response to evolving standards. So as new models evolve and there are different ways we may want to be able to describe those, we think that this foundational description of the clinical element data dictionary is going to be helpful to those efforts and one that'll be able to be responsive and adaptable to that.

Moving on to the next slide, the results, a much simpler problem than asking a question, but, nevertheless, you need a way to be able to send results back that identify and describe the patient populations or describe the population measures in response to the question that's being asked; and again, here trying to avoid yet another standard problem. There was some good work that has been done by CMS and by Lantana and by HL7, in the structured documents workgroup as it relates to category I of the quality reporting document architecture, and there was a vision for a category II and III, that we are working closely with them to be able to flesh out more fully, and we think that that's going to be a good foundation for being able to have the... an understandable way to be able to get the results back from a question which, in most cases, is going to be an aggregate answer, which is category III. And there is some HIT Policy Committee guidance, there are some public health exceptions, there are some audit exceptions for patient population level, so there is category II as well that deals with that. So, we're working very closely with HL7 and structured documents workgroup on this towards an upcoming ballot of both the new HQMF and new QRDA standards. We had a terrific meeting Doug Fridsma and Avinash Shanbhag over there at the May HL7 meeting, we're working hand-in-hand to move that forward.

Next slide please. So, concept mapping is an important area. We need consistently computable definitions for the basics of health care to be able to really express the kinds of questions we want to be able to ask, like type 2 diabetes, like angina, the list goes on of things that we don't have those starter sets today. Now, the advanced researchers will come up with their own words in describing it, but, we need those starter sets and I will say no more on this slide than, the Query Health community, by their earlier recommendations and comments, is fully supportive of the work that Jim Walker hopefully will get a chance to talk about and maybe Betsy as well, later today.

So, moving on to the next slide, kind of just a description of how this all works together. Next slide please. It starts with a query composition on the top left, where the query is composed using some, for example, i2b2 as a query composer, and it's visual drag and drop kind of approach to how you're going to compose a question; that's then translated behind the scenes into this new HQMF, sent through this policy enablement layer, you're now reading down here, on the left hand side, through the... and the question's inserted into query envelope. It goes to the receiving data source and there could be many receiving data sources, you're seeing one here. There's a translation back into kind of an execution language that's appropriate for the local system and actually, well, it's not shown here, there's actually an intermediate model that's exposed, that eliminates any, for those of you who have concerns about HL7

RIM, it really eliminates any of that from what the programs are working with, deals with a lot of the translation from the declarative to even more super-simplified than what you saw in the two HQMF comparisons; goes out to the clinical data sources, processes, comes back with a result and sends it back up the chain to a query results viewer. So that, in a nutshell, is the Query Health technical approach. If you look at the policy enablement layer, you can see a couple of points where a RESTful interface is specified; that is not a standard per se, but it is a way of facilitating easy adoption of this, and we think that's going to be very helpful to folks that are trying to do their own implementations.

On the next chart please, the reference implementations; there are three open source distributed query solutions that are in play here: i2b2, which is being used in around 60+ large health systems in the US here and Europe; PopMedNet which, as I mentioned earlier, is being used in a number of Distributor Query Networks here in the US; hQuery, which is the successor to some of the work that's been done out of PopHealth, very modern, kind of advanced internet based technology, search technology and what Query Health is doing here is it provides the standards overlay on top of what are proven solutions, it's standardizing the questions and responses and it's enabling that faster addition of data sources at lower costs. And so we think that this is an approach that really adds a real level of security, it adds that kind of privacy and policy control that we talked about earlier, and it's sustainable. So, if you think about it, we have sustainability in our relationship with HL7 for the standards, we have sustainability for the reference implementation and its use in real working Distributed Query Systems. And we have sustainability, as you're going to hear about in a minute, in real working Distributed Query Networks that are going to be applying this, as they move forward. So with that, I want to turn it over to Mike Buck, who is going to walk us through the Query Health Pilot work that is just starting.

**Michael Buck - Director for the Primary Care Information Project, New York City Department of Public Health and Query Health Clinical Workgroup Leader**

Great, thanks Rich. So to begin with, I will just give a brief introduction on all of the pilots that are here. We have a great group of folks throughout the country with a number of very interesting projects and initiatives, trying to use Query Health to solve real-world problems that matter to them in their jurisdiction. So, what I'll cover, you already heard from John Halamka, who spoke briefly at the beginning of the meeting about their work with the FDA Mini-Sentinel pilot site and Jeff Brown and their team at Beth Israel will be using the system to monitor drug use and medication effects in the community and very interested to see that pilot project kicking off here shortly, as well as the CDC has looked to expand on using... creating an interface with their Bio-Sense 2 data set that they've collected from sites throughout the country and setting up a Query Health queryable interface such that other jurisdictions can browse the information that's been collected from those data sets in a useable fashion, so looking to see where that will go.

The Massachusetts Department of Public Health, they've been working in aggregate data space for a while now with prior work with ESB and now with MDPHnet and looking to implement those standards for monitoring of disease conditions that are a particular interest for public health and monitoring in that space. And finally, the Mitre group with their hQuery platform that is kind of a second generation implementation from their PopHealth work that some of you may have heard about in the past. They will look to see what's kind of the robustness in the space of quality measures that can be represented using the Query Health protocols and standards, such that from Stage 2, how much of it can be measured in a uniform manner, much along the same veins of what they showed and were looking at with the PopHealth work. So, very interesting studies and have a lot of potential impact to really change and influence those projects in a meaningful way.

Go to the next slide. I'm going to now touch briefly on my particular pilot here in New York City and with my partners at the New York State Department of Health. For a number of years now we've using aggregate data to influence our policy and operational decisions here in the city, based upon of course the leadership from Farzad Mostashari when he was here, and subsequent folks that have been here since. There's been a lot of change in actually moving from what are great data sets, such as community health surveys and manual means of reporting and collection of information, which are great, but given the timeliness of how things change in a city as large as New York City, and the re-emphasis on health care reform, we really needed a system that would allow us to query and get aggregate data back quickly,

and so we've been exploring and over the last few years, developed a number of proprietary EHR solutions for doing aggregate data collection, which have been very successful, and have given us significant coverage in the ambulatory market. So, from what we've learned, having done a couple of them, of course is that in order to get complete coverage of the city, in order for us to be able to take the pulse of New York City, we needed a solution that could be applied generically across vendors and so, without continuing to do one-offs, this project hit us right at the right time, where we really needed a standard and so, we're stepping into this, our particular pilot looks to validate some of the usage of Query Health as a query mechanism by... in the next few months here in the summer, we'll look to deploy a Query Health instance based upon i2b2 and PopMedNet deployment on a number of primary care eClinicalWorks practices and learning some lessons learned from that, we will be able to feed that into building similar Query Health nodes at our RHIO institutions that are running on the Axolotl... systems platforms and being able to query these data sets will give us greater coverage not only for ambulatory but for the inpatient market sets that we'll be able to say monitor the obesity rates in the Bronx, or the diabetes treatment in Brooklyn and be able to aggregate that data across the city and produce maps of zones which might need greater intervention. So, it's exciting to see where this fits in operationally to our existing platforms and where we'll be able to expand this out rapidly and get not only vendor buy-in, but get organizational buy-in as we increase the coverage of the data that we have access to in this aggregate format.

Next slide. This is just a screen shot; quickly, based upon what we're calling the green CEDD, this is the ontology in i2b2 that we've created to represent the CEDD, it derives again from existing standards, much of it, the greening efforts of HL7, but also compatible with the consolidated CDA and Rich already mentioned its link to the QDM. So, this is the type of interface that a clinical staff person, without programming knowledge will be able to drag and drop and produce aggregate queries, will generate and go out in the standards, as previously described and return aggregate counts back to us to be able to influence our policy decisions. So, this is pilot's work that for me we'll be undertaking over the next few months and look to see this, hopefully this year, as we contract out with the RHIO vendors who are now building analytic platforms that aggregate the data across their various jurisdictions, we'll be able to send the queries out and get a real pulse of how the health of New York City really is in virtually real-time. So, very exciting, look forward to seeing how this turns out.

### **Rich Elmore – Office of the National Coordinator**

Mike, thanks a lot, and Mike's just been an amazing leader for this effort. So, thank you for all the efforts you put in and the direction you provided for the project. Will you go on to the next slide please. So here, the next steps. It's a bit of an eye chart, but basically there are three swim lanes, there's Query Health pilot timeline, which you see up at the top, and those are the pilots that Mike just spoke to. Then there's an HL7 ballot timeline in our coordinated work with the HL7 team with ONC to get that all ready and prepped for ballot. And then there's the reference implementation timeline, which is the development of the stitching together the standards, the overlay of the standards onto these Distribute Query Systems. We're real excited about that.

I want to take a minute just to mention the Clinical Quality Measures pilot, because I think to the point that was made earlier that, the timeline for Quality Measures is really long, I mean, it's two years to define a Quality Measure, it's probably five years from that point to be able to get it built, get it deployed and get answers coming back; and the reality is that if you had a dynamic query ability for Quality Measures, that would be very powerful; that would take that five years and bring it down to days, to weeks, and the impact on that, the ability to be able to refine a question and to be able to think differently about what you want to know based on what you've learned is really enabled. And so I think that a lot of these projects you're going to get different aspects of that and really excited about the quality of the group that we've put together, that the leadership that they're showing... that they've already shown, they're already doing this kind of work, and they're now helping us to figure out how to make these standards as good as possible through their pilot activities.

Next slide please. So, the idea here is that Query Health is delivering the standards and the reference implementation services for distributed population queries, there are kind of three threads; there's the standards, there's the distributed query solutions and then there are the query networks themselves.

We're implementing sustainability into each part of those, as part how we're moving them forward and we're really excited about that. We think this is a real game changer for how a healthcare community can begin to think about a lot of things. Quality measures, as we talked about a minute ago, this really ties to that Stage 3 vision of a learning health system, of a mechanism for knowing more about a population and to inform how you care for a patient. Health system performance, which is clearly on everybody's minds these days, population health disparities, rare diseases I think is a big one, comparative effectiveness and then, policies. A lot of times the policies that you can come up with are dependent on the tools that you have available and so, I think that having a distributed query capability, this could get broadly deployed into EHRs as part of this journey, the power of that could be phenomenal.

So, that is the update for the Standards Committee. I want to just also thank so many members of the Standards Committee who have contributed and provided guidance and direction on this. And, I'd like to open it up for questions and comments.

**Jonathan Perlin – Hospital Corporation of America**

Rich, this is Jon Perlin, I want to thank you and Mike Buck for just absolutely stunning work. It really does, I think your identification that it really is the basis for that sort of Stage 3 vision for a learning health system is absolutely terrific. We are running a little bit behind and I want to make sure that we give all topics full due; so at this moment, let's take this as primarily informational. What I'd like to recommend in today's remaining time, is that because it's also critically important and I want to make sure that it gets full due, is that we postpone the longitudinal coordination of care until our next meeting, but instead, at this moment, go to the Clinical Quality Workgroup for their update and then the vocabulary update and then talk about your presentation and those two items in aggregate. Unless I hear any objections from anyone, we'll proceed that way.

**John Halamka, MD, MS – Harvard Medical School**

And Jon, I completely agree, I was going to recommend the same thing; but thanks so much Rich for a very eloquent summary. We look forward to the pilots.

**John Feikema - Office of the National Coordinator**

This is John Feikema, just one quick word?

**Jonathan Perlin – Hospital Corporation of America**

Absolutely.

**John Feikema - Office of the National Coordinator**

I just wanted to recognize Rich, he's coming to the end here of a year sabbatical where he volunteered not only his time, but amazing leadership and this project is just one example of that and I thought it was important for this group to note that and to... I just wanted to get that out there publically.

**Jonathan Perlin – Hospital Corporation of America**

Well John, thank you very much. Mary Jo, we'd ask that the record formally reflect that recognition of Rich's work on behalf of the country by the Health IT Standards Committee.

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

Thank you, we will.

**Jonathan Perlin – Hospital Corporation of America**

Terrific. Okay, well that work and that presentation is a terrific segue to the to the ability to have data models that support more sophisticated approaches to advancing quality and with that, let's turn to Jim Walker.

**James Walker – Chief Information Officer – Geisinger Health System**

Thank you Jon. So, I'll try to get done in time that Betsy has her full allotted time. We have... next slide please. We have two Tiger Teams working in parallel now, and the first, the Essential Components team

is going to present recommendations today and then the second Tiger Team, that is identifying characteristics of quality measures, is hard at work and expecting to present some recommendations, I think, at the next meeting. Next slide. So, first just a quick thanks to the members of this team who have worked really well and hard to clarify some fairly tricky issues and come up with what really represents just about unanimous consent to some of these recommendations.

Next slide. So first I want to remind us of the scope, this is a very narrow scope of work for this set of recommendations, and that's just defined by the time needs. We needed to get a recommendation that would support Stage 2 early enough that all of the people who need to do everything else, based on it, would have time to work. And so this only addresses an infrastructure that would be critical for value sets that would support Stage 2, and specifically value set delivery and consumption; and I guess we probably should add validation in there. But, you will note, there are a whole lot of things that are not in the scope of this set of recommendations, and we plan to circle back to them just as soon as we finish this first bit of work.

Next slide please. This is a cartoon that is intended to make clear what we're going to be talking about today, you can see on the left there supposed to be sort of grayed out, is Phase 2, which we are not referring to today, and then on the right, Phase 1, is in view, and we want to talk about both curation of value sets and validation, and then delivery of value sets and obviously have in mind how those value sets would be consumed. You'll see at the bottom NLM and ONC on the curation side, NLM on the delivery side and then the various consumers indicated more illustratively than with any intention to be complete on their listing. Next slide then. Oh, I'm sorry, let's go back to that one. Then, rightly or wrongly, I thought it would be easier for us to think about the recommendations together if you had a word document in which all four of them were scanable together and so, if you can refer to the word document that came in the packet, it said something like letter May 24, I think. It has the four recommendations on it.

The first is that we recommend that NLM be established as the single authority for the validation of value sets, and you'll notice further on in this recommendation, we implicitly define what we mean by validation. But, it's probably worth noting that all of the participants on the team, including NLM, find this language clear and understandable, so, we hope you do. But that's worth discussing, perhaps. So, a single authority for the validation of value sets used in Stage 2 quality measures. NLM should serve as a single source of truth for the value sets and should publish periodic updates to reflect changes within the underlying vocabularies and/or changes made by value set stewards. So, the idea here obviously that the curation consists primarily in making sure that the value sets and the appropriate vocabulary, such as SNOMED and RxNorm and the others remain congruent with each other through time.

And then, the two bullets under that; that ONC should coordinate with other agencies, value set stewards and consensus organizations as needed for value set hosting and serving and delivery. So, that's sort of to be worked out and then NLM in that second bullet with cross-check the accuracy of Stage 2 quality measure value sets, comparing those value set codes and descriptors against appropriate source vocabularies to assess the value set validity, and there you the sort of implicit definition or maybe explicit, of what validation means in this context; and then suggest edits to the value set stewards so that things stay congruent. Okay, I don't know... I'm guessing maybe it's worth trying to do all four of them together and then have discussion after we've gone through all four. So, unless someone shouts out, I'm going to do that.

So recommendation two is that ONC should expedite the recommendations of previous workgroups, the Implementation Workgroup in January of 2012 and the Vocabulary Task Force in April of 2010 related to establishment of a publically available value set repository. As near as we could tell, and from the very excellent ONC staff work, those recommendations have been... that recommendation really, has been made twice; everyone believes it's still an appropriate recommendation, it's just one of those things that hasn't been executed yet, and so we recommend that that actually be executed now, so that Stage 2 has the support... so that the people trying to do Stage 2 really have access to those value sets in a standard and easy way.

Recommendation three is that that value set repository should build on the IHE sharing value sets SVS profile for storing and serving value sets and incorporates common terminology service 2 methods for managing vocabularies referenced by value sets and, I'm sorry, I don't remember if Chris Chute is on the call today, but, the stakeholders in both of those systems which are related to each other, agreed on this recommendation, in terms of how we use both of those assets.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

Yeah, Chris is on the call, thanks.

**James Walker – Chief Information Officer – Geisinger Health System**

Okay, thanks Chris, so when we get to comments, or maybe you want to say something now, I don't know.

**Christopher Chute – Mayo Foundation for Medical Education and Research**

No, that's fine.

**James Walker – Chief Information Officer – Geisinger Health System**

Okay. Then recommendation four is that we establish, and I believe the subject of this sentence is...I'm not sure who the subject is... I think the idea is that ONC would coordinate establishment of a web service for human and machine consumption of Meaningful Use 2 value sets. And as you see, the team identified a number of entities, one or more than one of which we thought would be appropriate to be the internet host for these validated value sets. And one of the things I should say, before I read the bullets, it probably has already occurred to you is that the one strong requirement that we emphasize is that if the repository appears in multiple places, that it should be mirrored or all should be referred to one instance, obviously so that the repository has one single and standard form rather than multiple.

So then the two bullets under that are, provide output in commonly used formats, and you see the specification, the different sorts of formats that different consumers might need to use the value sets and then support the creation of web-based views, based on quality measure and value set names and numerical identifiers. So the idea here is that it's easy to use, you could look up something meaningful to you, like a quality measure, and see the associated tools. So, I guess at this point Jon, it probably makes sense to go ahead and discuss these; the rest of the report is short and quick.

**Jonathan Perlin – Hospital Corporation of America**

I think that's right. Let's keep our comments very focused. Jim, you've keyed up four recommendations, let's get a sense of support or agreement with these recommendations from the group.

**John Halamka, MD, MS – Harvard Medical School**

And Jon Perlin, it may be that the group isn't completely familiar with the common terminology services standard set, so I just sent Mary Jo background that Chris Chute worked with me to prepare so that folks understand. This actually is a very common and simple way to do API calls, to get download, everything from simple word pairs to complete ontologies and, it's not as we had heard some other folks state today, inventing yet another new standard that we've never seen before.

**James Walker – Chief Information Officer – Geisinger Health System**

Thank you John.

**Jonathan Perlin – Hospital Corporation of America**

Terrific. That'll be great resource; with that, any comments for Jim and the workgroup?

**Stanley M. Huff – Intermountain Healthcare**

This is Stan Huff, just a quick agreement with the recommendations.

**Jonathan Perlin – Hospital Corporation of America**

Terrific, appreciated. Other comments?

**Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum**

This is Floyd Eisenberg. I just want to thank Jim for keeping the group together and coming up with a nice, concise summary. Thank you.

**Jonathan Perlin – Hospital Corporation of America**

Let me then ask the question, is there anybody who'd like to voice an objection to the recommendation or items that require any modification?

**Arien Malec – RelayHealth Clinical Solutions**

This is Arien and the... just to avoid the case where we make the recommendation a third time and nothing happens, I'm wondering whether we want also to ask for a.. to do a specific ask to ONC, to get back to the Standards Committee at some date certain with where this is going to go, and I understand that there's a lot of...there's an appropriations issue, there's infrastructure that needs to be deployed, but I think this is such an important recommendation that we need to be a little more directive in terms of... response back.

**James Walker – Chief Information Officer – Geisinger Health System**

Thank you Arien, we'll try to incorporate that.

**Jacob Reider, MD – Senior Policy Advisor – The Office of the National Coordinator for Health Information Technology**

And this is Jacob from ONC, we'd be happy to offer such feedback along with NLM and you may hear some of that from Betsy shortly.

**Jonathan Perlin – Hospital Corporation of America**

Terrific. So then we have recommendation to Arien's friendly amendment and positive response from ONC. Any other amendments, modifications? Okay, well hearing none, we will assume consensus with that modification from Arien and would also like to thank Jim, I know you have a couple more slides or comments you wanted to offer, but...

**James Walker – Chief Information Officer – Geisinger Health System**

Yes, it'll just take a couple of seconds. The other group is at work and I don't think there was anything else to say about that.

**Jonathan Perlin – Hospital Corporation of America**

Okay. Well then, kudos to the group, terrific, elegant synthesis of the work and obviously met with a great deal of support. It's great when pieces fit together, and obviously there was a linkage between Query Health and your report and the linkage between your report and Betsy Humphreys' report, and appreciate the continuing work that she's been doing, in terms of vocabulary and value sets... So Betsy, let me turn to you for your comments.

**Betsy Humphreys – Deputy Director - National Library of Medicine**

All right, can I just say to somebody who is in control, to advance my slides when they need to be advanced.

**Alan Merritt – Altarum Institute**

We'll so that, we'll take care of that.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Okay, fine. This report is essentially to update quickly on some developments in the vocabulary mapping type of thing that occurred since the last time I spoke to you, which is not all that long ago. Let me comment on the value sets matter, that there has been a lot of interaction between ONC and NLM about this, and I think that we both will be able to report back with not just another recommendation with nothing happening, but something actually happening pretty soon on it. However, if you'll go to the next slide, I

just wanted to say... give you an update on one thing; I had spoken to you before about the SNOMED CT to ICD-10 CM-Mapping which was released in late February, and the plan still we're on track for is to release a larger map in June. But, my colleague, Kin Wah Fung, received a great deal of interest in the demonstration tool of how you could use the map in a data creation environment and as a result of this, released in April, 2012, a fairly detailed implementation guide for it so that people can see what was done and potentially think about implementation something similar. The purpose of this map, just to distinguish it from the next one I'm going to mention, is essentially that this map will be updated as SNOMED CT and ICD-10 CM are updated and that we anticipate that it will be part of the capability that's built into systems that actually assist providers or professional coders in terms of generating appropriate statistics and bills from the EHR.

You can just quickly go through the next slide, I was just showing you this thing again. And then go on to the next one. Okay, so, I had mentioned, when I spoke to you last, that we were planning on releasing a mapping from ICD-9 CM to SNOMED CT and we had expected to release that in April; it actually came out in May. Basically it goes from the 8,300 or so ICD-9 CM codes that represent 90% of the use, based on 2009 data from CMS, both for inpatient and outpatient; and the purpose of this is an aid for one-time transition to use of SNOMED CT and problem lists for products or services where ICD-9 CM may be about the only thing that is stored now, to represent the patient problem... or the only codified information about the patient problem. So, this was very recently released and as with all of these things that we've put out, we'd be glad to get feedback on its utility and what we might do to make it even more useful. So, you can flip through the next slide as well, just to show it's not vaporware.

On to the next. So, there are two interesting developments related to the upcoming expansion of SNOMED CT and essentially the IHTSDO, International Health Terminology Standards Development Organization, which owns and maintains SNOMED, entered into an agreement in April with the Global Medical Device Nomenclature Agency, such that the GMDN vocabulary will form the basis for expanded medical device components within SNOMED CT and, the initial content from GMDN or based on GMDN, not fully modeled yet, but connected to SNOMED CT is going to be released as an extension to SNOMED CT in... and the planned release of this first path, is in August of 2012. So, this extension will be coming out after the regular July release of SNOMED CT. And the initial content coverage will be active GMDN concepts, not the obsolete ones, and it will exclude in vitro diagnostics.

So, if you'll go to the next one. Also very recently, the IHTSDO has signed an agreement with the American Dental Association, and under this agreement, all novel, that is the content that doesn't already come from SNOMED CT, which is in SNODENT, will be submitted for inclusion in SNOMED CT and that will come through via NLM as the US member of the IHTSDO and any content that is deemed not suitable for the International Release, because it may have US specific use or whatever, will then be incorporated into the US extension to SNOMED CT. And I think the initial editions are likely to appear in the July, 2012 release. I've been on travel, so some of this stuff I didn't get verified as precisely as I would have liked. But, I'll send you an update if that's not right.

The IHTSDO is forming a Dental SIG with the chair to be nominated by the President of the ADA and then to go through the normal IHTSDO approval procedure, and I can tell you that this development has been greeted with a fair amount of enthusiasm in many of the other international members of the IHTSDO that are looking forward to getting this ADA's content. And, I think that's it, in terms of what I was planning to present. We are working on getting the value set repository, validation, etcetera, organized and so I think that probably we'll be able to give you a lot more detail on that at a future meeting.

#### **Jonathan Perlin – Hospital Corporation of America**

Well thank you very much Betsy, as always, very thoughtful and concise presentation. Let's turn to the group for any comments on this or the previous two topics that you'd like to insert before we move to the public comment period.

#### **Leslie Kelly Hall – Senior Vice President for Policy for Healthwise**

Jon, this is Leslie and I have comments on the work that Rich did on Query Health and just additional kudos, but also would like to remind the group of our question that came from the patient engagement team which was, how do I compare; and a theme that was taken up by the group to say, can a patient get

patient specific information about how their care compares to national best practice as well as to that institution's practice. So, I leave that as a comment to say, we shouldn't forget the patient in these really terrific efforts of Query Health.

**Jonathan Perlin – Hospital Corporation of America**

Thank you very much for that most important insert there and let's make sure that as we thread forward, that your workgroup and this activity dovetail as when areas identify an opportunity for better support of patient and consumer. Any other comments for either Betsy, Jim or Rich?

**John Halamka, MD, MS – Harvard Medical School**

Betsy, this is John Halamka, and as you and I have been emailing, one of the key issues as we up this NLM curated repository and cross-maps, is that we all agree on one nomenclature per area of medicine. And I think we're very much there with regard to problem lists and medications and labs, and there may be some ongoing debate with regard to radiology and so, I just highlight that there has been some ongoing discussion of where LOINC is appropriate for radiology vocabulary and where SNOMED is appropriate for radiology vocabulary. Jon Perlin, not a comment that we need to resolve today, but just recognizing it's a placeholder for that common repository is going to have to have probably not two radiology vocabularies, but one.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

And also, to make sure that the work that the radiologists have done in terms of RadLex is linked in in a way that's positive and not duplicative. I actually feel that there's some real hope for rationality in this space and maybe we'll be able to report on that next time or the time after that, too.

**Jonathan Perlin – Hospital Corporation of America**

Right. Thank you. Well terrific. It's been a very robust discussion and I know we did not move to the discussion of the S9 initiative on long term and post-acute care. This is a hugely important topic. I appreciate (indiscernible) correspondence with John Feikema and just to denote to the Committee today that as ONC recently held a roundtable on long term and post-acute issues, and knowing that several Standards Committee members attended, let's make that part of a broader conversation at the start of our next meeting. So, John, I apologize for not getting to that today, I thought the discussion about NwHIN was critically important for two regards; one, inherently and two, some of the concepts that you're presentation would invoke are dependent on the interoperability that that presentation would provide. So, appreciate the robust discussion of the group and hope that's helpful in terms of having an even richer conversation about long term care and the continuity of information during our next Standards Committee meeting.

**John Derr – Golden Living, LLC**

Jonathan, this is John Derr, I appreciate that and just want to remind the group that maybe some of your staff might want to go to the LTPAC HIT summit on the 18<sup>th</sup> and 19<sup>th</sup>; Judy Murphy's keynote and Leslie's on it and I was at the S&I framework meeting and also on the roundtable and I wanted to thank Jim Walker for helping out on the roundtable a lot. So, we would like to have time for the other John to give his presentation at the next meeting on the 20<sup>th</sup> and expand that a little bit more so we can get a better understanding of where Stage 3 might be when we include LTPAC.

**Jonathan Perlin – Hospital Corporation of America**

Terrific, John. Any other thoughts in prelude to that discussion?

**John Feikema - Office of the National Coordinator**

No, that sounds great, thanks very much. We look forward to being able to present.

**Jonathan Perlin – Hospital Corporation of America**

Terrific. Thank you for your flexibility and John Derr, thank you as well for your comments. I want to also recognize Arien Malec, obviously there was a rich discussion around NwHIN and I think your email will serve both providing some clarity and summary as well as a basis for some continuing thought

development, as may help the efforts of the Standards Committee. Let me turn to John Halamka for any summary comments before we go to public comments. John?

**John Halamka, MD, MS – Harvard Medical School**

Well certainly. I'd like to thank everybody for the rich discussion that we had had this morning, which as Mary Jo Deering pointed out, all of us had thought it was going to be somewhat straightforward and it turned out to be quite rich and I hope what came out of that was a set of concepts that Arien had nicely summarized in his email, that we can use then as a basis for our ongoing discussion, which I'm sure will be as part of the Governance NPRM as next artifacts come out and we will converge to consensus. So thanks for all your hard work everybody.

**Jonathan Perlin – Hospital Corporation of America**

Terrific. And, with that in mind, let me add my thanks to you John, to all the members of the Standards Committee, to all of our colleagues who worked on all the workgroups in between; I think today's discussion demonstrated a huge amount of work, and to the members of the public who participate through their thoughtful comments and engagement throughout the entire process. Let me turn now to Mary Jo Deering, to invite members of the public to weigh in with any comments on today's discussion or any other input that they'd like to offer.

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

Thank you very much Jon. Operator, would you please open the lines for public comment.

**Alan Merritt – Altarum Institute**

If you'd like to make a public comment and your listening via your computer speakers, please dial 1-877-705-6006 and press \*1 or if you're listening via your telephone, you must press \*1 at this time to be entered into the queue. We do have a comment from Carol Bickford.

**Carol Bickford – American Nurses Association**

Carol Bickford from the American Nurses Association, thank you for a tremendous update on the Standards Committee conference call. One thing I'd like to invite you to do is update the acronym list and the glossary in light of the fact that we had numerous new terms identified today. It's most helpful for those of us who are popping in and popping out if there's a more robust location that we can actually find out what the latest terms are. Thank you.

**Jonathan Perlin – Hospital Corporation of America**

Thank you for that. Mary Jo, are there additional comments?

**Alan Merritt – Altarum Institute**

We have no further comments at this time.

**Jonathan Perlin – Hospital Corporation of America**

Okay, well then, I appreciate particularly the comment on acronyms. One of my colleagues invented the term PACS and it's not the image management that you may be thinking of, it's Progressive Acronym Confusion Syndrome. So, for those of us suffering from PACS, thank you very much for that reminder, because indeed there were many new acronyms; hopefully, that is simple testament to the amount of work and productivity by everyone. Wish everybody a happy, healthy, safe, enjoyable Memorial Day; hope that you do have a chance during that Memorial Day, not only to have fun, but to reflect on those who serve our country in so many capacities and thank you all very, very much, and the Office of the National Coordinator for all the great, hard work and accomplishment. I personally am very proud and I think today's discussion topics demonstrate that the work has moved really from theory into a basis to begin to realize the third stage of objectives, the better health, better value, better care. That's something to celebrate. So many thanks, we stand adjourned.

**John Halamka, MD, MS – Harvard Medical School**

Thank you.

## **Public Comment Received During the Meeting**

1. Arguments have come up that if an Exchange is not Meaningful Use Certified, then they are not a valid delivery model of the Population Health Files for Meaningful Use, could this ability be included in their validation process?
2. This is supposed to be a public process with transparency. Why is the committee sharing emails that the public can not access during this meeting? I believe this is a FACA violation.
3. An unrelated question, when is stage 2 guidelines expected to be released?
4. Where is that acronym list hosted?