

HIT Standards Committee
Draft Transcript
June 20, 2012

Presentation

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

And welcome to the thirty-seventh meeting of this Committee. It is a public meeting and there will be an opportunity for the public to offer comments both in person or online at the end of the call. I will ask all the members around the table to please identify yourselves when speaking for the transcript and thank you very much. I'm going to begin by taking the roll. Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America

Good morning.

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

I'm 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 Clinic College of Medicine

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

Good morning.

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

John Derr.

John Derr – Golden Living, LLC

Present.

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

Carol Diamond? Lorraine Doo? Floyd Eisenberg?

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

Present.

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

Jaime Ferguson?

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

Present.

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

Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Present.

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

C. Martin Harris?

C. Martin Harris – Cleveland Clinic Foundation

Present.

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

Stan Huff?

Stanley M. Huff – Intermountain Healthcare

Here.

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

Kevin Hutchison? Liz Johnson?

Elizabeth Johnson – Tenet Healthcare Corporation – 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

Rebecca Kush, I know, is caught in traffic. Arien Malec?

Arien Malec – RelayHealth Clinical Solutions

I'm on the phone.

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

David McCallie?

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

Good morning.

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

Nancy Orvis?

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

I'm on the phone.

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

Thank you Nancy. Marc Overhage?

Marc Overhage – Siemens Healthcare

Yes, good morning.

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

Wes Rishel ... Chuck Romine? Cris Ross?

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

Here.

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

Walter Suarez? Sharon Terry? Jim Walker?

James Walker – Geisinger Health System – Chief Information Officer

Here.

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

Okay, thank you. Back to you Jon.

Jonathan Perlin – Hospital Corporation of America

Good morning everybody, and thank you very much for being here, and thank you Mary Jo and the Office of the National Coordinator, as always, for stellar support of our meeting. Let me begin by turning the podium over to Judy Murphy, the Deputy National Coordinator. We appreciate your presence here and your leadership, as well as your shared history with this Committee. So, good morning Judy.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs and Policy

Yeah, thank you, good morning. It's good to be back home. I haven't been able to come to too many of the Standards meetings, so this is great. Well, I'm going to start out with fun stuff. Some of you, I'm sure, keep track of the different announcements that come out of ONC, and the first announcement that I'd like to talk about is the hundred thousand mark. I think maybe you know that as recently as about three to four months ago, both CMS and ONC set a goal of a hundred thousand providers attesting to meaningful use, and we have now surpassed that goal as of the end of May. In fact, the numbers are a hundred and ten thousand eligible professionals have actually been paid; so, very, very, very exciting, represents about 20% of the practicing professionals. And in the hospital space...(applause) yes, thank you. I think it's a tribute to the work of all of you guys and all of the people on the phone and our industry. In fact, I'll take a pause there and say, I continue to be amazed as I extend my reach in this space from my own little reality back in Wisconsin and then my tenure on the Standards Committee, to the role that I have now where I really get exposed to a lot more different kinds of organizations. I continue to be so impressed by the passion actually that most of the people in our industry approach their work and the volunteerism. In fact, I'll pause again and say thank you to all of you one more time for your service on this committee, it is just amazing the work that we've been able to get done.

So going back to the statistics from the hospital space, we have two thousand, four hundred eligible hospitals who have received payment, and that represents 48% of the hospitals, and that includes critical access hospitals, so that's really quite exciting. The total paid out is 5.7 billion dollars. So that being the case, another really exciting statistic is our regional extension centers. They're important because one of the things as we think about meaningful use is we don't want to increase our disparities; meaning the haves and have nots; and our urban or large medical centers and hospitals being able to achieve meaningful use and get electronic health records implemented and maybe our smaller hospitals, our rural hospitals, our critical access hospitals not being able to do that. So the regional extension centers have played a key role with the critical access hospitals, the rural hospitals as well as the rural providers and the small practice providers. And in fact, as of May, the regional extension centers have been working with one hundred and thirty-three thousand primary care providers and ten thousand specialists; so a total of 143,000 of our potential eligible professionals are working with our regional extension centers.

And I think that's another piece of work that I was a little less familiar with when I was on the Standards Committee and looking at that now, one of the reasons I'm excited about the regional extension center work is really around the proliferation, well identification and proliferation of best practices. So really looking at what it takes to implement an electronic health record, particularly in small practices, and what are the barriers and then how do you overcome the barriers. So, shameless advertisement in this space; a lot of the work of the regional extension centers of the past was sort of hidden on a website that was available to the regional extension centers only, it was the HITRC or the health information technology resource center. That information is being opened up now and put on HealthIT.gov under the professionals tab, and in fact within the next thirty days, all of the information that is appropriate to be ported for public consumption will have been moved over. So please pay attention to HealthIT.gov, lots of wonderful resources that have been identified through the regional extension centers that are being put under that first tab, that gold tab, the professionals tab.

In fact, I think that you all know, Mary Jo, I'm assuming you've announced this at some point in the past, that the materials for this meeting are also migrating to this website, under the red tab, did you ever talk about that yet? Okay. So, we're migrating the materials from the HealthIT.HHS.gov website; you probably all know, you go to that website and you click and you click and you click and you click and you get to what you need. Well this is going to be a few less clickety-clicks and it's going to be on the third tab, or the red tab, which is the policymaker/informatician/regulator/you guys. So all of the information for the Health IT community if you will and not so much the public at large, although it's certainly open to the public, will be on that red tab. And that also is being ported over as we speak. It's actually going to be linked back and forth for some period of time; I don't think we've actually identified when we're going to "turn off" the original spigot, do either of you guys know? Yeah. So, it'll be continue to be linked, so if you go in with your bookmark the way you always have, you'll still be able to get to it, but it's going to link actually to the other website, okay. So pay attention to that eventually and change your bookmark eventually, too.

Okay, so just a couple of other things that I wanted to highlight; as we think about the year of meaningful use 2012, and our fabulous statistics in terms of adoption, and it is really, really, really exciting. Of course we're turning to many other things, not the least of which is thinking about Stage 2, which I know you've had a couple of meetings about already and been spending a good amount of your time and also looking at the Governance RFI; and I know there's going to be some discussion about that today. Comments by the way on that I think are due in at the end of this month. If you recall, we extended that, so June 29, I believe, was the final date to get those comments in. In addition to that, of course, turning to Stage 3; and so Policy Committee is spending a fair amount of time right now, starting to think about Stage 3. We've got some of our specialty organizations, some of the working groups starting to look at what are some of the things that they want to make sure and get on the radar, if you will, of the Meaningful Use Workgroup, as well as the Policy Committee, as well as you guys. So, these windows seem to shrink forever, but if you've got ideas about what we should be looking at for Stage 3, make sure and start to bring those forward. I know that we are talking about Stage 3, doing a significant amount of work actually this fall. Okay, that was a correction; the RFI closed on May 29th; so, no further comment. Yeah, no I think it is June, Mary Jo, because we extended it.

W

...very much.

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

My apologies, misreading the body language in this room.

Judy Murphy, RN, FACMI, FHIMSS, FAAN - Office of the National Coordinator for Health IT - Deputy National Coordinator for Programs and Policy

No problem. Everybody was like, is that true? I'm pretty sure that that was true. Yes, all right, so it's always good to get things straight, and thank you for clarifying, Mary Jo, very, very, very important. Okay, so as we start to think about Stage 3, not only get that on your radar and start to think about things to bring forward, and I know again we've got some communities that have been doing that. The one I'm most aware of is one that's near and dear to all of your hearts because there's a gentleman at our table who has been very consistently reminding us about that community and that's John Derr and the LTPAC community. I know that they've got a fair amount of work that they're doing to bring forth some comments about the kinds of things that they think might be important in Stage 3.

Which brings up this whole area of disparities again and making sure that as we go forward, that we're aware of all the different communities that we're impacting; I talked about rural, talked about LTPAC, certainly there are areas, as we think about where electronic health records, also are; things about behavioral health, things like the criminal justice system and really making sure that we have the right levers in place for the implementation of electronic health records in those places. Even though in many cases, some of those folks, like criminal justice, are not specifically in the meaningful use program, because they're not part of the Medicare and Medicaid Program. We still want to look at our touch points and make sure that when we think about all the different areas that healthcare touches, and where healthcare information is collected, that we don't forget those people. School system is certainly another really good example.

So as we've been thinking about these Stage 3 activities, and I know you've been aware of this; the idea that the Policy and Standards Committee are working a bit more together and not as sequential. There's more of an iterative process, kind of a hand off back and forth, and I think that's been really, really, really helpful and a good signal of that were the two joint hearings that were held just last week. And so kudos to you all, I know that again was another trip to Washington, DC and a fair amount of work reading all that testimony and listening, and so one more time, I thank you so much. And last but not least, as we think about the future, is interoperability in health data exchange. And again, as has always been the case, a good chunk of your agenda this afternoon is going to be designated, if you will, for an update from Doug in terms of where we're at with the S&I Initiative, where we're planning on going. I know many of you around the table have been not only aware of the work, but concerned about the ability to get those standards out quick enough to meet what we need for Stage 2 to meet what we need for Stage 3 and so Doug will be giving a really robust update this afternoon. So with that, I will turn it back over our Chairs, to Jon and John. Thanks guys.

Jonathan Perlin – Hospital Corporation of America

Thank you so much Judy, terrific update. By way of introductory comments, I think very symmetric with what I've been thinking about this morning. It is interesting to note that this is our thirty-seventh meeting because when one looks at the agenda for today's meeting, it's a meeting that could not have happened, it's an agenda that could not have been contemplated thirty-seven meetings ago; because it transcends the sort of internally focused hospital and provider, office-centric build, to really the capacity for interoperable health information. That's why I think today's agenda is so exciting, the topics, some of them...and let me just add my great appreciation to so many again, I'm sitting next to Dixie Baker and I really appreciate the diligence with which you went through the remaining questions on the Governance RFI and to all who participated in that. I look forward to the report back on and the opportunity to formally close this phase of activity around those comments.

As we move to really an agenda that begins to instantiate capacity for interoperability, the capacity to realize the information flow and transitions of care. I do want to make sure...I want to echo Judy your comments that the last item on today's agenda, which I want to make sure that we start right on time, has to do with long term care. And when one thinks of both the needs of patients in long term care environment, the opportunity to support providers, the delicacy of transitions of the humans who are the individuals who move from one environment to the other. This is a critically important topic and one that look forward to John Feikema and John Derr providing a report back to us on. It's also a meeting where we address topics that are coming into their own right as well. I want to thank Marjorie Rallins and Leslie Kelly Hall, the hearings on clinical quality and patient-generated data are really terrific. And as I previewed the material, it's great to see that information coming to us in a form that we can imagine working with and really building into the health record and appreciate the really thoughtfulness of the way that you've framed the information to bring patient and consumer input and allow it to deport to our activities.

There are a couple of other sort of business items that if I could address. John Halamka, I want to thank you, Mary Jo and MacKenzie for keeping us on track in terms of a broader set of activities, a work plan that really framed our activities. All of us collectively made a commitment to look at radiology as an area that we know we must address. Simultaneously we heard from Judy that not only is this a point in time where collectively our committee, the Standards Committee, has been working with Stage 2, we note the proposed Rule is under review and hopefully coming towards completion. But that means that Stage 3 is pending as well. One can imagine that the Policy Committee will be asking guidance, they've asked for a closer working relationship, absolutely terrific, so that we're more sequentially locked into both the desire of what's intended as well as the technical capacity to support the intent and that's terrific as well.

I say that because while it may feel weather-wise like July or August in Washington here in June, during the heat wave, I think we have to contemplate what our calendars will look like and I appreciate not only the participation at the events between the events, such as the hearings, but also the travel to Washington. A number of you have asked before the meeting, what are we likely anticipating, and just by way of some of the logistics; so, July is an in-person meeting. I don't think we can, either on the basis of calendar events or on the basis of the work load, arbitrarily say that every other month is virtual. But we want to have an eye toward your efficiency, the Office of the National Coordinator's efficiency; but we are hoping that the August meeting might be virtual, thought if there's a lot of work in coordination with the Policy Committee, I think we'd have to reconsider that and I appreciate everyone's sort of forbearance. That said, as we look to the calendar for the remainder of the year, that every other month sounds good in theory; but a number of you have mentioned that kid's going off to college in August or one of your personal calendar events, Thanksgiving travel becomes more difficult, kids returning; other obligations, holiday travel. And so it may make sense, notwithstanding work demands otherwise, that those types of months be the ones that are more virtual. So, we'll try to be rational about this and I appreciate Mary Jo and MacKenzie trying to give us as many cues as early as possible because I know what a commitment it is from each of you to the work of the group.

I think it's just terrific also to see the maturation of activities within the Office of the National Coordinator, greatly look forward to Doug Fridsma's presentation on S&I. As well Judy, I thank you very much for the consolidation of web resources. What I realize is that our blue button is red and that will be terrific to have a one-stop shop for all the resources, as well as to the intent of the Federal Advisory Committee, the availability in a concise manner to all the public who also so thoughtfully contribute to this important process.

So with that, let me turn to...oh, I'm sorry let me ask you for completing our first action item of the day which is approval of the minutes. Once again, I appreciate the great work of the National Coordinator in a very thoughtful rendition of last month's discussions and open the floor for any corrections, amendments, modifications. Hearing none, we'll assume consensus on that, and move on with the day. And with that, I'd like to turn to my co-chair, John Halamka, for his comments as well. Good morning John.

John Halamka, MD, MS – Harvard Medical School

Well thank you and good morning everybody. So, like many of you I have one life, the volunteer life, in the policy world, but the other life in the trenches, actually implementing what we decide. And so as a CIO, I'm ultimately accountable for everything, though I have authority over little. And when I look at today's agenda, to your point, so many of the things we're going to work on today and for the rest of the summer, are those things that I actually need to make this real. So the state of Massachusetts will announce in the next few days, that it has a series of procurements it will award for state health information exchange connecting every provider to every provider by the end of this year. And it will be the procurement of those direct gateways, the certificate management, the provider directories, that goes beyond some of the regional HIE activity we've had over the last 15 years. So as we actually did those procurements, well, what did we need? Well, it turns out we needed a Governance RFI, in a sense, because we could deal with the direct standards; the S&I framework and the direct project have given us that, but who do we trust, and under what conditions do we allow them to be members of our gateway? And of course, everyone in the state of Massachusetts said, well should we invent this ourselves and I said no, we'll get the output of Dixie's work and we will get a wise set of guidance from the Federal Government which we can inherit.

Well, yesterday we had a discussion that would be I think use that Leslie would find interesting, which is if we are going to exchange data among every provider in the Commonwealth, how do we achieve meaningful consent? And, I don't mean meaningful use, I mean meaningful consent and the term that Jodi probably you coined, and one of the questions that was asked was, if any patient and family can have a say as to where their data goes, for what purpose and when, maybe we need patient-generated data around meaningful consent. And so I said again, similarly, we have workgroups that are going to come up with some policies and procedures as to what structured data a patient could provide under what circumstance that would be quite empowering as part of an ongoing consent process.

So all the pieces, policy and technology, are falling into place in the Commonwealth of Massachusetts because of the work on today's agenda. So, we'll get the RFI stuff that we need, we will get some early reports on patient-generated data, as well as we need to incorporate vocabularies and code sets into all of our health information exchange. We will not invent locally code sets and vocabularies; we look forward to the day when the National Library of Medicine curates and makes available for free downloads of all these things, as we've been asking for for two years; you'll hear from Jaime updates on that dream. And this Committee has expressed some concern, and we've had several phone calls about the role of the S&I framework going forward, how it articulates with this Committee, how it articulates with the standards development organization.

So, you'll hear from Doug, given that our funds do expire in 2013; what will the S&I framework do, what will it work on, what are its areas of focus, how does it articulate with this Committee and the most important aspect of Doug's presentation is asking for your advice, so he'll tell you where we are and where those initiatives are going and the new initiatives to come. But we want to really make sure that this Committee helps guide priorities, helps make sure that we give input on the standards gaps and then when there are big questions of where standards harmonization is going, the US realm is going, that this Committee weighs in. So, I look forward to that presentation. And then finally, for John Derr's benefit, I was asked last night, should the state of Massachusetts come up with a fund to fill the gaps for long term care and behavioral health where meaningful use does not provide incentives. And I said, the Federal Government should do that...the long term care issue, as everyone around the table today has said, isn't a local issue, it is a national issue and so we look forward to your comments, because like Medicare Part D has a donut hole, meaningful use has a donut hole, we need to fill that. So, look forward to today's agenda and making it real.

Jonathan Perlin – Hospital Corporation of America

Thank you very much John, and with that, why don't we dive right in to the agenda. As is on the agenda, our first topic is the comments on the Governance RFI and again, many thanks to Dixie Baker and as she relocates there, I'd ask the committee, particularly with respect to the presenter's later in the afternoon, the discussions, one of which has been deferred more than once, that we not try to re-litigate all of the comments, but if there are constructive amplifications, let's focus on those. And with that, let me turn to Dixie Baker.

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

Okay. I think I'm going to be here a while. All right. Clicker's here. All right, I have two presentations for you this morning. Both of them have to do with the recommendations around the NWHIN Governance Request For Information. The first set of questions that I'll report to you are the recommendations and comments from the Nationwide Health Information Network Power Team and the second will be the recommendations of the Privacy and Security Workgroup. So, you have here the members of our Power Team, and I want to thank all the members for their participation, not only in the RFI review, but also in...as you know, we're...our real charter is to develop metrics for evaluating standards readiness...specifications readiness for national standards, so, we'll return to that afterwards.

I want to start out, I know that a lot of people on this Committee may not have read the RFI to the detail that the people on the Nationwide Health Information Network Power Team have, and so I wanted to just start off with a brief context refresher to convey what the RFI actually is proposing, and this is basically what Steve Posnack reported for an hour last month, but I'm trying to reduce it to a single slide, with animation. So first of all you have the ONC will select a single accreditation body, and that accreditation body will accredit multiple validation bodies. And these validation bodies will validate what the RFI calls the Nationwide Health Information Network Validated Entity, or an NVE. And NVE and validation body, those two are really important for you to remember in our comments, because a number of our comments refer to them.

Then the ONC will endorse and adopt a number of conditions for trusted exchange, or CTE. That's your second acronym that you need to memorize; NVE NwHIN Validated Entity; CTE, a condition for trusted exchange. And then these CTEs are really requirements, sets of requirements that the validation bodies use to validate the NVEs. And of course the NVEs are the exchange nodes that enable providers to exchange health information among themselves. And then...that was John's hand...the ONC will also administer a readiness classification process, which is really the process that the NwHIN Power Team has been discussing and that we've been reporting back to you. All that work, actually made it's way into the RFI and so that readiness classification process is the process that assesses the readiness of the technical standards and implementation specifications to become national standards for the interoperability CTEs or conditions for trusted exchange. And then ONC will oversee the entire process. So, everything within that gray box that you see on the screen, is the governance process covered within the RFI. And it will do that with advisement from the Federal Advisory Committees, the Policy Committee and the Standards Committee. So, you may want to mark this page for future reference, just in case you get lost among the alphabet soup. The most likely to get confusing are the validation bodies and the NVEs; remember, the NVEs are the ones that are the exchange nodes and the validating bodies are those that validate those nodes.

So, with that, the RFI proposes three categories of conditions for trusted exchange. There are ten safeguard CTEs, there are three interoperability CTEs and those interoperability CTEs are the ones for which the technical standards and implementation specifications will be prescribed, and then there are three what they call business practices CTEs. All of the CTEs are provided in Appendix A of your handout today, but I'm not going to go through them in detail; but they are provided there. The RFI poses a total of sixty-six questions, twenty-two of those questions were assigned to the Nationwide Health Information Network Power Team to address. And I assigned these twenty-two questions to three categories; eight questions really dealt with the broad NwHIN Governance Policy; six questions dealt with this policy and process for selecting national standards and CTEs and eight questions addressed technology standards to support the CTEs. And I'm going to begin by presenting one overarching recommendation that really sets the stage for all of the other, all of the specific comments and recommendations that will follow. So, if you agree with us on that overarching recommendation, the rest should be pretty easy to work through. If you don't, we may be here for a while.

Okay, first to start with our overarching comments and recommendations...this slide I'm showing now really are some observations that we made. First is that a core value of the Nationwide Health Information Network and of the NVEs is a trust fabric, and that preserving this core trust fabric is essential, or this trust framework some people refer to it as, is essential to the success of the NwHIN. So we believe that the safeguard CTEs should be top-level trust principles that should persist over time. So these top level trust principles should not change often, and they shouldn't change, there should not be very frequent additions or deletions, they really should be pretty persistent trust principles that are essential for maintaining that trust fabric of the Nationwide Health Information Network. However, we believe that the interoperability CTEs will be influenced by market evolution to a much greater extent than these fundamental safeguards, and we believe that innovation should be allowed to happen from the bottom up, and that this top to bottom filtering should be avoided, to allow innovation and allow evolution of the interop...and strengthening of the interoperability. We also believe that the NwHIN governance should be light-handed, establishing and preserving the trust should be its core function, while enabling and fostering innovation in the marketplace. And finally, we want to point out that even a voluntary process can have a profound effect on business if NVEs and their subscribers are denied a meaningful choice. And by that what we're referring to is that just about every healthcare organization will need to exchange information with Federal agencies. And if those Federal agencies, as we expect them to do, say, we want you to use NVEs for these exchanges, and in fact we want them to do. It's really important that the constraints and requirements around becoming a validated NVE be...allow...not overly interfere with the marketplace and exchanges in the marketplace.

So, our recommendations. First, we believe that the ONC should establish these core safeguard CTEs and codify those CTEs in a Federal Regulation. And we believe that only these core safeguard CTEs, these trust...ones that are essential for developing and maintaining the trust fabric, should be in regulation. We believe that the interoperability CTEs should be established collaboratively by the validation bodies, with oversight from the ONC and the accreditation body. This is not to say that these interoperability CTEs should be outside governance, but rather that they shouldn't be codified in a regulation themselves, so that they require update each time an interoperability CTE is changed or added or deleted. And then finally, we think that the governance over the business practices should be achieved primarily through transparency; transparency of business practices and transparency of their measured performance against agreed upon service levels. And we believe that the NVE oversight should be responsible for addressing any anti-competitive practices that inhibit free-flowing data exchange without imposing absolute requirements through CTEs. So, that's our overarching recommendation and I'd like to pause here, to just allow you to absorb that, ask questions about it, make comments about it.

John Halamka, MD, MS – Harvard Medical School

So during our last meeting, we had this discussion that the process of governance should in some ways mirror the division that we have for meaningful use itself; the idea that you have a certification body that oversees the technical standards and the function, and then you attest that you are using the products in a meaningful way. So in effect, what you've done in this slide is codify our discussion from the last meeting, I think, by saying, oh actually, in a sense the safeguards are like attestation, you know, there's a big global principle that you're doing things right, whereas the interoperability is more along the lines of having the certification, the technical wherewithal, which will evolve probably fairly rapidly, and change over time and decouple those two principles. Is that correct?

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

No, not necessarily. We believe that the validation against the CTEs can take a number of forms, attestation may be one of them. But, there may be testing of the safeguard CTEs as well; like there could be testing of whether you can use a digital certificate to authenticate yourself as an entity. So, it could be testing; what we are saying is that as far as the regulation, the document that you have on your bookcase, the regulation itself, the only CTEs that should be in that regulation are those that are essential for establishing and maintaining the trust fabric. And all of the other interoperability CTEs should really be maintained, should be managed and maintained by the validating bodies collaboratively among themselves. And again, when they validate an NVE against those interoperability CTEs, they can use attestation in some cases, they might use testing in some cases; the difference is not attestation or not, the difference is whether it's in the document or not.

John Halamka, MD, MS – Harvard Medical School

But the notion of decoupling and allowing technology to move faster than principles...

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

...right...

John Halamka, MD, MS – Harvard Medical School

...what you codify, then the only other question I have on this slide is, thought it interesting that you said that the interoperability CTEs should be established collaboratively by the validation bodies rather than this Committee, ONC, an NPRM which results in a final rule and that sort of thing; and I presume you did that so that you allow this agility...

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

That's right. And if we go back to this, my wonderful picture here, this process, I think this is a...this process of figuring out what standards and interoperability specifications need to be assessed, and even the assessment process of their readiness for national standards, is still overseen by the ONC and involves the FACAs, right. But really figuring out, well we need a new interoperability CTE would be this collaboration among the validation bodies. So, identifying interoperability CTEs is really a collaboration among the validation bodies, with oversight by the ONC. Is that clearer?

John Halamka, MD, MS – Harvard Medical School

It is.

Jonathan Perlin – Hospital Corporation of America

We have a number of cards up. David McCallie, were you trying to signal in originally?

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

Yes, I was just going to offer to Dixie that something that we didn't really discuss in the group, but that would fit this model is that the business practice CTEs could be thought of analogously to the interoperability CTEs, that there may, in fact, be subsets and evolution of those, in a more fluid and what was your word Jon that you used, agile, yeah, thank you, agile way...parallel.

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

Good point.

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

We didn't address that specifically, but I think it fits.

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

Yeah, we did talk about and weave and have a slide that says how the validation bodies would establish the metrics to be reported through the transparency. Yeah...good point.

Jonathan Perlin – Hospital Corporation of America

I'm going to go next to Jodi Daniel, because there may be a matter of facts from ONC that we want to weigh in with.

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

So, this is actually very helpful in understanding your kind of big picture thinking about what we put forward, so I really appreciate the work of you Dixie and this group, in helping us think this through. I guess my question is, one, I'm curious more about what is meant by oversight from ONC and the accreditation body, what your thinking was there and I guess my second question is, if we look at validation as sort of a gold star that we may tack on other...we may tie to other programs or provisions or meaningful use or things like that, how do we make sure that it's aligned with the meaningful use requirements and the standard certification rules and things like that, if we do, as suggested in the second bullet, of leaving interoperability CTEs to the validation bodies. I just want to understand the thinking more on how that would work.

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

Well we certainly aren't...we know that there are interoperability standards that are in the meaningful use, obviously, right. We aren't suggesting we back out of those, right, but moving forward, we believe that interoperability CTEs really should not be codified in regulation, they should be really managed at a lower level. As far as oversight, as far as actually this whole recommendation's quite consistent with the RFI. This is not different from what's proposed in the RFI, and the RFI itself recommends oversight of the whole process by the ONC. So, we didn't talk about how our oversight might differ from the oversight in the RFI. And as far as I recall, it's not really defined at any further level than the ONC will provide oversight. Does anybody else remember any details beyond that? Or do you Jodi?

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

I was just trying to understand what your thinking was there.

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

Yes, exactly what the RFI says, ONC will provide oversight, that's what we meant.

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

And my third question's on the last large bullet, on business practices. Are there things...one of, obviously we're trying promote trusted exchange and make sure that information can flow to where and when it is needed. Are there...were there any discussion about, you talk about like NVE oversight, you seem to address anti-competitive practices or inhibiting the free flow of data, would you expect that there would be some like high level principles in our rule that would then be iterate...or kind of where the details would be fleshed out by the NVE, or we would just be silent on that; what is your thinking on that?

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

The high principles regarding trust fabric yes, would be codified in the CTE...

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

...and would that include things like not having anti-competitive practices or inhibiting the free flow of data, or is it just the more targeted security...

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

...more targeted to security and the trust fabric...

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

Okay.

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

Right. And we also talked about how the ONC might provide...would be expected to actually, to provide guidance and recommendations, you'll see that in some of our specific recommendations. But, for example, if you look at the business practices, it says, "the NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE." That's an example of one that exists in the RFI, and that's an example of one that we would see push down, not in the governance...not in the codified in regulation, but rather be pushed down and the validating bodies in collaboration, would establish this is, any kind of anti-competitive action that it saw out there, it would step forward to try to stop that. But it wouldn't be codified that you can't charge a fee in the law itself.

Jonathan Perlin – Hospital Corporation of America

It looks like, David. To put this to the question or where Dixie asked for amplification?

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

Just to Jodi's question. So, for example, we were concerned that the RFI asked specific questions about specific protocols that make sense today, Direct and Exchange, but we can't imagine that there won't be other useful protocols emerging in the future, perhaps with different business constraints around how they work. So, there could be fee-for-service kinds of things that take part in the trusted nature of the network, but are really different from today's vision of Direct and Exchange. And we just wanted to make sure that that flexibility was preserved somehow, with governance, whatever public-private means.

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

Thank you.

Jonathan Perlin – Hospital Corporation of America

So let's go to Leslie Kelly Hall, then Jim Walker, then Cris Ross.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

So, building upon the comments from David, one of the discussion items we had in this group last time, was the idea of a floor. Because we are initiating something new, to have perhaps some specifications on the technology up front would either a time delimited...this is good for a certain amount of time, but to offer up this process without specific direction and standards like whether it's Direct and Exchange as initially, do we run the risk of having this just flounder, rather than accelerate. So, is there a potential compromise that says we will specify floor, or recommend specifications of a floor technology, understanding that that can evolve, either that something evolves under the name of that technology over a period of time, for instance, when we specify a particular standard in HL7, that standard has its own evolving nature. So, could you speak to that floor; because I think there was a considerable amount of concern that without identifying a floor, we end up getting nothing.

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

Well, going back to Jodi's comment, we have a floor, you know, we have meaningful use and we don't mean to interfere with moving towards Stage 3 meaningful use, right. But, and in my opinion, this is...that's the floor. You know, the floor is being established, Stage 2 has use Direct, we expect perhaps Stage 3 might have REST and Exchange. Stage 2 has Exchange as an option. So, we have a floor, we have a number of interoperability specifications that are already codified in meaningful use; so it's not like we're throwing everything out, we're saying, we're establishing a floor through meaningful use, but moving forward on the governance, we really think that the emphasis and primary function of the ONC should be to preserve the trust framework and not to continue to manage at a very detailed level exactly which protocols are used. And you'll see some examples in our detailed comments.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Just to follow up, so but at some point in time if we do our jobs well, we work meaningful use out of a job and so, how do we continue if we have 100% adoption and market forces take over, how do we make sure that we're anchoring the structure to ongoing technology in the event that there isn't a meaningful use agenda in a future date.

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

Well do you think, once we achieve meaningful use, that the private sector will suddenly say, ha, government's gone away, we're not going to exchange information anymore? That's not...it's the momentum of the marketplace that we think will sustain this.

Jonathan Perlin – Hospital Corporation of America

Let's actually take a look back and dovetail to ONC, Doug Fridsma?

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

Thanks. Dixie, I just have a question, one that I think that was listed in the RFI was sort of this notion of the NwHIN technical specifications as a big tent, in that there were things that were ready for national roll-out, there were things that were in sort of regional or sub-national pilots, and things that were recognized as emerging standards as well. The idea there was that potentially things that were ready for national roll-out might show up in regulation, but there would be other ways to coordinate around those things that are going to be in the pipeline that need to be harmonized, that need additional work that needs to happen. I wondered if you could sort of comment on that in relationship of this sort of sub-regulatory framework and are there pieces that would still be needed to help organize and manage that piece?

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

Absolutely. And we portray that here, right? That readiness classification process there is exactly what you're talking about, right. And we perceive that to continue to happen, but that it would be done...you know, the ONC might recommend that that readiness process look at certain specifications, but that it be done in collaboration with the validation bodies.

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

So, and this kind of goes back to some discussions that...around how do we, in the long term, kind of create the organization or the structure around the standards that the United States adopts for healthcare information exchange. I know that with HITSP there used to be this notion that you could approve or kind of adopt a standard, you might be able to recommend one, you might be able to acknowledge...there might be gradations that allow for that; and so I wondered if the committee had had any discussion about that as well.

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

...for acceptance and recognition, a two-stage process for those who are involved...

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

That's right, and we would, you know, not all standards come from the Federal government, right?

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

Right.

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

Quite a few standards come from...

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

One would hope that they don't all come from the Federal government.

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

Right, and that's what we're acknowledging. You know, that a CTE that comes from the validation...from the collaboration of the validation bodies is no less part of the validation process. It still, and you'll see in our comments we say that, if the validation body collaboration decides on an interoperability CTE, it's part of the validation process and you can't become an NVE unless you are validated against those core CTEs. So, they're no less part of the validation, it's just that they aren't in the document that's on your shelf.

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

Good. Okay. Thank you.

Jonathan Perlin – Hospital Corporation of America

There are a number of cards up, so we'll go back to our order there, Jim Walker, then Cris Ross, then Jaime Ferguson, Anne Castro and Wes Rishel.

James Walker – Geisinger Health System – Chief Information Officer

So, I'm not sure quite how to...great work, as always Dixie. The second bullet on that slide, interoperability CTEs established by validation bodies with oversight by two different bodies doesn't sound very agile. I guess you considered and discarded the idea of having the accreditation body be where that is done with oversight from ONC and advice from validation bodies?

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

We didn't talk about that. We didn't consider that, right.

James Walker – Geisinger Health System – Chief Information Officer

It just sounds like this would be very hard to get anything out of as a process.

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

Yeah, David.

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

...our understanding of the proposed role of the accreditation body was fairly decoupled and removed from what goes on in the real world. So, we sought to push as much kind of hands on to the validation bodies, and they're essentially like trade organizations that would ensure that within the scope of what their focused on, you'd have interoperability and appropriate business practices, because the accreditation body is...I mean the example given was ANSI, I think, I mean they're not going to be worried about the details of the next version of direct or something. They're just way far away...

James Walker – Geisinger Health System – Chief Information Officer

Fine, but then you need a governing structure for the validation bodies and who's going to bring together and why would they come and...it just seems to me that there are a whole set of governance issues about that kind of structure.

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

And I agree, it's the ambiguity of what is public/private, how does that work in the real world?

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

And we are not recommending, I want to make it real clear, that this validation...the development of the CTEs by the validating...through collaboration of the validation bodies be outside governance; it's not, we're not recommending that at all. It's still within governance, but it's pushed down from the regulatory framework.

John Halamka, MD, MS – Harvard Medical School

To the point that Jim has made and David has made about the role of ANSI and our certification bodies. in effect, ANSI comes up with some straightforward rules to evaluate that a certification body is doing a good job. But ANSI isn't attempting to make the certification criteria, it's really outside of its scope. And so in a sense, you're using that same type of analogy here.

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

Exactly. Right, good.

Jonathan Perlin – Hospital Corporation of America

Okay, well thank you for that. Let's see Jim, we're going to go to Cris Ross.

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

Thank you. So, I think Dixie has done a fantastic job leading this group; I've been on a couple of groups that have looked at the RFI and I think it's been helpful that we've tried to create a higher level context as opposed to addressing each question individually. The one piece that I would add to Dixie's summary, I think that was context to a lot of our conversations is, what's the nature of the thing being regulated. Whereas meaningful use is aimed at eligible providers and eligible hospitals, where we understand what those are and they've been in existence for many, many decades. And the certification rules apply to EHR vendors, which have been around for twenty, thirty, forty years. An NVE is a brand new thing that we don't know much about. We don't know what they're going to be, we don't know how many there are going to be, we don't know if they're going to be non-profits or for profit, we just don't know a lot of things.

And so there were some instances in the RFI that seemed to presume one of two things, one of which is regulation was really necessary in order to create an industry, which makes me nervous. And the second is, there needs to be a high level of regulation, presuming almost a mature industry; so there are things in the RFI around things like price controls and required service levels, where we don't even know what these industries are going to be. So I think that it's important to put that context in place that we're trying to put regulations in place in pace with an industry that doesn't even exist yet. And so, this, I think well thought through and nuanced set of trying to get the right level of locality and right level of specificity felt to me to be really appropriate as we walked through that as a workgroup, and tried to think about real life cases. So, I just think if we're not thinking about the maturity of the industry in the same way that the Power Team thought about maturity and readiness of fit for different protocols, we should be thinking the same thing about the industry. So, I'm pleased with this, I think our other presumption is that this regulation is not a one and done, that hopefully the NPRM on Governance will not be the last word and that there would be evolution of that; perhaps in the same fashion as meaningful use is walked through stages.

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

Yeah, good point. Thank you. We should capture those in our comments. Good point.

Jonathan Perlin – Hospital Corporation of America

Jaime Ferguson.

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

Thanks. So Dixie, I certainly agree with the recommendation that the interoperability conditions should not be fixed in regulatory text or anything like that, but my question is about something that we've talked about here in the Committee before, is the relationship of the validation and those interoperability conditions to the Federal requirements of the Technology Transfer Act, which just as a reminder, requires all Federal agencies to participate in voluntary private sector consensus standards bodies and requires all Federal agencies to use voluntary consensus standards from those bodies, unless there's a good reason not to. And so, it appears to me that the RFI would create new agents of ONC that clearly are not private sector voluntary consensus bodies, and I think similar to S&I, which also is a Federal agent, it seems that that's in conflict with that direction to use the private sector consensus standards and so, what's the relationship that you see of the validation bodies to the use of those voluntary consensus standards.

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

Well I think this is consistent with that because the standards, the CTE standards that would be developed by the validation bodies collaboratively, would be private sector consensus standards...consensus standards, pardon me.

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

So you see the validation bodies as private sector consensus standards organizations?

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

Yes. Yes.

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

Wow, I do not. I just...fundamentally it doesn't seem that...

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

...because what's the...

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

...this is essentially an extension of a federal agency, it's not a standards organization.

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

They will be private-sector bodies, that was pretty clear in the RFI. I don't know, other people on the Power Team if you'd like to...

M

...be not that they would necessarily be for profit, they could be an extension of an existing organization in some fashion, but I don't think we presumed they were governmental.

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

We definitely didn't. In fact, we definitely presumed they were not government.

M

In part because the RFI asked the question about would a Federal rule help deal with state by state variations and avoid the possibility of you know, states creating regulations that would make it difficult to operate across state lines.

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

That's right, yeah. The RFI says...implies if it doesn't state outright, it certainly implies that they are private sector. If somebody has the RFI in place, we can...

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

It seems like Jaime, was your question was more about the standards body aspect of it or was it more about the pub...

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

I mean the requirement of the standards law is that the Federal agencies shall participate in private sector, voluntary consensus standards organizations and then select and use those standards, unless there's a good reason to use essentially federally developed standards. So, I'm trying to understand where the standards that are going to be required by these federal entities, you know, where are those going to come from and what's the degree of participation.

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

And I think we envision that some of those standards...many, most of those standards would come from existing standards bodies, but the validation body would profile it, if you would, for healthcare use. So, perhaps with an S&I framework like model for achieving consensus around the profile, although it might be in the focused space of that particular validation body, it's not starting from scratch.

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

So obviously what I'm trying to do, as you're seeking to draw the line between what the government does versus what the private sector does, I think that sort of in keeping with the practice of using the private sector voluntary consensus standards bodies, I just want to see that done here also, and not have the actual standards written by the Federal validation bodies.

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

Yes, we definitely did not envision those as a federal validating body agency. Would you like to read...

M

Well, the RFI does not say specifically, obviously, but it's under section 2b about actors and associated responsibilities, but, it makes a distinction between the ONC retaining certain responsibilities and talks about entities that certainly implies that they are non-governmental agencies. You know, selection and oversight process for an accreditation body that would be responsible for accrediting organizations interested in becoming validating bodies, for example.

Jonathan Perlin – Hospital Corporation of America

Okay. This discussion is terrific, obviously complex and I appreciate the threads, how can the process be streamlined and what are the unanswered questions. I hope that's helpful to ONC in terms of both providing a sense of direction as well as areas where there is further work to be done. Anne Castro, I believe you are next.

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

Thank you, I want to extend a little bit about what Cris was talking about earlier, but to be more precise, my perception is that this is about hospitals and EPs, because that's where most of the body of work that we've been working on has covered. In the future and currently, we're developing information exchanges to support innovative payment reform and I don't think we know enough to pass a rule that covers entities like payers, without understanding more about what those plans are developing into. Because I think that's something that is encouraged by the Federal government to achieve real health reform as compared to insurer reform. So, my recommendation would be to not cover payers or other entities involved that we haven't studied yet, either by hearings or additional information, to see what direction that is going in. I think my organization is very uncomfortable with the blanket aspect of this. And when you were describing your overarching picture, which is great, it was very helpful, you said providers and it's not providers or the perception is that it's a much...it's everybody, anybody who has any information exchange of healthcare data, and not just NwHIN, it's any HIEs or developing information exchanges.

So, I think that I'm comfortable with the hospital and the EP aspect of this and the NwHIN, but I'm not comfortable with applying the rules across the board on all those other organizations that we haven't studied yet, that I certainly have a vested interest in. But I haven't had a chance to discover those issues. So, thanks.

Jonathan Perlin – Hospital Corporation of America

Thanks. Wes Rishel.

Wes Rishel – Gartner, Incorporated

Thanks. I think I have to take a moment just to agree with others on Dixie's facility as a facilitator, if you'll pardon the expression. She has such a great way of digging a great big mess and sorting it out into little messes and then solving them one by one. And, I was not a participant in this discussion, I got to the meeting late, therefore I feel entirely qualified to speak about it (laughter). Could you go back to the slide that you had that had the drawing?

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

Sure.

Wes Rishel – Gartner, Incorporated

So, if we look at this in the context of what's going on now, validation bodies would be things like CCHIT and Drummond and a security institute, I can't remember the name of. CCHIT, of course, had its own program of establishing criteria for certification, still does, but uses instead the criteria established by NIST, when it certifies. The reason for that, as best as I understood it in the prior regulations, was that if you let the...if you wanted to have multiple validation bodies, you wanted it not to be controlled by a single institution. If you let them make up the criteria, there's a race to the bottom in terms of the criteria, because of the nature of the marketplace and this is just a box that people check in order to get their products on the market. Therefore, the establishment of validation criteria needs to come through separate governance than the individual validation bodies. Now...

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

And that's what we recommended. You don't...

Wes Rishel – Gartner, Incorporated

Where does that come from then...

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

You'll see it, it's one of the specific questions...

Wes Rishel – Gartner, Incorporated

Show me on the diagram where it is.

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

It's not in this diagram, but one of the questions was, can they use different test methods among the...I'm not quoting it right, but basically our response was that any particular CTE...between CTEs, CTE to CTE may be tested or validated in different ways, but every validation body must use the same ways for any given CTE.

Wes Rishel – Gartner, Incorporated

And did that section talk about the governance...

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

That's one of our synthesis...

Wes Rishel – Gartner, Incorporated

Did that talk about the governance of that process for establishing...what did it say?

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

It's part of the oversight of ONC and the accreditation body would oversee what the validation bodies do, but it's...our Power Team recommended that any given CTE would be validated exactly the same way by each validation body, that wouldn't vary. You couldn't go to the cheapest...

Wes Rishel – Gartner, Incorporated

So, it's confusing then to say that the validation bodies are setting the criteria, that there are several of them, and that they're not allowed to set different criteria.

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

We say, in collaboration, so it's not each validation body sets the criteria, it's a collaboration among the validation bodies that establish the criteria.

Wes Rishel – Gartner, Incorporated

I just would point out that since HL7 was formed in 1985, we've had collaborators who came to all our meetings and refused to use our standards. So, it's...I mean, collaboration is one of those terms that needs to be drawn out.

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

It clearly needs oversight and as I said, this is part of the whole governance, it's not separate.

Wes Rishel – Gartner, Incorporated

So, just trying to summarize; the conditions for trusted exchange are supplemented...first of all, the conditions for trusted exchange are, in fact...include among the things that can be conditions, recommendations to use a certain standard according to a certain flow and so forth...

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

Right.

Wes Rishel – Gartner, Incorporated

...that is determined in the definition of the conditions for trusted exchange and is a part of the condition for trusted exchange. Is that correct?

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

You know, the...I think your question relates back to what John was saying about you have a CTE, and we discussed this at the last meeting call, you have a CTE and then you might have the standards and the criteria that are used to validate against that CTE, and honestly, our Power Team didn't go into detail about how the criteria and standards would be specified. But, we did go so far as to say that the criteria and standards for each CTE would be the same across all validation bodies.

Wes Rishel – Gartner, Incorporated

Okay, so in accepting our input and working on a final rule then, the government may need it to be more specific than we've been...

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

Yes.

Wes Rishel – Gartner, Incorporated

...in this discussion. I...

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

I think that's a good point at both levels. The standards, the safeguard CTE will also need standards and certification criteria and presumably those would come from the government, as well as the interoperability CTEs. But I think that's a good point to capture in our comments.

Wes Rishel – Gartner, Incorporated

So, I would personally like to at least have this in the minutes, and since I didn't think to put it in anybody's recommendations, that the...there is no bright line between standards implementation guides and criteria for validating the operation...every time you try to do...I'm going to do a criteria for validating, you're in danger of finding, well, I need to be more specific in the implementation guide, but it's too late, that's already done, so I'm going to put something in here that was ambiguous in the prior step and so forth. That there has to be a way for a learning process to go on; with Stage 2, we are seeing some learning about what was standardized in Stage 1 and some changes. In general, while the ideal would be that the readiness and classification process would allow for a lot of that learning ahead of time, the reality to date has been, the learning comes...the learning takes too long when compared to the cycle of regulation and so we end up coming out in Stage 2, with a standard which I very much support, the Consolidated CDA, but we just cross our fingers because it hasn't been implemented.

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

Yeah, there are a couple of questions exactly about that.

Wes Rishel – Gartner, Incorporated

Okay, so I would say that this diagram, whatever happens finally, this diagram needs to support...needs to put somewhere the equivalent of the S&I framework.

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

I agree. I agree. We do have questions that address the learning cycle and piloting, etcetera, but you're absolutely right, this diagram doesn't include that and it should. Yes.

Wes Rishel – Gartner, Incorporated

All right, thanks.

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

Thank you.

Jonathan Perlin – Hospital Corporation of America

Appreciate the exchange of a critically important piece. It strikes me that this is more of a schematic than an operating plan and the questions help to refine how we get from schematic to operating plan, or what challenges would this schematic have or present to an operating plan. So, I really appreciate that thread of the dialog, that's why I've extended this portion, recognizing there are three sessions additionally and this discussion that Dixie would like to get to. So, let's take a final couple of comments and then we can dovetail back if we have additional time. So, David McCallie.

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

Yes, this is David McCallie. Wes, just to elaborate on that, I think what we recognized, or we struggled with in initially reading the RFI was that all CTEs seemed to be created equal and some of them really had profound global impact and some of them were really quite detailed around a particular use case of interoperability. So we sought to kind of partition at the right level, so the things that have to do with global trust are universal and go through a rigorous process and are even codified in regulation. Those things that need to fluctuate with market experience, of this works, this doesn't work, let's tweak it, would be pushed into the validation bodies. Whether you call that a CTE or not, I think is a good question. The validation bodies might have their own S&I like equivalent, maybe it is the S&I, maybe it's HL7; it depends on what they are...what scope and space they're operating in.

Wes Rishel – Gartner, Incorporated

Thanks David. I was closely associated with CCHIT during a dramatic period when we became aware we weren't going to be able to write criteria for meaningful use and I...on the basis of the individual work that CCHIT did, I thought there was a net loss in that process. But, on the basis of governance, from the point of view of how do you balance the forces and avoid centralization of control at a certain spot, I can understand why it went that way. I think that...we are obviously envisioning validation bodies as being similar to the current bodies in place, that is they're funded by the fees they charge, the people that they certify and so forth. I don't believe that putting it on them as effectively the competitors in the room, puts the judgment about what a standard ought to be in the right spot. I think that somehow there's a different set of bodies, maybe collaborating with the validating bodies, but somewhere the decision processes for what becomes the criteria have to be separate, I mean, that's just my thought.

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

Separate from a collaboration of validation bodies?

Wes Rishel – Gartner, Incorporated

Yes.

Jonathan Perlin – Hospital Corporation of America

Hm. If I might, John just said a word in my ear, and I think he should state that, because this really, unless we're hearing wrong, I agree.

John Halamka, MD, MS – Harvard Medical School

So what I think is that hearing all these comments, and it has been a great input, that this diagram effectively people agree with in principle and the separation and you have made between those policies which change infrequently and those standards and technologies which change rapidly, I think everyone agrees with. I think the challenge that people are expressing is having the validation bodies themselves actually coming up with the consensus of what those technical criteria should be, may not be something that we're comfortable with. And sort of one wonders if you should push that back to the Standards Committee or ONC or, you know, some, as you've stated, some other place than the validation bodies themselves.

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

Well, we really envisioned this as a sort of a...not bringing all the valid...everybody...all the validation bodies together in a conference and coming up with your CTEs, we envisioned there to be kind of a small circle in there, right, a validation body populated entity that would come up with these criteria and standards. So...

John Halamka, MD, MS – Harvard Medical School

Let's do what's called a lightening round. I want to make sure that we honor the rest of the agenda. This is a terrific discussion, so I think Jon has one piece of the summary, the other is that doesn't negate that there are many principles that have been espoused that represent the difference between a schematic and an operating plan, and all of those are recorded for the record as well. So let's take some very quick comments, you know, thirty seconds or less if you can get the concept across and we'll just go around the room circularly starting with Jim.

James Walker – Geisinger Health System – Chief Information Officer

My concern is that the schema does not identify a non-governmental executive body, a body that would aggregate learning, that would convene, that would do the hard work of achieving some kind of workable consensus going forward and I don't think we can finesse that and say, well, it will emerge, or maybe it will show up, or something.

John Halamka, MD, MS – Harvard Medical School

Great. So, terrific recommendation in terms of the overall schema. David.

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

Yes suggest Wes the validation bodies that we use in our internal discussions were directtrust.org and the public/private exchange group, rather than the current EHR certification body. So, those two groups are working kind of in parallel with the standards bodies that have established the standards that they are trying to get to work, and it's give and take and that's what we envisioned as the way it might go forward; so, slightly different examples for your same metaphor.

John Halamka, MD, MS – Harvard Medical School

Okay. Leslie?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I think that maybe if the schematic showed where are the points of entry for new standards, and how does that then get approved; because if we go back to say that meaningful use is what's guiding us and those standards in meaningful use, where's the point of entry and how the do they get sunsetted? And maybe that would help us.

John Halamka, MD, MS – Harvard Medical School

Terrific, great. Marc Overhage?

Marc Overhage – Siemens Healthcare

I think...I just want to...I'm a little worried about John's conclusion that where we think it is...I think there's a basic tension that we probably need to wrestle with a little bit more about where that is; as Dixie summarized the groups discussions, this need to have activities be able to happen sort of in the field if you will and drive upward and then the need as Jim said, and I fully agree with, public/private bodies. I'm not quite sure that we're all aligned on the direction that John summarized.

John Halamka, MD, MS – Harvard Medical School

Thanks. Unless I'm reading wrong, I mean I think there's a fair amount of comfort with the broader notion. I mean, they're terrific questions. Jim asked if there are more parsimonious process by, as I understood, by a conglomerating accreditation validation. Leslie's recent point having new standards enter, any number of things. But I think as a framework to start to frame those discussions and advise ONC and give them something to react to, I think we're in a pretty good place and this is, I think a terrific simplification of the concept. Great, it will take some refining at the schematic level as well as the operating level. And the other tension, as I read it, is between the detail of what needs to be specified a priori and what is possible to be an emergent phenomena. Leslie.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Well just a real quick point about building on Anne's comment and, not only point of entry for standards, but point of entry in process for new actors and roles, I think of patients and families, where does that come into play or new non-covered entities that want to participate or covered entities.

John Halamka, MD, MS – Harvard Medical School

Excellent point.

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

Well we didn't...this is not intended to be a complete process flow. It's really intended to depict the primary entities that are represented in the RFI. So, what I'm hearing from Jim and Marc and others and Wes and others, is that we really need to depict a public/private entity that brings together that are...in which the validation bodies are represented and the governments represented and that's where the new CTEs would emerge. Does anybody on my Power Team have any objection to that?

M

Um mm.

M

Great.

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

This is David. I mean I thought that's sort of the role ONC has been given in the stature, so I'm not quite sure how this thing differs from what ONC does.

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

Well, it just doesn't depict a separate entity which...that comprises both government members if you will and private sector members. So, it's not depicted on here. I think in our discussions, we envisioned that happening, but it's not depicted on our diagram.

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

To seek a parsimony of entities.

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

Yeah, but I don't think any of us thought that all of these validation bodies would get together in a conference once a year and come up with new CTEs; I don't think anybody envisioned that happening; but, we haven't...and in fact, it shouldn't depict it on this diagram because this depicts what's in the RFI. But our recommendation should make it clear that that is...that that's...

W

...trying for it not to be the Standards Committee?

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

Not necessarily.

W

Okay, because it just looks like that would be the entity.

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

It might be.

John Halamka, MD, MS – Harvard Medical School

...argument to your point is that if, as Dixie suggested, they redraw this, to make sure that there's that public/private entity, which could be the Standards Committee, providing this convening function to ensure those CTEs are developed for the validation bodies, would that be comfortable?

Marc Overhage – Siemens Healthcare

I think the key question is just how much, as Dixie said, how much do you want to try to pre-specify the details up front and how much do you want them to be derived from operating experience. And where do you want to draw that line in a way that works. And I think the experience we've had with whether it's Exchange or Direct or lots of other things to bend, if you get twenty people in the room who are actually doing things, you learn a lot more than when you get us in the room, who do bring in some cases hands on experience, but not at that same level of granularity.

John Halamka, MD, MS – Harvard Medical School

Last two comments, Wes and Cris.

Wes Rishel – Gartner, Incorporated

I think that we can say that there's a great deal of comfort with the presentation. I can say I think we must also say that we don't feel what we have seen has depicted the entities necessary to achieve the result.

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

Well, and I want to...I want to make it clear, what you see in front of you is not what...this is exactly what's in the RFI, exactly what's in the RFI. It is not what we recommended, for example...

Wes Rishel – Gartner, Incorporated

But I've heard...but

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

Wes, you mentioned the learning; you'll see one of our questions is that we think the validation bodies should encourage piloting and learning.

Wes Rishel – Gartner, Incorporated

So Dixie, does your...somewhere in your answers, does it name the other entity that we've been talking about here?

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

No.

Wes Rishel – Gartner, Incorporated

Does it identify it? Does it say what its role is? Then I think it's clear we're not satisfied that we have...

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

Well, it does talk about a collaboration of the validation bodies.

Wes Rishel – Gartner, Incorporated

Well those are good words and I certainly wouldn't want to go against them, but I don't think that that gets to the role of anybody being able to look at all that input.

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

I think we need another picture that depicts what we're recommending. This isn't that picture. This is a picture of the RFI.

Wes Rishel – Gartner, Incorporated

Well, I'm trying to take this a step further. I'm saying, based upon what I've heard that you're recommending, if we had that picture we would still need to have a discussion about it.

John Halamka, MD, MS – Harvard Medical School

We'd need to have a different discussion, we'd need to separate the operating capacity as opposed to the schematic overall.

Wes Rishel – Gartner, Incorporated

I've really tried to keep it to thirty seconds, but, this idea that directtrust.org would be a validating body for the standards that are used in direct implies that nobody else is validating for those standards. I mean, if the notion that we learned through meaningful use is that we want competitive validation bodies, then I don't see how they can be specialized to specific standards.

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

Well, that's definitely not...we are very clear in our answers that for a given CTE, every single validation body should use the same test procedures, the same test approach, same criteria, same standards, for any given CTE. But what we are recommending is that the validation bodies collaboratively come up with new CTEs and new criteria and standards. But, every one of them must use the same validation approach. We can't have NVEs that are validated against different criteria.

Wes Rishel – Gartner, Incorporated

We all agree on that. What I think we don't agree with is whether the association of validating associations is the appropriate place to develop new standards.

Jonathan Perlin – Hospital Corporation of America

Okay, I think that point's been captured once. Great. And Cris.

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

So, I was going to make a couple of points, one of which is what Dixie said, that this is not our...the Power Team's diagram, this is from the RFI. Perhaps we would have gotten to a better result if the Power Team had said, we don't agree with this structure for governance and we're going to come up with a different entity, so maybe we should come back and take a look at that.

Jonathan Perlin – Hospital Corporation of America

And that, I think is a terrific point to close on, which is that, let's take a look at that diagram next time and I think the discussion has been terrific, because by having a straw document to react to, we've been very concrete in our suggestions of what authorities live where, to what compromises the agility to actually operate in presumed marketplace.

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

Thank you, I agree. I think, last point would be, if we were to look, I think at some of the specific criteria in the context, this diagram might help test the consensus that John suggested. I think if we look at some specific cases, we'll find out if that makes sense or not. And I think the other principle here was that to the extent to which we're talking about validating bodies being active in this process, it would be to be additive, never to be subtractive. So, presumably not a race to the bottom, but a race to who can most quickly create an environment in which, if I'm an NVE, I want to go to that validating body because they're not only going to give me a check box, but they're also going to help me resolve some issues that were otherwise open.

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

Yeah, I think that we have twenty-two specific questions we need to go through here, and I think that a lot of what's been brought up here are...is directly addressed in those twenty-two questions and I think that what...the unique thing that I've heard here, and the only really unique thing I've heard, is that wherever in our question responses we mention collaboration of validation bodies, what I'm hearing here is that's not a collaboration of validation bodies, it's a public/private entity that comes up with the criteria and standards.

M

New body.

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

Yeah, new body.

M

Repurposed...

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

Or a repurposed body, right. Okay, so moving on to our specific responses. And please note as we move through these responses, let's look for places where we need to tweak the responses consistent with what we've just included, because we do want to capture this in our responses. So the first group of questions are responses to questions that address the broad, NwHIN governance policy. I don't intend to read every word in the responses, but I'll try to emphasize the key point. And I would like for you to attempt to read every word in our responses and I'll give you time to do that and make suggestions; because these are, this Committee's recommendations, so it's important that they reflect the thoughts of the Committee. Okay, and I suggest also you read on your paper form, not try to read it from the screen.

Okay, the first question is question #3: "How urgent is the need for a nationwide governance approach for electronic health information exchange? Conversely, please indicate if you believe that it is untimely for a nationwide approach to be developed and why?" And we believe that the effective governance is absolutely critical to establishing and maintaining the trustworthiness of the NwHIN and we think it's timely, we think it's urgent, we think it's the right time. We believe that, as we've discussed, that the key requirement for governance is to establish and maintain this core trustworthiness of the NwHIN and we do question the need for additional regulation beyond what's needed to assure that trustworthiness of the NwHIN. We don't see a need for regulated CTEs addressing interoperability and business practices, David, other than those essential to preserve the trust fabric. And we think, as we said, that the services assurances, what they call the business practices CTEs in the RFI, really should be left to transparency and market competition instead of codifying them in regulation. So, comments? I'll give you time to read the details.

Arien Malec – RelayHealth Clinical Solutions

Dixie, this is Arien.

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

Hi Arien.

Arien Malec – RelayHealth Clinical Solutions

And I apologize, I haven't been spending as much time with the Power Team as I probably should. Was it the sense of the Power Team that trust is currently not being preserved in information exchange or is it the sense that additional trust or clarity in trust would encourage or facilitate information exchange; because I think you come up with completely different approaches to oversight and regulation in each of those situations. In one, you've got a set of actors who are behaving badly and you need to restrain them. In the other, you've got a set of actors who are tentatively poking their toe in the water and you want to raise the temperature of the water to make sure everybody says it's okay to come in.

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

David, you can...

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

This is David. Arien, I'll respond to that. I think our discussion assumed that the current process that Direct trust and Exchange have been going through to figure out how to establish trust, is the right process, but it's not finished and it's a lot more difficult than anybody expected. So, I think our working assumption was the goal would be that the trust framework would be good enough so that entities...NVEs could interact with each other without requiring pair-wise business associate agreements. That in fact, they could, like with direct trust, connect under the assumption that the other end of the channel was meeting certain minimum agreed upon security standards. And that that's the right attitude, it's just not finished and it's a lot harder than anybody thought. You get these questions like the Federal bridge and so forth...

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

And it's fragmented. We recognize that it's fragmented right now. It's not a uniform, consistent set of trust principles across both direct and exchange right now.

Arien Malec – RelayHealth Clinical Solutions

Yeah, got it. So it's not that there are...the conclusion wasn't that there are sharks in the water, the conclusion is the water's too cold.

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

They're in two ponds, they're swimming in two ponds.

Arien Malec – RelayHealth Clinical Solutions

Right.

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

And eating each other...

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

Yeah. Okay? Moving on to question #4: "Would a voluntary validation approach as described above, in the RFI, sufficiently achieve this goal and if not, why?" And we agreed with the voluntary approach and this is...our response here is just as stated, as we've gone over, that...and we mention in our initial observations, is that given that this NVE validation may become a de facto requirement, it is extremely important that the CTEs that are put in place treat it as if it were a requirement, even though it's voluntary. That's basically what that says. Okay.

Question #8: “We solicit feedback on the appropriateness of ONCs role in coordinating the governance mechanism and whether certain responsibilities might be better delegated to and/or fulfilled by the private sector.” This cuts to the core of exactly what we’ve been discussing. We think ONC should focus on the governance mechanisms to ensure the trusted exchange and let the private sector, through validating bodies, focus on interoperability, and we think this is consistent with what is proposed in the RFI. I think that this is the first of the questions where we should really make it clear that the validation bodies, it should be a public/private body that comes up with these interoperability CTEs, based on our previous discussion.

M

...change.

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

Right. So where we say should be delegated to the validating bodies, let me suggest that we should be delegating to a public/private body...CTE body, whatever we want to call it.

Jonathan Perlin – Hospital Corporation of America

Mary Jo, MacKenzie, we can capture that? Perfect, thanks.

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

Okay. Questions 9, 10 and 11: Okay, question 9 has a brief answer: “Would a voluntary validation process be effective for ensuring that entities engaged in facilitating electronic exchange continue to comply with adopted CTEs, if not, what other validation processes should be leveraged for validating conformance with adopted CTEs?” And our answer was yes, a voluntary validation process could be effective. Does anybody disagree with that? Okay. Question 10: “Should the validation method vary by CTE? Which methods would be most effective for ensuring compliance with the CTEs?” Before answering, look at the CTEs, the CTEs are in Appendix A. And this is Wes, what I was saying; for a given CTE, the validation method should be consistent across validation bodies.

Jonathan Perlin – Hospital Corporation of America

...Chris Chute.

Christopher Chute – Mayo Clinic College of Medicine

Yeah, sorry to interrupt. I want to go back to question 9, and what are the implications if a body that wants to participate in health information exchange, because these criteria are therefore voluntary, opts not to adhere to those criteria, what are the consequences, in terms of their privilege to be able to participate in the health information exchange community? I mean personally, I think if they don't want to play by the rules, they shouldn't be able to play. But that's not what this says, if I'm interpreting it correctly.

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

The implication in the RFI is that it would be up to the exchange principals, shall we say, the stakeholders to decide. For example, CMS might decide, or Mayo Clinic might say, anybody who exchanges information with me has to be using an NVE for that exchange and the implication is that's what would bring about the motivation to play, because the entities you wanted to exchange information with, required themselves that you use an NVE.

Christopher Chute – Mayo Clinic College of Medicine

Might I suggest that has the risk of introducing a patchwork of compliance criteria of chosen elements that Mayo Clinic or some other organization might choose to emphasize or not emphasize. And it strikes me as a recipe for chaos if there's inconsistency with what the requirements are based on voluntary requirements or bilaterally communicated requirements that are determined among the participants. I think an alternative of having a uniform set of expectations, and I'm perfectly at peace with the idea that the interoperability criteria would be established by this fabled once and future body that we've been talking about all morning. But I think once that body has made an annual deliberation, let's consider it that way since we recognize these will be in flux, that it would be problematic if you sort of had to query every entity that might be participating; well have you or have you not voluntarily agreed to adhere to these criteria and sure you're doing business with that Kaiser organization, but what does that have to say about your adherence to...I mean, Kaiser may have negotiated a waiver on this point or Mayo Clinic might have negotiated, but it becomes an unpredictable rendering.

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

That's not...I didn't communicate that clearly, obviously. There are...what the RFI proposes is there would be a core set of CTEs, and we recommend that that core be these trust fabric...

Christopher Chute – Mayo Clinic College of Medicine

I get that...

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

...that everybody needs to comply with, or you don't get validated.

W

Or what?

Christopher Chute – Mayo Clinic College of Medicine

I get that.

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

You don't get validated.

Christopher Chute – Mayo Clinic College of Medicine

No, that I get. That's quasi-mandatory, but now you're saying that the interoperability, so this other pond, we've talked about sharks swimming in different ponds. This other pond is going to have it's set of sharks, or at least dangerous waters...

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

There could be core CTEs in interoperability as well. There could be core...

Christopher Chute – Mayo Foundation for Medical Education and Research

That's a nuance you've only introduced in this sentence.

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

It's in the RFI, that there are core, the safeguards are core and then there could be...there will be, by definition from the meaningful use, there will be core interoperability CTEs as well, but there could be other CTEs that would apply only to certain NVEs. Like, for example, one of the CTEs that's in there now really doesn't apply to an NVE that doesn't persist data, health data; there are a couple of them like that; that if you don't persist data, it really doesn't apply. And we also recommended the transparency of exactly what you were validated against.

Christopher Chute – Mayo Clinic College of Medicine

Let's not confuse the notion of not applicable with a perception of voluntary. I mean, I can see where things would not pertain, that's fine; that should be explicit and you know, those organizations that do not persist data, whatever. I mean, you can define the exclusions intelligently. But I think it's, maybe it's a personal thing, maybe I'm a control freak, that's my problem, but I would have concern if the answer to #9 is categorically yes.

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

Yeah, I see...so you would say, yes, so long as it was very clear what CTEs the NVE was validated against.

John Halamka, MD, MS – Harvard Medical School

The friendly amendment that I would offer is, we have complete certification, we have modular certification, right, and so when you see, oh, this person is modularly certified for emergency department systems, I understand what they are certified for.

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

That's the spirit.

Christopher Chute – Mayo Clinic College of Medicine

Okay, and that's a good spirit, but that's not what it says.

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

Yeah, it...

Jonathan Perlin – Hospital Corporation of America

Mary Jo, go ahead.

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

It might help you to know at this point how the Policy Committee is looking at all of these because, indeed, they are answering these as well. They have suggested that for this...there's a question in here how indeed will a perspective user differentiate as to what a given NVE has been accredited for and not, because we recognize that a potential NVE will have multiple lines of business, and it may only in fact, seek validation for a particular stream of its activities; and all the rest are certainly not regulated by governance, obviously they're covered by other laws and regulations and requirements. And so the Policy Committee is saying that for this to work, then ONC would certainly need to come up with a very crystal clear way of publically listing, sort of like as you say, the modular certification, exactly what they have been validated for. And even perhaps a time frame, if a time frame comes up.

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

We talked about how they would make it...that's what I was talking about, transparency, make it very clear what they were validated against, but we didn't get the time frame.

Jonathan Perlin – Hospital Corporation of America

So, if I heard this correctly, the summary of three points. This answer needs to be modified to embrace the applicability modularity aspect, the core aspect which relates to...which is what does voluntary mean if you don't do this, what? And my understanding, please correct me if I'm wrong, is that in the absence of being certified against core, that you wouldn't get to play.

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

Right, that's right.

Jonathan Perlin – Hospital Corporation of America

Does that capture? Okay. So let's capture those and perhaps offline electronically we can circulate text that addresses those. Thanks Chris.

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

Thank you Chris.

Jonathan Perlin – Hospital Corporation of America

So, we were on 10, and that actually could segue back to it.

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

So #10: "For a given CTE, the validation methods should be consistent across validation bodies?" I think we should further capture our earlier discussions, not only validation methods, but it's criteria and standards, and I'm going to add to make that clear. Because they could all have test methods, but different criteria, so I'm going to add those there. Question 11: "What successful validation models or approaches exist in other industries that could be used as a model for our purposes in this context?" And we mentioned the payment card industry, PCI, the extended validation certificate process, and NIST NVLAP process, national voluntary laboratory accreditation program. Are there others that we want listed? Okay.

Question 17: "What is the optimum role for stakeholders including consumers, in governance of a Nationwide Health Information Network? What mechanisms would most effectively implement that role?" And we said, the governance of each validating body, validation body, should seek to have stakeholder representation in its internal governance. We believe that both NVEs and the validating bodies should have input into overall NWHIN governance and changes to the CTEs. I think we should add to this one, add the public/private fantasy and future, isn't that what you say?

James Walker – Geisinger Health System – Chief Information Officer

Jim Walker. Want to reinforce that, I mean, that's one of the reasons to repurpose something that already has these criteria, you know, that has all of the right stakeholders present, that is all of its deliberations are on the record, you know, a whole set of criteria, and that would be the value for repurposing. There are some bodies that are designed...

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

...to be open and...

James Walker – Geisinger Health System – Chief Information Officer

...from the beginning to be that kind of body, and to expect...to try to specify that each one of these validating bodies does all those things, would probably be wrong-headed and also never work.

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

So are you suggesting we add...

James Walker – Geisinger Health System – Chief Information Officer

All I'm suggesting is that if we say that original scheme needs a public/private stakeholder entity that deliberations are on the record and has the right advising relationships and has the right abilities to bring the right information to it for its deliberations. Then we've solved a whole set of problems all at once and we can just keep referring back to it.

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

That's what I thought, it should be like a FACA-like.

James Walker – Geisinger Health System – Chief Information Officer

Yeah, something.

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

Okay. All right, the next question 56: "Which CTEs would you revise or delete and why? Are there other CTEs not listed here that we should also consider?" And I would remind you, all the CTEs are in Appendix A of your handout. And we repeated, we think that the regulatory CTEs should be limited to those that are necessary to establish and preserve the trust fabric; and the interoperability and business practices should be relegated to this public/private entity. Our comments on the CTEs, the one that talked about meaningful choice, we noted that meaningful choice needs to be defined. The S-3, means it's a safeguard; S means safeguard, I means interoperability; so interoperability CTE #2, "an NVE must follow required standards for establishing and discovering digital certificates;" we suggested changing that to digital certificates must be used to authenticate the identity of organizations on the Nationwide Health Information Network. And I would like to note that this is an interoperability, it's labeled interoperability CTE, but this is an example of one where it's interoperability but it's also essential to the trust fabric. I-3 is "an NVE must have the ability to verify and match the subject of a message including the ability to locate a potential source of available information for a specific subject." That's a perfect example of one that would not necessarily apply to every NVE, and it's one where you would want to know, has that been certified against that. That's a good example, in fact, yeah. I'm going to note that. Okay, comments?

Jonathan Perlin – Hospital Corporation of America

Jaime.

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

Thanks. So, I certainly agree with the framework of saying that what's fixed in regulation should be what's necessary to preserve...establish and preserve the trust fabric. In terms of CTE S-1, I think we really have to question, and this doesn't do it yet, but I think we really have to question as a Committee whether amending or rewriting HIPAA, the HIPAA security rule, is necessary to establish and preserve that trust fabric. I personally don't think that's a necessary approach and this doesn't question it, so I think we should question it. I think that needs to be re...

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

Yeah, for those of you who don't know what S-1 is; S-1 basically says that the HIPAA Security Rule has a number of implementation specifications that are labeled addressable, and if they're addressable, it means that you still have to implement it, but you can do it in a different way; you can justify why you're implementing it in a different way. And S-1 says that to be an NVE, you must treat those addressable as if they were required. Now, to not lose my thunder for my second presentation, but, the Privacy and Security Workgroup really went over that one in detail and the Privacy and Security presentation here has all of the addressable implementation specifications listed. And none of us thought that it was un...any of it was unreasonable, because all of those addressable are really things that most entities do anyway, especially an exchange entity. So, I would suggest that you look at the specific ones, look at Appendix A of presentation 2, and you'll see what they are.

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

But I also think that, in line with Anne Castro's earlier comments about the broad scope of applicability, that this kind of a rule could have beyond the kinds of entities that you're contemplating in those comments. There's a fundamental conflict in terms of scope of authority of basically rewriting HIPAA for all those other purposes and things that we don't know, and things, for example, that are today in the existing NWHIN established by the ONC, such as claim attachments and electronic submission of medical data to CMS. And so I think there are a lot of questions about scope, in terms of the applicability of S-1 and it's really beyond, Dixie, I think what you described in terms of those exchange entities.

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

I see what you're saying. So, you're saying that S-1 really legally goes beyond what it's authority...

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

I think that should be questioned and examined.

Jonathan Perlin – Hospital Corporation of America

Terrific. Let's go to Jim Walker and I know Wes Rishel wanted to weigh in on this as well. I think this discussion is terrific and very helpful. I do want to do a bit of a time check, it's 11 o'clock and at 11:15 we should report from the hearings on clinical quality and patient-generated data. We have Dr. Rollins here and I want to honor her schedule; so at 11:15 we're going to go to that. And, we'll have a couple of options. We can do a working lunch on this, which would be probably first preference, or an additional call subsequent to the meeting, but, we owe this guidance back to ONC. So, let's be succinct in our comments, very helpful, I don't want to preclude the inputs, but, let's be real focused.

James Walker – Geisinger Health System – Chief Information Officer

So this is Jim. From a standards perspective I think it would be a real mistake to have two different versions of HIPAA that apply in two different contexts; I think we want one standard. We don't want to be creating second standards.

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

Yeah, I understand what you're saying. I do understand; because they will be business associates and it's a subset of business associates that are required...yeah, I see what you mean.

Jonathan Perlin – Hospital Corporation of America

Wes.

Wes Rishel – Gartner, Incorporated

Okay, so my colleague here has called up this section, and it says, an NVE must comply with certain sections of HIPAA security, as if it were a covered entity and must treat all implementation specifications within those as required. I sort of object to the characterization of that as rewriting HIPAA. I think that's the kind of characterization that's used to make emotional impact rather than to guide the discussion. I read that and I thought, HIPAA has security regulations that has outs for one doctor practices. It has outs for small practices. Do we want an NVE to be able to use those outs, and I thought no. I thought that if the data that is under control, or in trust to this NVE is not only the data generated by their own business, but the data generated by all kinds of healthcare, that we should expect of an NVE the same level of compliance that we would expect from a small insurance company, or a large clinic. So, I personally concur entirely with saying "yes" to S-1.

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

I think there are two points here; one is, are they reasonable, and I think I agree...I totally agree with you that Privacy and Security Workgroup agrees with you, they are absolutely reasonable, they are not unreasonable at all. But I think...the question is, should they be made CTEs instead of changing...and maybe that's what they're suggesting.

Wes Rishel – Gartner, Incorporated

I would argue that if they're not made CTEs, then they're still addressable.

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

Yeah, yeah, yeah. And that's what they're really proposing Jaime, they're proposing a CTE, they're not proposing changing HIPAA; they're proposing a CTE that says, you must interpret it as if it were required.

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

...with that characterization I think that factually, in terms of the application of existing HIPAA regulations, this changes those regulations fundamentally for things that are explicitly covered in HIPAA. And so I think that it is factually correct to say that this has the effect of rewriting HIPAA in those areas. So, that's just what it does. You may not like that characterization, but that is what it does.

Wes Rishel – Gartner, Incorporated

I would say nothing of the sort, I would say it takes certain HIPAA regulations and applies them to any NVE.

Arien Malec – RelayHealth Clinical Solutions

Yes, this is Arien and I would note that it's a mistake to confuse a floor with a ceiling. I think there are many places where HIPAA sets a floor, but that shouldn't be interpreted as constraining any other regulation or oversight to set additional objectives above the ceiling, as long as they're voluntary. In the same way that, for example, the American Hospital Association noted that OCR has oversight over disclosure to patients, that has a thirty day window. It was claimed that HIPAA sets both the floor and the ceiling. I think it would be a mistake to take a position that HIPAA's designed to set both the floor and the ceiling and that no additional governmental oversight can go beyond the floor that HIPAA sets.

John Halamka, MD, MS – Harvard Medical School

Jim or David do you have comments on this.

James Walker – Geisinger Health System – Chief Information Officer

This is Jim. As a process point, I think it would...I think you suggested it Dixie, it would make sense to me, and I would support, making those parts of HIPAA CTEs, separate from HIPAA, so that they would just be in regulation as...

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

That's what they're recommending.

James Walker – Geisinger Health System – Chief Information Officer

...but then the reference isn't...it doesn't create the impression that we're sort of talking about HIPAA...

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

Oh, I see, yeah, yeah.

James Walker – Geisinger Health System – Chief Information Officer

...or something like that. HIPAA is what it is, this is not HIPAA, it may be the same language and the same requirement, but, we haven't created sort of a second HIPAA.

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

That's a good idea, just go through the addressable ones and make each one a CTE.

James Walker – Chief Information Officer – Geisinger Health System

Yeah.

John Halamka, MD, MS – Harvard Medical School

...reasonable. David.

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

This is David. Just to reiterate Arien's comment, which appropriately came to us from the ceiling. A number of ONC staffers were on one of the Tiger Team calls where this got a lot of debate and it was very clear that they wanted us to comment on whether or not they thought it made sense for a voluntary certification attainment to set higher standards for those who volunteer to be judged by them, than HIPAA. That was the question they were asking. So they were very clear that the combination of voluntary and a higher ceiling, if you would, was what they wanted opinions on; it was Joy Pritts and others were there. So, I think...

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

I think the approach that Jim articulated better than I did is the right answer, is that we recommend not that they have a CTE that says for HIPAA you must comply with the addressable implementation specs, but rather to have an individual CTE for each addressable implementation spec and make it a separate CTE, not even reference HIPAA.

John Halamka, MD, MS – Harvard Medical School

So, I'm seeing a lot of nodding of heads at the Walker Amendment, just consider...

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

The Walker Amendment is perfect.

John Halamka, MD, MS – Harvard Medical School

Perfect. Okay. So Dixie, in the interest of time, let us move on.

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

All right, okay. Oh, I thought he said you were going to eat or something.

John Halamka, MD, MS – Harvard Medical School

...in fact Marjorie has found your topics so important she has agreed to defer her presentation as you continue, so please, go ahead.

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

Okay, just before I move on. Did you look at the other, S-3, S-2, S-3, the others? Okay, the next one, this business process. We had comments about all three of the business process CTEs. CTE business process 1 says: "An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE." And we thought that the oversight of the NVE should seek to address any anti-competitive practices including, but not limited to this, that would inhibit free flowing data; but that we shouldn't include these absolute requirements like this as CTEs. CTE business process 2: "An NVE must provide open access to the directory services it provides, to enable planned electronic exchange." This is a perfect example of a CTE that we thought is at a much more detailed level than a top level CTE should be. And we don't think protocol specific...CTEs should be protocol specific. And then the final one: "An NVE must report on users and transaction volume for validated services." We think that the actual performance should be transparent, but that the minimal levels should be left up to the market and that the validating...validation body should collaboratively determine what performance measures are reportable. So, we changed this collaboratively to refer to this public/private entity, is that right? Okay.

Okay. All right, moving on to the responses to the questions addressing the policy and process for selecting national standards and for adopting or modifying CTEs. Okay, this first one...now all of these really relate to exactly what the NWHIN Power Team is all about. So, we were pleased to see that our work actually made it into an RFI. So, "what process should we use to update CTEs? Well this relates to CTEs in particular. Top level CTEs, as we've said, should focus on policy and should not change often, because we think these top level CTEs should be codified in the law. We think the lower level CTEs should specify standards and criteria for certifying an NVE against a top level CTE. We recognized...we thought about how...this relates to an earlier conversation here. We thought about how certain NVEs might become specialized or they might...and so the market might encourage them to provide special services in particular areas or to support other standards, besides those that are required in the CTEs.

And we thought that this was legitimate, that we shouldn't shut that down, but, we suggested that a model similar to the HIPAA approach for creating a hybrid entity might work where...and HIPAA says that if there's an organization only part of which is a covered entity, and they also do other stuff that is not covered under HIPAA, that they declare themselves a hybrid entity and the portion of the entity that is a covered entity has to conform and they have to make it real...a clear distinction between the two. And we thought that this would also work with the NVEs. And this goes along with modular approach, I think as well. But the hybrid entity would say, okay, this part of our business is an NVE validated against these sets of criteria, and this part of the organization is not an NVE. So that's what we're suggesting. The rest of this, I think is what we've discussed, and that there be a clear differentiation between the two. The final point we make on this one is that the certification process should allow for bilateral version skew, which is something Wes brought up before with respect to the standards for the meaningful use. So that the standards, as they are and the CTEs would be allowed to evolve and yet the NVE could still operate. Are there any questions or comments about that?

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

It just strikes me the longer I sit here and think about this, that voluntary is problematic for everybody involved because we're going to have to construct different information exchange requirements with every entity that we do business with. And I just want to go on...that to go in the record, that that is a huge impact to the information exchange entities, especially the ones we don't know about. I think it's easy to say this for hospitals and doctors, because that's what we're experts in from a Committee standpoint, but we're not experts on what that means to payers and other entities down the road, looking to get into innovative healthcare payment scenarios that will really reduce the healthcare cost curve. And the issue of when are the rules going to be established, can I get in there and do what I need to do to validate a payment methodology, because I need time to do that and data collection over time, so when do I get a rule...CTE created that covers me.

So all of those issues, I guess they're building for me. I totally understand the appropriateness in the context that we have been talking about this for three years, in the hospital and physician exchange, to the degree that I'm a payer and don't live in that world anyway, but at least from a knowledge base I've learned a lot. But from all those entities that this is going to cover by default and the complication of voluntary and variation by HIE that I'm going to be dealing with probably thirty of them in my state because none of them want to use the state HIE, I'm really getting worried about this approach. And I want my comments on record because I'm a payer here, and I think I represent that. I need to represent that constituency and the complication that this is going to create. Thanks.

Jonathan Perlin – Hospital Corporation of America

Jim Walker and Wes Rishel.

James Walker – Geisinger Health System – Chief Information Officer

So, a recommendation of parsimony. If we said look, what we want to start with is to create a trust fabric, and we're going to identify the core requirements that anybody in healthcare can connect with anybody else in healthcare and be able to trust that the information will be handled appropriately; technically we'll be protected appropriately and that's all we do in the first stage. It seems to me that that would get us a long way down the road, and then there's only one thing, there's not twenty versions of it, and John, I think your modularity makes sense, maybe farther down the market. But it seems to me that it's hard enough just to say, could we create an environment, an ecosystem in which people could connect with each other and not have to worry about information security and patient privacy and confidentiality. That would be plenty to bite off this time around.

John Halamka, MD, MS – Harvard Medical School

Let me clarify what I meant by modularity. There are different architectural approaches to different nodes. So imagine that one node is a quality data aggregator and holds three million patients personally identified health information versus another node that is a transmission gateway with no persistence. You might have different conditions apply, that's all I meant.

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

Yeah, right.

James Walker – Geisinger Health System – Chief Information Officer

Absolutely, no question. But, just at this first level, it can hardly be too simple. This is so unbelievably complex that anything we can do to make it simpler means that all the participants in this, hospitals, patients, skilled nursing facilities, other long term PAC; that we can create...if we could create something simple enough that people just said, "Oh, okay, they have this little stamps, I can share information with them." That would be maybe enough for the first round.

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

So I think what you're saying, the two of you together, I think what you're saying is that you agree with the separation of trust fabric and making it regulatory, but you're going further to say that you believe that should not even be voluntary, that to exchange information...health information, you need to meet this trust fabric requirements.

James Walker – Geisinger Health System – Chief Information Officer

This is Jim. Otherwise I don't think we move the ball down the field; that's the problem is people are scared to share information with somebody who they don't know their information management practices. And yes, I think if we did separate it, then we could accomplish the one relatively big thing and then start doing the interrogating and gathering information and experiments to start characterizing the next sorts of modularities, which John, I totally agree with you, you're right, I just...I think even to do the simple thing would be a remarkable achievement.

Jonathan Perlin – Hospital Corporation of America

Let's go, wrap up comments on this. We've got a couple of presentations, as I've mentioned. We will do a working lunch, understand that to be able to provide the time with feedback, we'd have to provide more notice than would be possible for even a phone meeting. So, let's take a lightning round and the rest of conversation on this topic. Dixie we'll come back during a working lunch. I'll note that Bregitte has a capacity to order a box lunch if you haven't already done so, that's available to you. She's just outside the door. So, we'll start with David then go to Leslie Kelly Hall, Wes Rishel and Cris Ross.

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

Lucky for you I don't eat lunch.

Jonathan Perlin – Hospital Corporation of America

David?

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

This is David. I mean Jim, I understand that point and certainly we felt in the workgroup that the trust stuff was the stuff that really mattered and was the stuff that should be the focus of the core CTEs that everyone would achieve. But the notion that you can't do healthcare exchange until you get that certification, I think would be incredibly disruptive because there's a gigantic amount of secure exchange that happens today. And, so the notion that it be non-voluntary, at least in the short run, is just not an option, I don't think. So, our compromise was, it's voluntary, we know that over time that voluntariness will be less and less an issue because you're going to just have to up and do it, but, you start voluntary and you focus on the trust and so it's new avenues of exchange, the ones that really haven't taken hold yet, that are going to be the real winners in the short run.

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

And the RFI actually acknowledges what we all know, that if the Federal agencies like CMS and MHS and VA say, you have to use an NVE, it's essentially non-voluntary...

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

Yeah, the tail will wag the dog.

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

...without being non-voluntary.

Jonathan Perlin – Hospital Corporation of America

Leslie.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I just think it's a really hard balance these two points of view that we're considering. I think that in some cases, the market will drive this adoptability. If it's less expensive to have one interface and replace all of my existing point-to-point communications that are secure and my existing framework, that's a great driver to move. But, I still struggle with this idea of a floor or a minimum requirement set that isn't voluntary, because right now we have so much ambiguity and so much different ways to do things. We haven't gotten to a nationwide health exchange yet, with standards in place that could be adopted by people, with voluntary structures that could be used by people. So, we're trying to fill a gap and promote exchange nationwide, and so I don't know the right answer, I just know there's an answer we need to agree on and move forward to promote what Jim described and I think what David's cautions are.

Jonathan Perlin – Hospital Corporation of America

Thanks. Wes.

Wes Rishel – Gartner, Incorporated

I have general question that may create a basic misunderstanding I had. I have not read this NPRM as supplanting other regulations that enable or fail to disable secure communication right now. So for example, I've read nothing in this thing that says, you're going to have to start sending HIPAA payments using this scheme, or HIPAA...right? Okay, so it's not, we're not rewriting HIPAA, we're not changing the requirements that payers have to use to do HIPAA or any of that. That's simply not a characteristic of this regulation. Okay. I think that I further understand that there's nothing in this regulation that says any two entities that want to exchange data can't establish a bilateral agreement and exchange data that way. Now, they might be liable under HIPAA, or they might be liable under GINA for privacy concerns, but there's nothing in this regulation that says they have to do something different, okay? This regulation simply says, if you're going to get this trust mark, then you have to do these things and there's an understanding that that trust mark may be required by entities you do business with. Okay, so with that as a background, I wonder Anne if you could show me which...was it a specific part of this comment that you were replying to or was it more general.

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

I think it was more general, but it was the realization that I will be having to deal with multiple entities that will independently decide what that level of...or what the level of adherence that they want me to act with them, so I will have to address it different for each one potentially.

Wes Rishel – Gartner, Incorporated

If you want to have the trust mark...

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

If I want government contracts, I assume it will be written into all of them, and it's just a natural go down the road. My point is, we don't know what we don't know about payer interfaces they impact. The ones I'm concerned about are not the HIPAA ones, maybe claim attachments, I want to talk about that because that's healthcare information. But, I'm not worried about HIPAA, I'm worried about what I'm getting ready to do in my ACO planning and my payment methodology determination, the rules that we're going to establish for reimbursements, not necessarily aligned with what CMS has decided. Our ability to move forward in those...that environment.

Wes Rishel – Gartner, Incorporated

So just let me understand. You think that in new roles that are not previously established or regulated, there is a likelihood that payers would be impacted in a way that's substantially different than providers would be impacted, is that correct?

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

I do, because of what we don't know. I anticipate...

Wes Rishel – Gartner, Incorporated

So, one thing to say when we don't know is, we can't do anything until we find out and we can't find out because we can't do anything. All right, so that's a formula for doing nothing. I am wondering what alternative you would suggest that allows NWHIN to move forward and meet your requirements.

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

At a minimum I would love some additional data gathering on payer interfaces with healthcare information, to educate the team making the recommendations.

Wes Rishel – Gartner, Incorporated

Is it reasonable to believe that payers, such as yourself, that are forward looking, will be responding to the NPRM?

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

Absolutely. And in a panicked way, by the way. And I'm worried that that will not crystallize in real beneficial messaging. So I'm going to help my plan crystallize in beneficial messaging, and this is an awesome opportunity for me, but I think that will be missed by all the rest of the payers who are going to feel lumped into something that they had no idea that they were getting lumped into, because NWHIN was direct and contained to something providers and EPs do, not every healthcare exchange that will exist in the future.

Wes Rishel – Gartner, Incorporated

I don't think you...

Jonathan Perlin – Hospital Corporation of America

...I want to be respectful of time on this point, and I think a number of great points have come out. I've heard pretty emphatically that: 1. Need to be mindful of the payer community, not just the provider community. 2. Variability introduces a complexity; Jim Walker argued that perhaps there's a core that one initiates with. I think a number of these concepts are ones that we should provide back to ONC for further refinement. But, I agree with the thread. Wes, final comment.

Wes Rishel – Gartner, Incorporated

One more 10 second question for Anne? So, specifically were you taking on bilateral skew?

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

Was I what?

Wes Rishel – Gartner, Incorporated

The last sentence in...

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

I don't even know what that means, can't help you. Maybe we can talk offline.

Wes Rishel – Gartner, Incorporated

All right.

Jonathan Perlin – Hospital Corporation of America

And the third was just a clarification, this was not intended to supplant any of the secure exchange that was going on today and Wes, I think your comment that there would likely be business incentives, business partners that require a trust mark as basically a mechanism of moving forward, to enter into an arrangement that one can envision in the future accountable care or otherwise. Cris, did you want to comment or...

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

I'm going to be very brief. I think the Walker rule of let's do very parsimonious solution, to start with some basics makes a ton of sense. I'm a little bit worried about the comments around the table at the end that this will be voluntary, so let's not worry about it and people can...because I don't think this is going to be voluntary, it's going to be a requirement on procurement contracts and other kinds of things. So, it's sort of like the old *Ghostbusters* movie, you know, don't cross the beams. If you take this rule and another one, it suddenly makes something pretty potentially worse. So, I think we should assume that this will be a mandatory rule, that it'll be applied to a lot of entities and that we ought to have a set of rules that we think everyone can live with; that if I'm connected to that NVE, I know it's going to be trustworthy, HIPAA compliant, secure, private. I don't know what all their interfaces are going to look like, I don't even know if they're going to provide all the services that I want. That's for me, on a contractual relationship to figure out what that NVE and for the market to develop. But we don't have a market yet, we don't have anything to test this against, we don't have any pilots to try; feels like we should start with absolute basics and allow innovation in the market, period.

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

I think what I'm taking away from this is, in our comment about the voluntary approach, we should mention that it may be problematic for payers and payers should be considered, and then you'll see we have another question about the learning environment and piloting and I think that we should mention payers included in those pilots.

Jonathan Perlin – Hospital Corporation of America

Just very quickly. I think...I like Chris', there's probably a bunch of entities that are going to be involved in this and we're not even sure what all of them are, I'm guessing, let alone what the impact would be on them. So, it's trying to be careful about the whole ecosystem.

Jonathan Perlin – Hospital Corporation of America

Okay...

M

...Anne's core concern is, let's make sure that whoever I play with, I'm going to understand what they can do from a trust and reliability standpoint, but to not get into an aggressive rule around all capabilities and homogeneity prematurely.

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

Yeah, both Jim and Cris, in our initial comment, we pointed out even a voluntary process can have profound impact on business. If you guys have anything to add to that, would you just sent it to me and we'll be happy to do that.

James Walker – Geisinger Health System – Chief Information Officer

It's just the language. This is Jim. It's just a language game. It's like saying, we're going to say voluntary and you need to remember it means mandatory. It's just we shouldn't use the word is what we should do.

Jonathan Perlin – Hospital Corporation of America

Okay, we're going to resume with question 61 during lunch. Dr. Rallins, understand you're...are you flexible for fifteen minutes? I think we have Betsy Humphreys on the line, Jaime is that? Will that work for you or...Okay.

Marjorie Rallins – American Medical Association - Director of Measures, Standards and Informatics for the Performance Improvement Division

Are you ready for me now?

Jonathan Perlin – Hospital Corporation of America

Are you okay to wait fifteen minutes? That would work for you?

Marjorie Rallins, DPM – American Medical Association – Director of Measures, Standards and Informatics for the Performance Improvement Division

Yes.

Jonathan Perlin – Hospital Corporation of America

Do we have Betsy on the line?

Betsy Humphreys – Deputy Director – National Library of Medicine

Yes, on the line.

Jonathan Perlin – Hospital Corporation of America

Okay Jaime, appreciate the work on the vocabulary task force. Dr. Betsy Humphreys joining us once again. We're going to keep to a pretty tight agenda on that, and then Dr. Rallins, I apologize for the delay, we'll go to you momentarily. So...

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

If it's okay, I'll just report from here instead of moving over to Dixie's table. So, this is a report from the Vocabulary Task Force and with a recommendation for the Committee, completely different topic, which is, recommendation for guidance to be given to measure developers, specifically developing eMeasures for use in certified EHR technology. But first, in order to sort of set the stage for this, I'm going to talk about some plans at NLM, I don't know if Betsy is actually going to announce things or not. I'm not convinced that there's an announcement today, but there are plans at NLM...

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

Say next slide.

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

Oh, I'm sorry. Next slide please. There are plans at NLM for creating a value set authority center that has a number of features that I wanted to relate back to the recommendations that were developed by the vocabulary task force and approved by this Committee actually in April of 2010. So, you may recall, we held a series of public hearings, we got input on vocabulary requirements and we crafted a couple of recommendations, a couple of multi-part recommendations. And so, it's just immensely gratifying and satisfying to see that the plans of NLM align almost perfectly with those recommendations, with the help and assistance of ONC and funding and support from CMS as well. So, I'm not going to go through, just in the interest of time, and trying to keep things going, you have the detail in these materials that were distributed for the Committee, but essentially, NLM value set authority center will be able to support the needs of value sets for meaningful use and so this also supports the need for those value sets to be used and supported by the measure developers in particular.

Next slide please. Continuing with the...back one please to we're at recommendation 2. So, this has to do with providing the infrastructure and processes for control over the value sets. There's work that is yet to be done in terms of specifying and enabling access and private sector alternatives through APIs, as is mentioned here. But the alignment with our previous recommendations and, again, to see the fulfillment of that vision being done in NLM, I just want to thank, on behalf of the task force, want to thank ONC and the NLM as well as those at CMS who are involved and have supported this. Which leads us to our next slide, which is a new recommendation; and this has to do with some observations of work that was done relatively recently by some of the measure developers in making requests for amendments or changes to the standards that we've...the vocabulary standards that we've already specified for meaningful use.

And so the essence of the recommendation is to provide guidance to the measure developers that they should, in general, use what already exists in the vocabulary and not try to, for example, pre-coordinate large parts of a new proposed quality measure in a new SNOMED concept that no one actually uses in documentation. There is plenty of experience and evidence about what actually works and what is used in the vocabularies, in the standard vocabularies in the real world. And so the basic idea is that we should provide guidance to measure developers to use what is used and to use what exists in medical documentation and coding first and foremost. But it also says that there may be cases where there is a good policy reason to use the measure itself as a forcing function, in fact, to require a new behavior in terms of documentation and coding and so, no problem with that. But let's be deliberate about it and leave that up to a policy process to make that decision, rather than leave that up to measure developers to create new concepts and new forms of documentation that otherwise would not be used.

So the task force is recommending that we provide this guidance to the measure developers. And we're also recommending that the committee endorse NLM supporting the measure developers with the infrastructure as well as enabling the existence of consulting assistance, so that the measure developers can gain more expertise in the standard vocabularies that they can use in that measure development. And so, the third bullet on slide 4 here, talks specifically about providing evidence to the measure developers about what is used in the vocabularies. And if we could go to the next slide please. This is an example of that kind of information that could be provided to the measure developers. This talks about the convergent medical terminology, which is a donation from my organization actually to IHTSDO and the NLM that we've been working on for a couple of years.

The slide outlines the details of what's available in that information, but, this looks at the actual SNOMED and other concepts that are used in the electronic medical records by actually over 20,000 physicians and approximately 45,000 nurses. And so, this is widely used and comprehensively in tens of millions of medical records. So, the idea here is that we've gone through and determined, based on scope of practice, what's used in a number of different clinical domains and made that available. This is an example of problem list subsets that include other information about the problem list subset such as alternate display names or interface terminologies, cross-maps and so forth. But this is the kind of information that NLM already is providing, so our recommendation is for the Committee to endorse NLM providing this kind of support to measure developers so that they can better use the standard vocabularies that are in meaningful use.

Jonathan Perlin – Hospital Corporation of America

Okay, do you want Betsy to comment before we ask for consensus on this point, or...

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

I think David and Cris perhaps.

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

Yes, David McCallie. Just a question about the avoid creation of new pre-coordinated codes. I mean, there's probably a long debate behind that, but, I notice there have been some debates, some discussion recently about places, for example, of mapping ICD-10 to SNOMED, where it would require in SNOMED post-coordination to match. And there was at least I think a suggestion made, that there were going to be some extensions to SNOMED to allow for pre-coordinated matches to make that translation easier. Are you saying not to do that?

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

No, that's not part of this recommendation. Could we go back one slide please. So that's an example of a case where there is a policy reason and a policy direction to create changes in the standard vocabulary, which is to have SNOMED pre-coordinated terms that match the ICD-10 terms, the ICD-10 CM terms that are going to be used. That work is under way. That's part of both SNOMED International and a US extension in the NLM. What this is saying is that measure developers shouldn't make stuff up on their own.

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

Okay, and it certainly makes sense. Second question, which I think I know the answer to, your top twenty-five hundred problems is very useful for systems design user interface optimization and the like, but you're not suggesting that no other problems count.

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

Oh no, these are convenience...these are what would be classified...you may recall from our previous work in the vocabulary task force, we identified convenience subsets versus defined value sets where a defined value set is the entire universe of an enumerated list of codes, terms and concepts that's used for a particular purpose. Whereas a convenient subset is something that, it's here you can use it if it's convenient for you to; these are all the convergent medical terminology example of problem list subsets, those are all convenience subsets. So, we're not suggesting that anything should be limited to those, but this is just evidence of what's actually used in the real world, as I said, tens of millions of medical records.

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

Thank you.

Jonathan Perlin – Hospital Corporation of America

Floyd Eisenberg?

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

Okay, so really just a quick congratulatory comment, because I think this is a terrific step forward. My one question is, my assumption is this is to be made available to measure developers creating eMeasures, under government contract. Will it be available also to others not under government contract, but creating eMeasures?

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

And just to respond to that, and Betsy may also want to respond. But I think that the NLM currently provides support throughout the US, as well as throughout the world, to all licensees of the UMLS, and so I think that seems to be the way to do it, so it's not necessarily just those who are under government contract.

Betsy Humphreys – Deputy Director – National Library of Medicine

This is Betsy yes, that's true. In terms of setting this up, which is what we will be doing with funding and backing from CMS and assistance from ONC and we're extremely grateful to Jacob Reider in particular, and others as well, I think that we will have a focus on meeting needs that are immediate to Stage 2 meaningful use clinical quality measures. But the intention is that the capabilities will be broadly available to anyone who can make use of them.

Jonathan Perlin – Hospital Corporation of America

(Indiscernible).

Stanley M. Huff – Intermountain Healthcare

Stan Huff. First, I'm very excited, I would congratulate the NLM on the progress that's been made on value sets. I think...I don't think we want to downplay the significance of having that national repository of value sets, and so that's great. The question I guess is, can you scope more, say more about what you mean in the phrase, "except where a policy process." I guess policy process seems pretty open and if we're not careful, the measure creators could think that they're a policy process.

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

That's a great question. Doug, I don't know if I can turn to you to talk about, what could we define perhaps to clarify as what's a policy process that would potentially determine the need for new forms of documentation and coding for eMeasures?

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

I'm not sure I have an answer for that, but I do think that certainly the discussions that we've had around the NwHIN governance and I don't know who made the comment, you know, take a look at the existing structures that we have and see if we can be parsimonious as we sort of figure out if there are missing pieces or the like. There's also this notion about establishing both internally, as well as to the external world outside of the United States, what are the standards, the value sets, the vocabularies, the kinds of specifications that we think are important to drive interoperability and the like. This is an important piece of that puzzle, to be able to say, from standardizing meaning, standardizing what we mean and the value sets that would be associated with a particular concept. Trying to figure out how to do that plus the structures and the transports and all those other things, we're really starting to talk about establishing what are the standards that the US Government has around clinical care; and I think it may be part of the longer term discussions. We're going to have a similar discussion, actually, when we talk about the S&I framework, in terms of how do we make sure that we're working on the right things and that we're establishing the right priorities and that we've got a portfolio of standards that we can update and that we can deprecate and then we can add to as we go forward. So, to me, this is part of that larger governance discussion and I don't know what that process is going to be, I think that's something that I'm hopeful that this team can help us understand what would be the issues there as well.

Jonathan Perlin – Hospital Corporation of America

(indiscernible)

M

I feel compelled to echo the previous speakers about my unbounded joy and enthusiasm for this unannounced, but imminent vocabulary value set center. It's been something that for many of us in the community has been a goal and aspiration for decades, quite literally. So, I agree with Stan, this should not be understated, this is a big deal and we're very excited about it, most of us. More substantively, the issue of the measure developers having vocabulary elements, I think it's crucial that we make a distinction between what I would characterize as algorithmic determinations or calculated value determinations and vocabulary elements. Clearly many of those inferred notions should have a conceptual anchor, so I'm not opposed to making names or terms or concepts for things that are otherwise calculated or algorithmically derived.

But when we're talking about implementation, it's terribly important that we distinguish between assigning a vocabulary notion, a conceptual notion, to these things and understanding how people and providers in the field are actually going to generate this information. It's not necessarily going to be anchored to a vocabulary element, but has to be associated with some kind of algorithmic or derivational formula, so that people understand. The example that Floyd and I were talking about before the meeting is normal blood pressure. Normal blood pressure as a conceptual term should exist, I have no problem with that, but for measure developers to assert that this is the concept is not sufficient. It must be associated with some kind of algorithmic or calculated value derivative to definitionally and operationally make clear what is meant.

Jonathan Perlin – Hospital Corporation of America

Okay, before we go to Betsy for final comments, notwithstanding the commentary, the good discussion we just had, may I assume a general consensus of enthusiastic support? Great. That seems pretty clear. I congratulate you, this really is a step forward as we contemplate the progress that will be available with this resource. Betsy Humphreys, we'll turn to you for any other comments.

Betsy Humphreys – Deputy Director – National Library of Medicine

I don't have any. We're very glad that with the support that CMS is providing for this, that we're able to move ahead on this.

Jonathan Perlin – Hospital Corporation of America

Terrific. Jaime, anything?

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

Thank you.

Jonathan Perlin – Hospital Corporation of America

Well we thank you and the task force, terrific work (applause).

John Halamka, MD, MS – Harvard Medical School

And Betsy I presume some more formal enumeration of what you'll be doing will be coming forward as signatures are gathered and approval's gained.

Betsy Humphreys – Deputy Director – National Library of Medicine

Yes, and I was discussing this with CMS and ONC, we are in constant discussions, actually, around this point. But, everyone is fine with this being announced, so, you can say we announced it today with more details to follow.

John Halamka, MD, MS – Harvard Medical School

Okay.

Jonathan Perlin – Hospital Corporation of America

Congratulations and thank you.

John Halamka, MD, MS – Harvard Medical School

And so the blog will reflect.

Jonathan Perlin – Hospital Corporation of America

All right. Well, thank you very much, terrific presentation and thank you Dr. Rallins for your flexibility on time and to invite you and Leslie Kelly Hall to sequentially provide the report from the hearings on clinical quality and patient-generated data.

Marjorie Rallins, DPM – American Medical Association – Director of Measures, Standards and Informatics for the Performance Improvement Division

Okay, thank you very much and good morning everyone. Let me start off by saying that personally I found this meeting extremely engaging and informative, although my charge today is to provide you with an objective summary, and I'll do that. And I would also ask that any Committee members who were in attendance, Liz, John, Floyd and Leslie to please jump in and add color commentary as necessary. Next slide. You want me to do it? Okay, sure. Okay, so, and I'll be brief today. The meeting context and objectives were to leverage the experiences of Meaningful Use Stage 1, and all of the preparatory work in preparing for Meaningful Use Stage 2, in order to inform the thinking of how we move forward with developing requirements for Meaningful Use Stage 3. With the additional context of thinking about how we would do things differently, and gathering that information from a spectrum of stakeholders that may be looking at things differently than they have been done before. And then the objectives for the two committees were to get guidance to support standards recommendations and also to get guidance as to what are the policy tools that are available to help users be successful with meaningful use. So that would be the Policy Committee's objective.

We heard from four panels; the first one was the high performing healthcare improvement organizations and the analytics that support them. And the major theme was how can IT support the improvement those organizations quality agendas and we wanted to approach that with a forward thinking focus rather than a focus of what went wrong in the past; and that was moderated by Ahmed Calvo. Panel two was clinical decision support, the improvement arm of quality improvement and that major theme was linking QI measurement and clinical decision support and that was moderated by Norma Lang. The third panel was eMeasures and the major theme was improving the eMeasure landscape and that was moderated by Eva Powell. And the fourth panel was EHR vendor perspectives of necessary components of quality improvement; the major theme is embedded within that name and Floyd Eisenberg was the moderator for that particular panel.

I would say that the major observations from those days again, it was a very engaging discussion, was the committee was impressed by the consensus across stakeholders with respect to progress and challenges. We also learned about the progress with respect to standard setting, tool kit building, data dictionaries and value set repository work. And we heard about a desire for outcome measures and a need for concurrent and prospective measurements and less of a focus on retrospective measurement; but we also heard that there's still a place for process measures. One of the things that I didn't add here was there was a current theme on the focus of the patient and some themes that came from the National Quality Strategy. So. The key take-aways with respect to assessing the role for Federal policy and related standards in an effort to help users be successful with meaningful use were in the areas of quality measures for meaningful use, and that's no surprise because there's currently a Federal role there. But we also heard testimony that related to the use of quality measures in programs where there currently is no Federal role, such as the pay for performance programs at the state and private level. And there were questions about whether there can be or should be a Federal role there.

We also discussed maybe there's an opportunity to facilitate coordination, harmonization and dramatic acceleration with respect to the progress that we just talked about, and maybe there's an opportunity to facilitate real-time interoperability or to facilitate first time movers, as Paul Tang described them, who adopt standards early, such as using value sets or structured data, or using quality measures that incorporate the new concepts such as functional status or care coordination. We also heard that there's a need, probably a Federal role, to leverage the role of the patient and issues related to governance in the transparency of information. So, in closing, and I'll stop here, you can see that there's a lot for both committees to think about and I think the goal is to move forward jointly and iteratively together and it seems that this panel helped things get started on the right path. So, should we move on to Leslie and then we can take some questions if necessary?

Jonathan Perlin – Hospital Corporation of America

Let me just take Chair's prerogative to thank you for a really very thoughtful summary and to thank all who participated, both in providing testimonial at the hearing, as well as facilitating those panels or otherwise participating from the workgroup. Any comments on this particular topic before we move to Leslie? Well again, great appreciation, terrific and let's move to Leslie Kelly Hall.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Okay, thank you. I just would also like to comment that this kind of a meeting couldn't have been held a few years ago, without a lot of guffaws and eye-rolling. And this has moved on to, I think, a lot of champions in the room discussing how do patients interact with health information technology and therefore their providers. So there were several panels in place. We heard a wide range of input from patients themselves, from experts in the field who are currently using patient-generated data in their care processes, as well as users in quality of patient-generated measures and outcomes and innovators like Quantified Self as participants and providing feedback to this group. We not only looked at how patient-generated data could be used, but also what are the challenges related to patient reported and patient-generated data and I'd as those that are also in the room to chime in if they have other comments from that meeting.

So, I'll overview several things. CMS discussed the HCAHPS and other patient reported outcomes and discussed that that will continue to grow, the rely on the patient for further information. Patient-generated health data, a white paper was presented. I'd encourage all of you to read it; it had some great and instructive information as well, and provided some use cases and workflow and technical descriptions, and could be actually a foundation for future S&I framework. Patient-generated data is also not equally helpful to every patient or provider or situation in generating improvements in health. And this was underscored in several ways; one was that the importance of expectations being set, that to make patient-generated health data successful and interoperable. There needs to be a clear framework of use, frequency of sharing, data to share, how the providers use it, whether the providers accept that data into the record or simply use it for information only; and then the accuracy of the data, what was the rules around that data and data's use. We also learned that patient reported outcomes can compliment traditional clinical and administrative data. In fact, there was testimony about the accuracy of the patient data, often being much more so than what had been interpreted by the clinician in many cases.

The physician is responsible only for the use of the patient-generated data that the physician has actively chosen and specifically incorporated into the patient's medical record. This came from within the white paper, but quoted from AMA, I believe was the original source. Patient access to education materials was an important to avoid unnecessary communication, furthermore we heard discussions about the appropriateness of health literacy and languages and also that patient-generated data was an important safety check. We heard from a patient who actually saved his own life by acting as a participant in providing information around his intolerances.

There was discussion around considering what could be done in Stage 2 as well as in Stage 3, and there was not a bright line, there was gray around each of these, but, there was support for having patient-generated data included in some way. There seemed to be more prevalent use of questionnaires and responses. There was recommendation of a progression of measures for patient-generated data; the first might be the volume of use, then the types of use and then the use itself. There was a very provocative discussion around the whiteboard as a metaphor for collaborative care and communication. As we know in the inpatient setting, that whiteboard is used to communicate with all parties, and this was thought of as well, how could that metaphor be expanded across healthcare, so that all parties could be communicated with just in time information and also have that information fill in a record. The DA reported and believed that patient-generated data is a key component to improve healthcare and health status and is making efforts to evolve that in their provision of care. There is an emphasis and discussion of experience and value, that the value of this information can improve health status, but were needed to have standardization of how that data is received. The workflow was underscored over and over again, how does patient-generated health data get incorporated into the workflow, how is synchronization handled and security.

We also heard that registries are an important part of patient-generated health data for collection and dissemination and said it should not be considered outside the realm and really part of what we consider the overarching electronic health record. I think more the ONC definition of EHR than perhaps our definition of EHR as a single thing. And that mobile will be a game changer for patient-generated data with expectations of users, could potentially overwhelm us without some sort of structure in place to accommodate patient-generated health data. We heard testimony about the use of validated tools and we also heard ideas about investigating new ways for patient-generated health data to become interoperable; perhaps through an S&I framework, APIs were discussed, using direct and a consolidated CDA. So, take advantage of existing structure and existing environment and add a new player was heard over. Patient reported outcomes or PROMS, we heard about the need for multimodal delivery and collection, like IDRs or patient-facing systems.

The concerns up front that we heard over and over again were workflow, information overload and liability. And those do need to be considered; however, I think as Deven McGraw stated, these are not game stoppers. Implementation has gone better than expected; we heard that over and over again where there were fears up front, they actually proved to be not as onerous as expected and that patients were positive and that workflow was not adversely impacted. We heard about PAM scores and the need to contribute patient readiness as an overall consideration with patient-generated health data and that a modular approach for EHRs or bolt-ons to patient-facing systems or EHRs could be considered, especially around things like pediatric and family care.

So some of the conclusions are that patient-generated health data should be able to be accepted into the EHR but they might be a condition with which the clinician decides, based upon whether the clinician feels that that is relevant to that episode of care or not. There was debate about that, but standardization was important, interoperability. There was the idea of multiple respondents, include patient-facing systems, shared decision making is an important concept. Include expert systems outside an EHR, that idea of bolt-ons and also including quality as a concept for patient participation, and not limited by legacy systems. So there was also discussion of value, and where the value of patient-generated health data is where that intersection occurs between the patient and provider. But also, going forward, it's much more broad and includes a larger care team. Now, this is a great idea and concept, but it's also a little bit like art, you'll know it when you see it. So, predetermining value up front of where those intersections take place is quite difficult and today, all of us filter information that we see in our inbox or that we see in our records, and I think that will continue for some period of time.

So, conclusions. The standard of care is evolving and may include patient-generated health data. I think Deven McGraw also spoke to when is that standard of care going to include patient-generated data, and it's something to consider. And that where it's been implemented has improved quality and patient confidence. The patient-generated health data to incorporate values, intolerances, advanced directives and preferences could fit well within a CPOE structure. Workflow, structured data and expectations need to be well defined and understood. Each pilot that was successful did this up front. New technologies like mobile health and new data sources may overwhelm the providers who have not initiated an approach or structured approach for patient-generated health data, and patients are the source of the majority of data in the record and that patient-generated health data electronically is a logical next step. It matters because they allow clinicians to see a richer picture of the patient's day to day health and not necessarily all data goes into the EHR, we need to include necessary to clinical decision making and that value-based reimbursement may make patient-generated health data more pervasive.

Concerns exist, however pilots have proved positive. Patients are very eager to participate and are more engaged in care and treatment, patients can provide accurate and useful information and patient-generated health data will require computing and human intervention. Attribution is a very important part of acceptance so when that data comes into the record, it clearly states that this is patient-generated or perhaps even family or caregiver generated, and the process will vary by providers; the process for use and acceptance. The data structure, however, should be constant and standard. That's it.

Jonathan Perlin – Hospital Corporation of America

Let me again congratulate you on very thoughtful synthesis, express appreciation to all who participated. We have a number of cards up. And Liz, let me start with you.

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

Thank you Leslie. This is Liz Johnson. I would...did an excellent job of really consolidating what we heard, but I would really boil it down to something fairly simple and that is, that patients want to be engaged, they really don't always understand some of the complexities of why some of their information is not already being part of the record, it's very clear. I think the providers at the table, those clinical providers and hospital providers want that to happen. So our job is a very difficult one, but one that's critical and that is, it goes far beyond what it looks like to the Meaningful Use Stage 2, which is download and view. It really goes to how are we going to build standards where that data can begin to be incorporated. And one of the discussions that we had, both in and outside of the panel was, should we pick two or three populations to start with, maybe because the needs of a patient receiving palliative care are different from a chronically ill patient are different from a well patient. And those that we heard from most frequently were chronically ill patients; so, our sample wasn't large enough. Again, just incredible food for thought, lots of enthusiasm, even when the liability issues came up, which are real, which is if you act on data that's inside of a clinical record and it's from a source, even if tagged that you can't verify, how do you deal with that. So, exciting times, but lots more work to be done.

Jonathan Perlin – Hospital Corporation of America

Thanks Liz. So, let's just go around with the cards that are up. We'll go Rebecca, David, John Derr and then Marc Overhage.

Rebecca Kush – Founding President and CEO of the Clinical Data Interchange Standards Consortium

Yes, I was at the hearings as well and I just wanted to make two comments. One is, I was really encouraged when they see a little bit of what they can do with this data, and then they were actually asking for more standards; so I was really encouraged to hear that. And the other thing was, I'm always thinking of where research fits and where we can do something with Meaningful Use 3, and a lot of things that they were struggling with and trying to...basically asking for are things we do all the time in research; so like using electronic diaries or IVRs or those kinds of patient reported outcomes with audit trails and regulated requirements I think could be leveraged.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I'd like to add to that, because I think there was a hand in glove idea with patient-generated data, whether it is for care or research, there really is opportunity for consistency and parsimony with data collection and data standards. In fact, great enthusiasm for that, so thank you Rebecca for bringing that up.

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

David McCallie. So, I know the answer is that I should have come to the hearings and I would know the answer to my question, but, and I'm not trying to be facetious, but, the patient-generated data is what drives healthcare already in the sense that if a patient didn't show up with some data, there would be no healthcare. What's different...where does this...what is this patient-generated health data refer to that's different from the process of patients bringing data to their providers already? Is there a clean distinction?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

There is; one is patient-generated and basically accepted electronically and the other is interpreted and entered by some sort of intake process, the provider or clinician. So, there is a natural filter, every time any one of us acts as an interpreter for another individual. And the testimony we received talked a lot about the accuracy of the patient information, which I think was a surprise to me. But that distinction is patient-generated and electronically accepted.

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

So the distinction is, you're calling it patient-generated if it doesn't go through the clinician interview process...the stuff that goes around...

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

In this particular case, this is patient-generated...electronic patient-generated health data.

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

So David, let me add to Leslie's explanation, if that's okay Leslie. This is, I am the patient and I put the data in myself, no one is an interpreter or a third party interpreter. So, if I say, my left arm hurts and this is how it's described, I describe those symptoms and so but it's even more specific, it's all the glucoses coming out of their homes, it's all of the mobile device generated data as well, which is not routinely coming into our systems today.

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

Although much of that does come in today, just through the process of the interview.

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

But it comes in...so as a nurse...

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

...got an electronic...

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

...I become...but as a nurse, I become the interceptor of the data and the interpreter, as does the physician, in lieu of, "I, Liz Johnson, the patient directly enter the data into the record myself." Does that make sense? Not...okay, so you asked me a question about...

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

If I send an email to my physician and get an answer, is that patient-generated data?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

It could be. The messaging is a part of it. So let's think of patient-generated data as: one is I respond to a clinician's request; that could be a questionnaire, that could be a message, that could be me filling out a form. Another patient-generated data might be that I am the initiator of that data, and I'm sending you something that I think is important to my health and you should be able to receive it. I have my own observation, my own result that's coming into the record. Another might be that I am amending or adding additions to some data generated elsewhere, like a collaborative care plan or collaborative record. And those are just three examples of the differing types. But it was clear, for instance, that I can't remember which testimony received, but a physician talked about, I can talk about what I prescribed, but only the patient can tell me what they're actually taking. And that became a very important reconciliation point and I think hit home to many people.

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

My only point is that all that happens today...

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

It doesn't.

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

...it even happens in a paper record and so, what it sounds like this is an attempt to maybe formalize it, better structure it, better...

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

And so I would just challenge that because today I can't write something and hand it to the doctor to be placed in the chart, even manually.

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

Sure you can.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Well, in general, the doctors interpreting.

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

(indiscernible) one other thing that's different is that the information is not only what is reporting at the time of the visit...

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Asynchronous

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

So it could be...there could be more data points, it could be over a period of time, it's not just...in fact, patients, I've heard this before, that patients when they go into the doctor's office don't necessarily accurately report the symptoms they're having over a period of time, as they would if they actually were recording them as they were experiencing them. So, there's also a filter that the patient has input on it when they're in the doctor's office. So, I think there's also this...the frequency or the timing that is relevant and may be different than the way it's occurring today, as well as the form and the ability for it to be in the patient's own words.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

That's great Jodi. And also I think the asynchronous approach is the same kind of thing with timing.

Jonathan Perlin – Hospital Corporation of America

If someone actually has a definition that's sort of more formally developed, otherwise, I think it's one we need to seek. I would offer that...

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

We have a definition that came forward in the white paper, and I would be happy to pass that on as part of the testimony.

Jonathan Perlin – Hospital Corporation of America

That would be great. Floyd were you going to make comments at this point?

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

I was just going to say the example that was provided by the patient was a number of adverse events that occurred related to PICC line insertion, knowing that he was getting...that he had a thrombosis and had to convince the doctors to do an image study to find it, and wanted, and put on the white board, that he had a reaction and never should have a PICC line and he wanted to have that input in the record, ended up in the OR and had a PICC line, and then a PE. So, the issue is, patients want to enter the data themselves and have it known it's from them because what was interpreted by a physician did not get to his point.

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

The failure there was, in that case, I read that use case, the failure there was the clinician failed to be a good clinician, it was not a failure of IT systems.

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

That was just one example. So...

Jonathan Perlin – Hospital Corporation of America

Let's get that definition, let's look at it because I think, David, your point is well taken. Patients who've uploaded their blood glucose from glucometers, since that became available. On the other hand, it's not the general practice that everybody does that; one can imagine with mobile devices, proliferation of functional data, VA, Tim, the VA is at lead in terms of use of functional status assessments as self-reported measures that aren't assessed by a professional. I think that may be a part of the element; it's not an assessment or judgment. But, it's obviously nuance. It's clearly not a bright line either, I mean, where's the boundary today between telemedicine and electronic health record, not to throw another sort of definition out there. But, let's get that and let's take other reactions and then we'll go back to working on the response.

John Derr – Golden Living, LLC

This is John Derr. The word that we use is longitudinal and not episodic care, and I think that's what they want. And there's also, they wanted data that was real-time, being real-time where somebody could take action, including themselves, and also stated this is a culture change, and survey part was as important to the patient as it was to the doctor. I mean, they wanted to have skin in the game and we call it longitudinal care where you can pro-act on things way early, rather than react to them. And they wanted help in quality measures and standards to be able to help themselves, in effect, and not have to go to a clinician to get everything, but be able to do some work on themselves.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

That's exactly right.

Jonathan Perlin – Hospital Corporation of America

Terrific. Thanks John Derr, and we'll go to Floyd Eisenberg next.

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

I just want to reiterate what I heard through the day was, we are in the midst of a culture change, and we have to address standards around it. I can't remember if it was during that day, but it might be, that someone referred to it as the patient spring, I think it was that day.

W

Um hm.

Jonathan Perlin – Hospital Corporation of America

Marty Harris.

C. Martin Harris – Cleveland Clinic Foundation

So, I think this is a very interesting space and I don't think we've even seen the end of the beginning of this yet, in terms of information. But I just wanted to go back to this comment about action, because we've had patients who have entered data, over four hundred thousand now, remotely. And it's sort of that's the novelty when you begin, but it really is about action and as I looked at this list, one other category that I think we should do is make sure we understand what that means to both the provider and to the patient. And it's an expectation gap that I think is really beginning to grow. I think patients want to get their information in, but they also have an assumption about what someone is going to act on it, whatever that means to them. On the clinician side, structurally it means that I'm getting data that in fact may allow me to improve outcomes in the long run, and maybe some short term clinical decision making as well. So, some process to help the patient and the clinician bridge that gap as we go through this field I think is going to be very important, or else we're just going to have major disconnects.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

And I think we heard from the people that did testify that that setting of expectations up front, what is the data we're collecting, what's the timeliness of the use, how is it being used, who is providing it; those kinds of very specific, up-front things were important. I think that's the case with anytime you bring in something as disruptive as an industry change that this could bring, there has to be first some early on steps.

Jonathan Perlin – Hospital Corporation of America

Marc Overhage.

Marc Overhage – Siemens Healthcare

Just, and again, I like David wish I'd been able to be at the meeting, but maybe you talked about this and I'd be curious. You mention the PAM score in particular as an example and I wonder if there was any discussion about the cost structures today for some of these patient measures; PAMs a great example. There are significant costs associated with the use of and how that...whether that came up.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

The cost was not discussed and this was discussed as an example of patient reported scores of some kind, not as an end-all. But the idea of patient confidence was discussed in almost every testimony that when the patient participated with their own data, they were more confident in the providers care and more confident in their ability to self-care. I think that was an underscored theme, but that particular measure was simply part of the testimony and as an example.

Jonathan Perlin – Hospital Corporation of America

Jodi Daniel, last word.

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

And I have the definition if you'd like me to read it out loud for folks, from the white paper, and anybody who would like a copy of the white paper, it is part of the hearing materials in the record and I think it was actually...it was very well done and it's very helpful in thinking through some of the issues. It says PGHD are health-related data including health history, symptoms, biometric data, treatment history, lifestyle choices and other information created, recorded, gathered or inferred by or from patients or their designees, to help address a health concern. Patient-generated health data are distinct from data generated in the clinical setting and through encounters with providers in two important ways; first patients, not providers, are primarily responsible for capturing or recording these data. Second, patients direct the sharing or distributing of these data to healthcare providers and other stakeholders. In these ways, patient-generated health data compliment provider-directed capture and flow of health related data across the healthcare system. So, that was the working definition that was presented at the beginning of the hearing and that guided the discussion.

Jonathan Perlin – Hospital Corporation of America

Terrific. Well, I think that's very helpful. Why don't we reflect on that definition in terms of the implications. I think the point that was made, patient spring, Floyd, I agree. I mean, I think the whole spirit of clinical relationships is changing for the better with a balance, sort of concurrence with the advances in technology, suggests it will be accelerated. Marty, your comment's right on point as well, that it's a cultural shift and one of the things that we can do to anticipate this, to think about how we might accommodate, in terms of the ecosystem, that is emerging. Leslie, any final thoughts?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I do. Yes. I do think this is an opportunity because it is a green field, to start with standards and make those available so at the time the organizations start to accommodate patient-generated data, those standards exist. So, there is work going on right now in HL7 on a consolidated CDA template for patient-generated data. We also have work being done on the blue button in direct that helps in the transmit of patient data eventually. So, I think there is great opportunity for us to set that stage, and I would encourage that effort.

Jonathan Perlin – Hospital Corporation of America

Terrific. I don't want to lose that thread, generous offer from Rebecca Kush in terms of what may already be available to transfer over from the research contacts. Well, to both of you, Marjorie Rallins and Leslie Kelly Hall, many, many thanks for just very thoughtful...providing thought-provoking discussions today that clearly will direct a good bit of our work going forward. So, thank you so much for that.

Marjorie Rallins, DPM – American Medical Association – Director of Measures, Standards and Informatics for the Performance Improvement Division

Thank you.

Jonathan Perlin – Hospital Corporation of America

So, some personal patient reported data. I'm hungry. I suspect many of you are as well. For those who have not found your sandwiches, I believe they're outside of the door. Let's take literally about three to five minutes for bio-breaks and picking up sandwiches and at 12:30 sharp, we'll resume our discussion of the governance responses. Okay. Let's reconvene, let's pick up with Dixie Baker and we're going to go back to, on the slides, and it was question #61, which is...Okay, let's resume where we left off. We're going to go back to the Power Team responses. We're on question 61 and Dixie Baker will be leading us through the remainder of these questions, and we'll go immediately from that to the Privacy and Security, that should be a shorter discussion, because not only has the workgroup dealt with that, but we actually saw those responses and the changes that Dixie will present are the ones that we had suggested before, so that should, hopefully, be fairly quick and allow us to get to Doug Fridsma's discussion of S&I. So, without further adieu, Dixie, thank you very much for your flexibility.

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

Okay. All right. I think we got through 62 here, and the only change to 62 is it will change that community of their own, we'll reference the public/private standards entity that we have talked about. So, question 63: "What would be the best ways ONC could help facilitate the pilot testing and learning necessary for implementing technical standards and implementation specifications categorized as emerging or pilot?" This is...we spoke briefly about this with respect to comment that Wes said earlier, and also, this is the first of several questions that relate directly to what the NwHIN Power Team has been doing. So, as I mentioned earlier, we think that the validating the entities, or in this case the public/private standards entity that we've been discussing, should encourage the pilot testing and investigation of these emerging and pilot standards. So, ONC's role would be identifying what these emerging and pilot standards are, and then they would be piloted at the NVEs with encouragement from this public/private entity...standards entity. Comment? Oh good; it's good to catch you all with your mouths full.

Okay. Question 64: "Would this approach for classifying technical standards and implementation specifications be effective for updating and refreshing interoperability CTEs?" And they did...they included...you may recall that at last month's Standards meeting, one of my slides showed this graphic that had four quadrants in it, and it depicted how standards moved from emerging to pilot to national standards, based on their maturity and their adoptability. Well, that picture is in the RFI and so when we say we endorse this framework, that's what it is referring to, is that picture. So we agreed that classifying standards as emerging, pilot and national standards is consistent with what our Power Team has been doing. And we noted that although this...something else that was brought up this morning, although the process makes sense, the actors and their roles still need to be clearly defined and, I think we need to emphasize that in our response. The only change I'll make to this, so far, is in that last sentence, "we recommend that this public/private standards entity be responsible for collaboratively identifying interoperability CTEs with oversight from ONC. Any comments?"

Okay. Now, the next ones I think will go really fast, because the question was "What types of criteria could be used for categorizing standards and implementation specs for interoperability CTEs?" We would prefer criteria that are objective and quantifiable and we just said we recommend using the criteria and attributes that we've briefed to you before, that the Power Team has identified. So, the next set of questions address...

Jonathan Perlin – Hospital Corporation of America

There is a question from Leslie Kelly Hall.

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

Yeah.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Dixie, I just had one comment back two slides, my mouth was full. The role definitions that you also articulated, also the idea of roles that could evolve, how do new roles get entered and how do old roles get sunsetted, just that, as we think in the future of patients and families.

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

Yes, yes, yes. We'll add that; actors and their roles, how will evolve? Got it. Thank you. Okay. These are the responses addressing technology standards to support CTEs. You'll see that these are at a much lower level of granularity than the high level CTEs we've spoken about up to this point. Question 39 is: "What standard of availability, if any, is appropriate?" And we felt that availability requirements are service specific and so, we think it's unrealistic to specify a single availability and as we've covered before, we think transparency is more important and actual...it's more important to be able to see the actual measured availability that to set and codify an availability requirement that is intended to cover all situations. So, measured availability.

Okay. The next one, these questions 45 and 46 both relate to this condition I-1, "An NVE must be able to facilitate secure electronic health information exchange in two circumstances; when the sender and receiver are known and when the exchange occurs at the patient's direction." And our first comment really had to do with the condition itself. We didn't feel that it addresses all the reasonable circumstances for exchange, and it doesn't use the language that's commonly used to describe these exchanges. We noted that the conditions under which it's appropriate to exchange health information are specified elsewhere and we suggested that the conditions not be specified in the governance regulation at all. And then regarding the questions, we answered both of them in the same way, that the trust fabric should be decoupled from the transport mechanisms and that the transport standards should not be specified in governance regulation, but rather the governance regulation should require transparency with respect to which transport protocols the NVE supports and how it supports these protocols. Jim?

James Walker – Geisinger Health System – Chief Information Officer

On that question, or the condition, when the exchange occurs at the patient's direction, as if the sender and the receiver are not known? Is that the way that is meant to read?

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

It's and, it's and. When the sender and receiver are known and when the exchange occurs...not or.

James Walker – Geisinger Health System – Chief Information Officer

Right, but what I'm saying is, when the exchange occurs at the patient's direction, the sender and the receiver are known in that case also, correct?

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

Um hm.

James Walker – Geisinger Health System – Chief Information Officer

Okay, the first time I read that, or the first three times, that didn't dawn on me.

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

That's a good point. It's really not clear, because it says in two circumstances, and then it gives them...yeah, yeah.

Jonathan Perlin – Hospital Corporation of America

Jim, if I might, I think Dixie your inclination not to over-specify is on target. Jim, to your point, suppose the patient says yes, send it to an oncologist...send my x-rays to the oncologist you recommend. So, I mean, what does known mean, I mean it's known sort of categorically but not specifically. And so, one can envision a circumstance where the patient directs transfer of information, but the receiver is not known. Or, on the other hand, my doctor is Smith, have the lab send it to me...I mean it's known, but if it's not known with some degree of specificity...I think the inclination not to overspecify the circumstances of transmission...

James Walker – Geisinger Health System – Chief Information Officer

How can you send it if the receiver isn't known? That's like saying, I'm going to send a letter but I don't know the address.

Jonathan Perlin – Hospital Corporation of America

No, no, the patient directed transfer of information...

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

I mean, we didn't like...I mean our reaction is to basically say this is not needed on good criteria for a lot of those reasons. But, if you were pushing data to a health exchange for future query, by as yet unknown individuals, then you're sending data somewhere when the receiver isn't known yet, and they haven't queried for it.

James Walker – Geisinger Health System – Chief Information Officer

Okay. I think the language could be clearer so that people understood...

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

Will make the comment that the language isn't clear, but our main comment is going to be that it really doesn't belong in the...okay.

James Walker – Geisinger Health System – Chief Information Officer

My point's irrelevant then. Sorry.

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

Well, in case they reject our overall comment. Okay. Question 47: "Are the technical specifications, domain name service and the LDAP, appropriate and sufficient for enabling easy location of organizational certificates? Are there other specifications that we should consider?" We don't think the governance regulation should specify these approaches as exclusive. We think they're appropriate for use, we just don't think the governance regulation should specify them as the only ways you can discover digital certificates. And further we don't think the governance regulation should specify protocols for certificate discovery at all. We think that questions 45 through 47, all three of these that we've just discussed, are at a much more granular level than is appropriate for a governance regulation.

Question 48: "Should this CTE condition I-2, require all participants engaged in planned electronic exchange to obtain an organizational or group digital certificate consistent with the policies of the Federal Bridge?" And we concluded that this is a policy question, that will be looked at by the Privacy and Security Workgroup, so you're going to have to hold on to see what the Privacy and Security Workgroup has to say about it. Okay, the next question is...this has to do with the ability...the NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of information about that particular subject or patient. Question 49, 50 and 51 all three relate to this condition I-3; 49 says: "Should we adopt a CTE that requires NVEs to employ matching algorithms that meet a specific accuracy level or a CTE that limits false positives to certain minimum ratio? What should the required levels be?" This question relates directly to the Power Team that Marc led, but we again, don't think the NVEs should be required to meet a specific accuracy level, but they should be required to publish their accuracy level and the method that they calculated their accuracy level. We also pointed out that this particular CTE should only apply to those NVEs that need to match a specific individual with their individually identifiable health information. And as John pointed out this morning, some NVEs could do nothing but kind of a routing function, so it wouldn't apply to everybody, so we think it's a very situational CTE. So we don't think there should be a CTE that requires a particular algorithm or a minimum accuracy level.

Question 50 says: "What core data elements should be included for patient matching queries?" And we referred them to the work of the patient matching power team that Marc Overhage led last summer. But, we probably should reiterate in that, what we said in the last one, that we don't think it should require particular algorithm or minimum accuracy level. "What standards should we consider for patient matching queries?" And we felt that the standards are protocol dependent; we gave as examples, for exchanges that use the Direct protocol, the CDA header is appropriate and for exchanges using the Exchange protocol, the cross-community patient discovery algorithm...or data. So, again, this type of CTE we think is inappropriate for the governance regulation.

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

Question. Dixie, just a quick question. On the fact that we don't require a specific level of matching algorithms, so it's sort of a buyer beware kind of thing. Will the transparency of what they are able to do be available to the consumer?

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

Yeah, that's what we recommended is the transparency that you know what their availability level is as well as their matching accuracy level is and how it's measured. They should publish and make...

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

So, to us from a standards perspective, what I would say is because the knowledge for example that you hold in this area is not equivalent to the normal consumer. We need to be clear that people need to read that part of what they're buying, because otherwise they're going to think all NVEs are the same, and they are not, right?

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

That's a good point. That relates to question 49.

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

Right, exactly.

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

Yeah.

MacKenzie Robertson – Office of the National Coordinator

Excuse me, this is MacKenzie. I just wanted to remind everyone to please identify themselves before speaking for the transcript. Thanks.

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

Liz Johnson, MacKenzie.

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

On the matching, there's some processes that there's a human intermediary who can validate and refine the match, other processes where there isn't any sort of double checking or confirmation processes. Is that part of...is that relevant to this? It would seem to me that somehow we'd need to try to communicate that to customers.

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

Yeah, that would be, in my mind, that's part of the method of calculation. If they publish exactly how they calculate, their accuracy level and this is how I calculate it, that's what we're talking about.

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

Or maybe if they assume a human intermediary...

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

They should say so.

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

See, there are some processes I think, where it should be possible to look at a lower quality match, if there's a human intermediary, and then the human intermediary can confirm or disconfirm the match. So that for instance a patient wouldn't miss having their information applied to them in a situation where the clinician could confirm that they were actually the person at issue. Seems like we'll need to represent that in some way here.

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

Yeah, we should...in other questions what we've said is that these...this public/private entity, when they specify the criteria for validation, they specify how they're going to make it transparent, how they're going to publish, and I think that we should state that here as well.

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

David. One elaboration on that. I mean I think that one of the things that was clear to us as we worked our way through this is that the original notion was fairly limited to an NVE set of services that were fairly similar to what we have in Exchange today; and we were trying to cast this as something that could be more appropriate to as yet unenvisioned services. And therefore, being so specific about how you match patients was premature and at the wrong level, so you might have a system that works in say the military that's completely different matching algorithms and logic and accuracy than something that's a public health submission, data submission process. I mean, so we were trying to say, push those details down into the validating bodies for specific services, make sure they all meet trust, but push everything else down.

James Walker – Geisinger Health System – Chief Information Officer

Totally agree. This is Jim.

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

And I've captured that.

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

Dixie, this is Cris Ross. I don't think I was at the meeting where we discussed this, but the other issue is, it's not clear to me that the presumption should be that every NVE is going to engage in anything that requires patient matching.

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

Yeah, we said that. See, we say under question 49, this CTE should only apply to those NVEs that need to match a specific patient.

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

Understood. So, again I think we probably should be clear that the requirement should not be that every entity have a capability to do patient matching; some may not want to do it at all. Again, one of these issues that not all NVEs will be identical.

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

So, do we need to add more than what we have here?

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

I don't think in general we have called out very explicitly the idea that we think that NVEs may come in different forms and styles, and that they may not all carry out identical missions. I don't know if we've put that clearly enough in some of our preface materials generally.

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

So we say this CTE should only apply to those NVEs that...so you're suggesting we put another sentence that all NVEs provide different services...

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

I apologize. Reading the comments on 49, I'm perfectly happy with it. I just think in general we have not called out the issue that NVEs are not identical and that they will not all be expected to do the same service, and when they don't offer a service, they shouldn't be required to validate against that particular service.

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

Yes, as a general...okay.

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

Yes, as a general rule. Thank you.

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

Yes, yes, yes. Good, good, good. Sorry. Okay. Let's see, did we finish? Yes. So, now that's all twenty-two of the Nationwide Health Information Network Power Team questions assigned to us. So now the Power Team will be returning to the business at hand. That review of the Governance RFI was sort of a diversion from what we were doing; but our core task is to develop these recommendations for criteria and metrics for assessing the readiness of standards and implementation specs to become national standards. So, we'll resume that work starting at our next meeting, which is scheduled for June 28th, next week. So, the steps we have ahead of us, and I especially want those of you who are on the Power Team to pay attention to what we have, where we're going now, because we really, really need your help. We need to complete defining the metrics for the defined criteria, we have two more criteria that we have not yet even preliminarily defined metrics. And then we need to define the process for applying those criteria and metrics to the evaluation of standards and implementation specs. So, we plan to report our preliminary findings and recommendations at next month's meeting, Standards meeting. After that, we're going to do...we're going to test those criteria and metrics with a to be specified specification and then, just to make sure that they fit, make sure that they work, it's an exercise we want to go through. And then we'll present our final recommendations in August.

Jonathan Perlin – Hospital Corporation of America

Terrific. Dixie, thank you very much for this first order of business. I really want to thank the entire Committee for the very thoughtful discussion. I think, particularly the overarching principles which so much help to frame the subsequent responses to the questions. Now, we're actually going to segue directly into another presentation, again, this is something that not only has been addressed by the Privacy and Security Workgroup, but actually came to us previously and so, suggested that we focus on the highlighted red material, which are the changes really based on the recommendations from our last discussion.

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

Yes, I gave you guys our preliminary recommendations at the last meeting and so in your slides you have today, all of the changes and the questions that we had not addressed at that time, our responses are in red, so we should be able to just zero in on those responses. And unfortunately Walter is Chairing an NCVA...meeting today, so he's not able to be here; but I thank him for all his hard work, and the work of the entire workgroup. So, you know there were sixty-six questions, we were the workgroup, Privacy and Security Workgroup reviewed only six questions that were assigned to us plus one additional question that the workgroup members had a high interest in. And as I have here, the changes and additions to the recommendations that I reported last month are shown in red type, and those are the only comments I'll address. I would also note that although the Privacy and Security Workgroup did not make the overarching recommendation that the NwHIN Power Team made, the comments of the Privacy and Security Workgroup are completely consistent with the approach that the Power Team recommended.

So, this is the question that we weren't assigned, it had to do with the voluntary validation approach and there were no changes from what I reported at the May meeting, so you may take a minute to just read over that and if you see any discrepancies, let me know, or points that you would want to make. It's emphasis is really on building the NwHIN brand. Okay. The next question relates to condition S-1, which is the one that Jaime referred to earlier that refers to the security rule. And this is the one that proposes making the addressable implementation specs required. So, since we're talking about the recommendations of this Committee, I'll include the same recommendation here as we discussed earlier, that instead of referencing HIPAA, that they make each of the addressable implementation specifications explicitly required in a CTE. The only change I have there is that the workgroup did look carefully at each individual addressable requirements, which are in Appendix A by the way, and agreed that all of those requirements are reasonable. And, I think that's all I wanted to say about that.

Okay. The next question, 23: "Are there other security frameworks or guidance that we should consider for this CTE? Should we look to leverage NISTIR 7497 security architecture design?" Again, we made no change, made the same recommendation we went over at last month's meeting. The next question, 45, has to do with the types of transport methods and standards that NVEs should be able to support. And the Privacy and Security Workgroup notice came to the same conclusion as the NwHIN Power Team, that they didn't think it was appropriate for the governance model to dictate the transport protocols. Question 47 relates to, remember we had this question when we've talked about the NwHIN Power Team and again, the Privacy and Security Workgroup thought that the governance regulation shouldn't include this level of detail.

Okay, here's a comment that we didn't get to address at the last...or some comments, at the last meeting. And this comment was: "Which CTEs would you revise or delete and why? Are there other CTEs not listed here that we should consider?" And the detailed recommendations are on the next two slides, actually more than two. But, we also made an overall observation, some of our workgroup noticed that some of the CTEs are duplicative with this HIPAA addressable implementation specification requirement. So we recommended that the duplicate requirements be eliminated, so that they only have one CTE; they don't have two CTEs basically saying the same thing. I think that once they break out, if they break out...if and when they do as we suggested, they break out the addressable implementation specifications into separate CTEs, these duplications will become more obvious and it will be clearer which ones overlap.

This one is an important...S-2 is an important one for us to discuss here. The original CTE was: "An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly." And last month, we recommended one change, what we recommend this month at this meeting is, our final recommendation, should must only facilitate electronic health information exchange for parties it has authenticated, consistent with the Federal Identity Credential and Access Management of FICAM, trust framework at assurance level 2 or higher, and must implement an appropriate certificate policy that accounts for identity proofing and level of assurance. Just for your information, the assurance level 2 is just above 1, which is no assurance. And assurance level 2 means that there's some confidence in the asserted identities validity, but it certainly isn't two factor authentication or show up in person; it's not a really high level of assurance.

And our comment is that we wanted to reassert our recommendation that all digital certificates used by organizations exchanging the information within the NwHIN must be issued by certificate authorities that meet FICAM standards. Now that's not to say they must be cross-certified with the Federal Bridge, it's to say that they must meet the FICAM standards.

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

The only clarification or question Dixie, because I'd forgotten we had written that, it was a long...it was at least two or three meetings ago, is the debate that the Tiger Team got into when we pointed out to Joy that there was some inconsistency about the way the current FICAM rules are written that are really individually focused and not group focused. So I think some of the same Federal Bridge issues pertain, and we may want to soften this to say, you know, consistent with FICAM approaches, but they don't actually account for group level identity.

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

Yeah, I think that that's what we...it's not FICAM because that's not the same as cross-certification with the Federal Bridge, but I do think that we should capture the organizational certificate element that you're referring to, yeah.

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

Right, because that's different than the way they think about it.

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

Yeah. I'll just incorporate at the organizational level. Good point.

Jonathan Perlin – Hospital Corporation of America

Wes, were you trying to weigh in?

Wes Rishel – Gartner, Incorporated

Yeah. I guess I have a general issue when we talk about other organizational frameworks, are we saying that we're taking the idea of assurance level 2 from the FICAM framework, or are we saying that the authentication must be consistent with the framework? I'm just afraid that very few people will understand what that means and do you have a little bit of probability that they might actively misunderstand in the sense of draw different conclusions. So, I'd like to see the language be a little more explicit in terms of what you're trying to draw from those other documents.

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

Yeah, I think you're right. It looks like two separate things, and I think we should probably change it, consistent with assurance level 2 of the Federal Identity. Would that make it better for you?

Wes Rishel – Gartner, Incorporated

As long as, somewhere it needs to be clear whether you're intending to invoke all of FICAM.

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

That's what I meant. If we put "consistent with assurance level 2 of FICAM, and must implement appropriate certificate policy. Would that make you happy?"

Wes Rishel – Gartner, Incorporated

Well not so...I just a...try another 25 milligrams, see if that works. The...what...I would almost say it would be worth an explanatory sentence saying this is not meant to imply that all of FICAM applies. That would be the last 25 milligrams for me.

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

Okay, we'll put that in there.

Wes Rishel – Gartner, Incorporated

Thanks.

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

All right, let me make sure I note that. Okay, S-4 was then next one that we...

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

Sorry, you didn't cover S-3.

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

That's because it's no different from the last...

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

Okay. But I have a comment.

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

Okay.

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

And, I really think that in terms of S-3, for meaningful choice, this is an area where there are a number of potential conflicts or collisions with existing law in the area of HIPAA and FDA regulation of human subjects research in particular. And I'll just give you two examples of that where the scope of applicability of the S-3, we may want to consider recommending that that be examined for constraints, because in the current NwHIN of claim attachments and electronic submission of medical records data to CMS, to support the medical necessity of a claim, is part of the NwHIN. And so, in essence this provision would, in the case of HIPAA, would give consumers an opt-out from HIPAA transactions in that particular case. And so then, I don't know the potential consequence of that, would it be that they would lose insurance coverage, or would it actually change HIPAA in other ways, it's just a set of unknowns around that.

Then, in the case of the current IRB control over the use of data for human subjects research, this clearly would conflict with the current FDA regulations as they're implemented for research projects all over the country and so, I think that the scope of applicability is something that it may be appropriate for the Committee to say, at least needs to be examined for possible constraining so there aren't those kinds of conflicts.

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

So, needs to be examined with respect to conflicts with existing law.

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

And I think HIPAA transactions and human subjects research are good examples. I'm sure there are others.

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

Okay.

W

Population health.

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

Population health, public health reporting, so if you're mandated by one agency, but the consumer opts out, what does that mean. I don't know.

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

David. The Tiger Team where that phrase meaningful choice got picked up from Markle and echoed into a variety of these regulations, you know made that point Jaime that you're making very clear, is that meaningful choice occurs in the context of existing law and there are some transactions for which the patient is not involved in the choice at all, and others where they are. So, I think it maybe needs to be comma, as consistent with existing law. But, the other thing that occurs to me here is that we still are going to struggle for a while with the scope of this NwHIN. There's one notion that it's a very narrow thing that's basically this current union of Direct and Exchange; and then there's this broader notion that I think we've been pushing for, that if you focus on the security and trust issues, you could encompass a variety of additional healthcare exchange types.

The question that Anne has raised is does that include payment type things and I think, in the long run, it probably does, but it's a good reason why these criteria are modularize, like John suggested, so they only apply within certain spaces. So, things that are carving out claims attachments and claims payment are well regulated and maybe you gain some trust that they're following appropriate group certificate management policies, but otherwise it's carved out from query response look up in an HIE, which has it's own set of CTEs that are different.

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

And if I can just make one other comment, just to amend. I think another potential issue with this one is the fact that many of the intermediaries that we have been talking about, previously I was talking about things we haven't really talked about, where it could apply. But many of the entities that we are talking about don't have a relationship with the individual patient or consumer, of any kind, especially if they're an intermediary that is essentially doing transaction routing...

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

Well that's our response, that's what we said, would not apply to every NVE, would apply only if they had their own repository.

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

But some of those intermediaries may have repositories, and yet still have no relationship with the consumer, and so I think it's the relationship with the consumer is the part of this that I was trying to get to.

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

Yes, totally agree. And direct relationship with the consumer. Okay. And I captured, “and a direct relationship with the consumer.” Thank you. All right. The S-4 originally said, “NVE must only exchange encrypted IHHI,” and we suggested revision so it said, “An NVE must ensure that IHHI is encrypted when being exchanged,” because it may be encrypted by another entity. S-5 is that “the NVE must make publically available a notice of its data practices.”

Jonathan Perlin – Hospital Corporation of America

Advance one slide.

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

Oops. Oh sorry, thank you. “The NVE must make publically available a notice of its data practices describing why IHHI is collected, how it is used and to whom and for what reason it is disclosed.” Now the RFI, in the body of the RFI, it goes into considerable length to describe the difference between what an NVE would be required to disclose versus a HIPAA notice of privacy practices or NPP. But if you just read the CTE, you get no sense of that, and basically, the big difference is that notice of privacy practices specified what the covered entity can do with a patient’s data; it doesn’t say what they do do with the patient’s data. And what they’re proposing in this CTE is that an NVE would have to disclose what they actually do with the patient’s IHHI and make that public. So, we suggested...we noted that this CTE doesn’t capture these nuances and that they also need to clarify that the information the notice needs to include when describing this actual incidences, when the IHHI is collected, would need to be updated periodically as well.

Jonathan Perlin – Hospital Corporation of America

Anne Castro.

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

Just me this time? Well, I like the what if there is no consumer-facing presence, may not apply to every NVE. I just want to echo again, I’m worried about the generalization of this statement, which is better than not having a statement. But, it is a big burden; same story, move on.

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

It’s a big burden to disclose?

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

To disclose to everybody, every IHHI that goes on at the payer.

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

Well to disclose it, I mean, you could just publish it, you don’t...

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

Not individually?

M

That’s not required.

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

Make publically available.

M

(Indiscernible)

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

You mean just the privacy policy. Okay, we do the privacy policy. I apologize for overreacting.

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

Yeah, the data practices policy is what it says.

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

Okay. I took it to mean something a little more...

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

It's talking about what they do with data, why they collect the data, what they do with it.

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

I took it to be the deeper meaning of the bigger issue of disclosure on an individual basis, and that was incorrect. Thank you.

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

No. It's public notice.

Jonathan Perlin – Hospital Corporation of America

Thanks for clarification. Jim Walker.

James Walker – Geisinger Health System – Chief Information Officer

So back to Jaime's point about the question whether the NVE has a relationship with the patient or other individuals affected, not today obviously. I think we need to really think about what that means. There will be responsibility with respect to the patient, there's fiduciary, there will be a set of things that constitute a relationship with individuals and I'm guessing, we're going to need to think that through parsimoniously, but still understand what the criteria for that are, and maybe, in different settings, there will be a different kind of responsibility to the patient, it won't just be a sort of on/off switch.

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

We called it, in our response to this one, a consumer-facing presence. What he referred to as "no direct relationship with the consumer." A consumer-facing presence may be a better way to put that, right?

James Walker – Geisinger Health System – Chief Information Officer

Well, but I think it's going to need to be more nuanced than that; this is Jim; is what I'm saying. I think a consumer relationship is different than a patient relationship, there are all kinds of things that providers are supposed to owe to patients that a seller doesn't owe to a consumer. There are probably things owed to people that are neither consumers nor patients, public health kinds of things. I just think we need to think through what the various kinds of relationships could be and what they will mean.

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

And types of notice as well. We should just make a comment that a lot of details need to be...yeah. Okay. Got it, thank you. Okay, moving on. We didn't change our recommendation regarding S-6, but S-7, this we...it said: "An NVE must operate its services with high availability," and we suggested changing it to, must publish its actual availability and describe the method used to measure availability, which is consistent with what the NWHIN Power Team recommended.

Jonathan Perlin – Hospital Corporation of America

I think we may have a question on the prior, Leslie Kelly Hall.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Sorry Dixie. I have a question about commercial purpose and the definition of that. So for instance, if I'm an NVE and I am a durable medical equipment company passing information between covered entities, but I collect data in order to improve product, is that commercial use? If I'm a PBM, and I now am an NVE sharing my information across NwHIN, and I use that drug information, as I do today, to determine usages and distribution. So I do think that if this has broad adoption, the definition of commercial purpose has to be quite clear, because there are different roles that organizations take and in some cases the use of that data is quite appropriate and commercially necessary; sometimes that commercial use is to improve patient care, so could fall under operations under the HIPAA. So, it would be nice to see what is meant by that.

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

Okay.

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

This is David. The Tiger Team discussion on this really centered around the consequences for the legally identifiable part of the de-identified information that's of concern to healthcare entities and doctors and the like, whose information is not required to be stripped out of so-called de-identified information. And there was quite a vigorous debate on the Tiger Team about this. But it's a pure policy issue, I don't think it's a standards issue.

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

Yeah, it really is. Yes.

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

It's a really important issue, but it's not a standards issue.

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

But I've captured your comment. Okay. We had a general comment about S-8 and S-9 in that both of them relate to interactions between the NVE and the individual consumer. And we thought that these CTEs could provide a channel that undermines the clinicians professional responsibility to not only to withhold information deemed potentially harmful to the patient, but really to manage health information as well. S-8 had said that "to provide electronic access," and the only comment to revise...we suggested it be revised to "if an NVE assembles or aggregates health information, then it must provide individuals with an electronic copy of their IIHI. That's what our recommendation is. And what we deleted was the part that says that results in a unique set of IIHI because nobody could define exactly what that was. So, what is a unique set and that was our only real recommendation.

The next one said, "That if the NVE assembles or aggregates health information, then it must provide individuals with the right to request a correction and/or annotation to this IIHI. And this is where we...originally it had said that the NVE must make the change, and we felt that the NVE shouldn't be responsible for changing clinical data, but it should be the responsibility of the entity that is sending it through the NVE. So, we said that the NVE should refer the patient, if the patient says this information is incorrect, the NVE should refer the patient to the organization that provided the data to make any corrections.

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

But Dixie, this is David again. On the Tiger Team, I think it was the Tiger Team discussion of this point, I mean there was general agreement I believe that it is conceivable that there are NVEs that will, in fact, create data that does not exist at any single contributing system, by synthesizing and joining the data together. So, the NVE will produce new data, and I think that's the essence of what they're trying to get at here is "unique IHI." So, you could take two independent data points, merge them together and conclude something at the NVE level that neither contributing system is aware of or could they fix. So, I think that this doesn't work.

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

But an NVE is not going to make conclusions...

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

You know, a risk for...

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

...it's going to aggregate, but it's not going to make inferences from it, it aggregates it.

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

Sure it can.

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

So it shouldn't come to any conclusions about it.

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

Certain NVEs absolutely will do that, they'll do risk scores, they'll do readmission predictions, they'll do drug compliance assessments based on a combination of what the doctor ordered and what the pharmacy says the patient has picked up. There will be a lot of places where NVEs do value-add services, or things that we think might become NVEs, produce value-add services that are a derivative of data from primary sources.

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

In their role as an NVE.

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

In their role as an NVE. A PHR would do that.

W

Too blanket.

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

But that's in their role as a PHR, not in their role as an NVE.

W

Right, that's what I was asking, in their role as an...

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

But a PHR may want to become an NVE. The NVE remember is a trust brand, so that PHR is offering you a valuable healthcare service, well you may be willing to pay for it, it's assembling data from all your providers and it has the brand that says, "I'm a member of the NVE. I've been certified that I follow those trust policies, I behave in an appropriate way, I have a group certificate from the Federal Bridge..."

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

When I exchange, when I act as an NVE, not when I act as a PHR. That relates to our whole comment about being able to segment out the different services that you provide.

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

But you're limiting NVEs to only those things that move data around on behalf of other people and I think the scope is much broader than that. I mean, again, we're in opinion mode rather than consensus mode, I apologize, but the discussion on the Tiger Team was that we...these NVEs may well, in fact, create knowledge in the sense that they take data contributed and assemble it and deduce things that are now potentially correctable or at least annotatable by the patient. Now maybe at that point they are also covered entities, and fall under a different set of laws, about what access...

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

Yeah, that's a good point.

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

...patterns they have to follow, but.

Jonathan Perlin – Hospital Corporation of America

Rather than try to engineer the exact language here, let me suggest that...I mean, I think the scenario is one certainly I can identify with. Let's see if we can't comport the language and pass that around or toward that end. Yeah, Leslie, Leslie Kelly Hall.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I think about the TRW example in credit reporting, now that there's an aggregate information, I as a consumer go through hell to try to change that. So, there is that distinction of when there is new information, how and what are roles. So if the NVE is only acting as an exchange agent and the certification is of that exchange, then that line has to be clearly identified.

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

Yeah.

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

The credit reporting agencies was the exact example that was debated in the Tiger Team.

Jonathan Perlin – Hospital Corporation of America

Mary Jo Deering, you wanted to weigh in.

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

I just wanted to say that ONC gave guidance to the Policy Committee that because this is not an NPRM, what you are giving is comments only, and you don't need to strive for consensus. If indeed you can just articulate the different views; that's perfectly acceptable.

Jonathan Perlin – Hospital Corporation of America

That's awesome.

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

I should have said it earlier.

Jonathan Perlin – Hospital Corporation of America

I think it's always the goal to take a topic and provide as much consensus opinion, but, I think this conversation has teased apart that there is a role-based set of activities, different regulations and in fact law may apply to the different roles. And, what can we envision in terms of multiple roles simultaneously how they'd be managed. But with respect to that trust badge, what needs to occur. It may be that in the spirit of comments, Mary Jo, back to ONC, that something that ONC and the Policy Committee would have to grapple with in terms of multiple conceivable roles. So, additional on this point, Anne and Jim and then we'll close this one out.

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

I'm back to the same thing which is, the scope and I'm just not sure if that's a big statement at the beginning of this or is it a lot of interjection on every detailed item, and I'm concerned that that come out clearly, because we keep bumping into that. Call it roles, but it's the scope issue of what this covers and all the complications that brings to the table. Thanks.

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

We can make that comment. I think that David addressed also...his example, addresses the working groups concern about that result in a unique set of IHHI, it may be this concept of creating new information is...that's what they're driving at here.

James Walker – Geisinger Health System – Chief Information Officer

This is Jim. I just, I think in this case it's more than just the unique data, or unique constellation of data, I think it's about the intended use and back to sort of Jaime's thing, what's the relationship to the customer or victim. And so, if the language could try to identify this kind of relationship that David was talking about, where you're really bringing information together, making inferences and then suggesting some kind of action to somebody on behalf of, or maybe directly the recommendations to the patient. As opposed to, you bring a bunch of information together in the course of doing your work, it is a unique constellation of information, but no one's making those sorts of inferences or acting on them. If we could try to capture that distinction, I think that is what we're banging around about with S-8 and 9; then we'd have a clear way to move forward.

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

And I think that it's more the beginning of your statement than the end, that they're providing services directly to consumers.

James Walker – Geisinger Health System – Chief Information Officer

...anyone else, I mean, they might send it to the doctor and say, it looks like this patient has...is on two medicines that are dangerous together, and so the service could be provided to anyone sort of related to the patient, including the patient. But the point is, that you're aggregating the information, analyzing it and acting on it, rather than just happening to put together a unique or new constellation of data.

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

Yeah, I'll make that point. That it needs more work around the services provided around the aggregation. Okay. Got it. Okay. Safeguard 10, it had said that the NVE must have the means to verify that a provider requesting an individual's health information through a query and response model has or is in the process of establishing a relationship with that individual. And this...we thought that that was really hard to prove and so we suggested the rewording that you see there, that they've given as a purpose a treatment of the patient whose information is being requested.

Jonathan Perlin – Hospital Corporation of America

Jaime, were you seeking to weigh in on this or, Jaime Ferguson?

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

So I like the change because it fixes a problem in the previous articulation which was that in many cases in care processes there are indirect relationships and this would have implied only direct relationships. However, query response is used for many purposes other than treatment of the patient and so I think that's a different problem area for this. So currently, in the NwHIN Exchange, the permitted purposes, in fact, the largest exchanges are using that model are not for treatment, it's the Social Security Administration for disability determinations, for eligibility for Social Security Disability. If this were put in place, then it would seem that they would have to stop doing that electronically for fifty million Americans who are getting it now, or something like that. So, it think that's another area where this one may need to be re-examined.

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

So are you suggesting we add others, or is there a better word that treatment?

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

Well how about for permitted purposes.

Jonathan Perlin – Hospital Corporation of America

Either established or establishing relationship with patient, I mean, keep it broad.

M

...challenge, The Social Security Administration achieves patient consent to do the look up, it isn't treatment at all that they have consent or permission. So I like the term for permitted purposes.

M

And that's the term that's used in the DURSA and elsewhere.

Jonathan Perlin – Hospital Corporation of America

David McCallie.

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

Yeah, actually, not right now. Let me wait.

Jonathan Perlin – Hospital Corporation of America

Well, this is the last item for which there were changes, and I think it's very helpful and I think your point was very well taken. There are some things that are sort of supervening or overarching principles that need to be there. Mary Jo and Doug, I hope we've, and MacKenzie, I hope we've supported your needs in terms of good feedback. I really appreciate the richness of the discussion. I think it was time well spent and I especially want to thank Dixie Baker for heroic leadership. Think about what we just went through. (applause) It's absolutely terrific.

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

I have one more announcement. There's a hearing on July 11th, a public hearing on identity management. So, I know some of us don't get early enough notification of these public hearings, so I wanted you all to...and it's jointly by the Policy Committee and the Standards Committee. So, mark that on your calendars please.

Jonathan Perlin – Hospital Corporation of America

Great. And David, you had a brief comment.

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

Just in thinking back and listening to our really great discussion on the RFI for NwHIN governance this morning, it strikes me that it's almost as if we would end up with nothing actually changes. In other words, I'm not sure when it's all said and done, what has been added if you took all our recommendations and rolled them up, other than group certificates. So, it's an interesting question of looking at this from the point of view of, compared to the status quo today, what actually would be different if we had this governance in place. Because if it's just to do for permitted purposes that are already permitted purposes and we're not going to extend and go beyond HIPAA in any meaningful way, I'm not sure we've changed anything. So, just strikes me that may be where we want to end up, but I'm not hearing...

John Halamka, MD, MS – Harvard Medical School

In the case of the state of Massachusetts, we hope to eliminate bilateral DURSAs and in fact go to this new model of sort of cloud-based trust fabric. So, it changes the game operationally. Maybe not policy wise...

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

But all those...so you'll expect, where did all those constraints that are in the DURSA today, where did they go, you expect them to be...I mean, because you'll still want to make those decisions.

John Halamka, MD, MS – Harvard Medical School

So what would happen is our individual...organizations would say, we agree that if you are part of this trust fabric, that that is sufficient and so the terms of the DURSA now apply to participants in the trust fabric.

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

But I'll bet that you have characteristics in the DURSA that go beyond trust, there are things like permitted uses and whatever. I mean, I actually think we can add a lot of value by doing this, but I keep hearing us whittle it down, from legitimate concerns, and I wonder, is it whittled down to such a small number of actual changes that it's actually not adding much value.

John Halamka, MD, MS – Harvard Medical School

So as I've said several times before, that as we think of our job of taking the ten thousand dollar interface and turning it into the five hundred dollar interface, we've taken a three week legal process and condensed it into three days. How about that?

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

That would be a step in the right direction certainly.

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

Well, it certainly will open up options for exchange, because we are recommending that they not dictate that you have to use this standard, you know, transport standard. It just says whatever transport you use, and whatever you use the data for, you have to show that you're trustworthy. And I think that's a step.

Jonathan Perlin – Hospital Corporation of America

Yep. So Doug, we've left you fifteen minutes.

John Halamka, MD, MS – Harvard Medical School

So again, as I said at the beginning, many of you had concerns that the S&I framework having substantial reductions in funding as our funds and in 2013, would going forward want to have the right projects, the right priorities, the right application of resources and the right articulation with this committee. So we gave Doug the bold charge, tell us where you are and where you're going and how this committee will have better input in the future. So, if he's promised not to read every bullet point, and maybe just give us that wonderful Gantt chart that you have showing the progress, then we can go to the questions at the end. And more to come next meeting.

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

Well thank you. So we're going to try to cover everything in fifteen minutes; I'll see if we can't get us back on track. Hopefully we'll have a little bit of time for discussion. Let me just say two things. First, the value of this presentation is not me providing you information; you can read the slides as well as I can; the value is actually in discussion. And so, if we don't have time for the discussion, I would then ask that perhaps we have additional time to discuss it as well and we can come back and remind people of the conversation. The second this is that with apologies to my team, that spent a good deal of time kind of putting together a summary of each of the initiatives, I'm going to try to just very, very quickly go through those. I hope you folks can take a look at them on the plane rides back home and then provide me any feedback that you can based on that. But the team did a really nice job of putting together all of the activities that are ongoing and I'm certainly happy to answer any questions regarding that.

So to that end, what I'd like to do is just step through some of the introductory slides, frame some of the conversations that we're having about the standards and interoperability framework, and then skip to the end, tell you about a couple of the new initiatives that are coming out and then to queue up some questions that I'd like to have some discussion about. So...

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

It's in the separate handout.

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

Oh, I'm sorry, separate handout.

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

...behind Betsy and Jaime.

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

Separate handout. So the first thing that I'd like to say is that the ONC's commitment to enabling rapid standards development has not diminished with the end of our funds. So, we did use some of our funds to help accelerate this, but in the HITECH act, Congress gave us authority to identify the standards, implementation guides and the certification criteria for standards that would enable health information exchange. And that's something that is not tied to our dollars, but is ongoing, as part of ONC's responsibilities. So I think it's important to separate out the funding mechanisms that we had within ARRA and really ONC's commitment to making sure that we have standards that will help support electronic health records and interoperability. So while we won't have the ARRA resources after 2013, the funding for the S&I frameworks will continue to support coordination around key initiatives. And we'll talk a little bit about what we're thinking about that, give you some examples of some of the new models that we're exploring with this and then hopefully get some of your feedback about how best for us to proceed.

So we're working with the community to find ways to make ARRA and Federal investments go even further. So, for example, we're working with the California HealthCare Foundation to develop a new standard for laboratory ordering interfaces and they're providing a lot of the resources for the pilots and the implementation and the work out there in the field. What we're doing is trying to make sure that they have a national platform to get input on what they do, provide some coordination, resources across some of the other initiatives that we have and continue to support that in a way that provides our ability, our focus then is on coordination and harmonization; whereas those folks out there in the community are doing a great job leading the community, implementing and giving us feedback about what's working and what's not.

So one of the things that we've talked about is, where does the S&I framework work the best and where doesn't it work the best. You know, because I'm always suspect if you say, well, you can do anything in the particular model and things like that. And I'll give you some examples of things that have worked and things that haven't. So, I think our sweet spot is when there are existing standards that are out there that need incremental refinement, maybe they need to go to finishing school, maybe there's a couple of standards out there that need to be harmonized, but they're really on the right track. I think we do less well when we've got some rapid iterations and innovations. So, for example, MicroData was in initiative that we tried early on. I don't think it fit the framework as well as we would have liked, and so, that told us that if we're doing rapid iterative development and we're just doing kind of brainstorming kinds of things, it doesn't help us as much to have the coordinating infrastructure that we have within the S&I framework. Maybe there's a different approach, maybe there's a way we can link those, but that is something that we've observed.

The second thing is, if there are a lot of empirically validated standards, we do a little bit better there. If we have to start from scratch, it's much more costly for us to do that and it doesn't necessarily speed things along. So there are other mechanisms that if you're starting from scratch, maybe there are some other ways that you can engage the SDOs or you can do some other things that would be helpful as well. The things that are helpful is when we don't have a lot of consensus. If we've got different approaches that are trying to solve the same problem, and they've got things that are incremental and which there are some existing standards, we don't do a bad job of bringing those groups together in a public forum to try to reach consensus on a path forward. And so, when we think about the things that are useful, the things that we should work on, it kind of falls into those shaded areas as well. Now we could make those boxes smaller, maybe there are some other axes that we could look at as well, but we're really trying to take a look at the S&I framework and identify those things that we can really help support with our initiatives going forward.

So, another way to look at this same sort of thing; if there's an incremental approach that will solve this problem and there's a high degree of consensus, it may be that we can enable public comment through a rule making process, an NPRM or the like. Perhaps we delegate that to HIT Standards Committee working group and get input and feedback into that as well. If there's a low degree of consensus and that we're kind of in that low degree of incrementalism and high of consensus, maybe the SDOs can help us there, maybe there are community driven pilots, maybe we need to engage the MicroData community, for example, and have them iterate for a while and then bring us something that we can start to refine and get larger consensus. But when we're in sort of that sweet spot, where we've got some moderate-to-high degree of incrementalism that will work, and a moderate to low degree of consensus, that's the area that we can sort of provide the greatest value.

And here are some examples, I apologize, it's a little hard to read with the red there. But, just some examples. It think it shows that better in the print of some initiatives and kind of where they would track with things. And so, this notion of Federal Bridge cross-certification isn't something that we necessarily need to address in an S&I framework; we've got a lot of initiatives within our Privacy and Security Tiger Team that can provide us that input. When we're talking about federated provider directories or MicroData or those sorts of things, maybe that's something that would fit into a different bucket, and that when it comes to immunization reporting, maybe there's a way that we can just sort of have the HIT Standards Committee review that and provide recommendations. I think the vocabulary task force is another group that's been highly productive in giving us good recommendations that are fairly focused. So this is sort of where we see the ecosystem. So I think one of the things that we have to...one of the questions that we have to answer is, what are the things that we really need to target within the S&I framework that will provide the greatest value; so that we're actually driving the kinds of things that S&I framework can help with, and allowing those that are doing innovative work to be very, very productive and those things that are already solved problems to be able to get public comment in other venues.

So there's a couple of other things that we've been thinking about as well, is the ways in which we could support different S&I initiatives. Much of the work that we've done to date has been things that we've tried to accelerate to get us to Meaningful Use Stage 2 and to really sort of drive this process forward. And I think as the ARRA dollars go away, we need to think creatively about other ways that we can support some of these initiatives as well. And so, there may be some things that require strategic support, so we have targeted investments in specific components within the ONC and the partners objectives. We might partner with a group to say we'll provide the harmonization piece, but we want you folks to help us with the implementation and the pilots, because that's expensive and you guys probably know better how to do that.

There may be some things with limited support where we provide facilitators to help guide the meetings. We helped provide a strategic direction that says, here's the target and these are the guardrails and we want you guys to be successful in getting that; to help support that community and to provide a national platform for folks to go to to get that. And then there may be other options, you know, using self-serve. Maybe what we can do is we can provide that platform and say, let people do what they will with it, but we aren't going to necessarily help you with the targets or the guardrails, but this is a process that you can reuse as part of what you do. So we don't have all of these entirely fleshed, I think that's part of what I'd like to get from this group, to get some feedback about things.

But certainly when we think about the California HealthCare Foundation, we're not providing full support there, it's really a strategic support. We're saying, we would like to help with kind of harmonization, but we want you to take responsibility for some of the early pilots. I think when it comes to some of the long term care, the LTPAC work, we're kind of in that range between limited and strategic support because these are activities that are really being driven by the enthusiasm of the community. And we want them to be successful and we want to provide them the resources that make them part of our community and can help harmonize with that as well. This is a slide that I've stolen from Steve Posnack, it sort of is a riff on some of the other slides where we've taken a look at the various levels that we have. But this really has all of the different things that we have with regard to vocabularies and code sets, content structure, transport and security as well as some of the other activities related to this; all in one neat graph that you can take a look at and study at your leisure.

But, I think the thing that's important to recognize is that we have taken a very pragmatic portfolio approach that we hope will allow us to have reusable building blocks to solve different problems. It's the reason why the content structure includes HL7 V2 messages as well as HL7 V3 messages and some of the other standards like NCPDP script and the like. We've got a variety of vocabularies and code sets, again, that are specific to particular goals like LOINC to help us with laboratories and RxNorm for medications and the like. And then, on our transport and security, we have the direct specifications as well as the SOAP secure transport that's derived from the NwHIN Exchange specifications as well. So, there's a whole set of different things that we have within our portfolio as well. And I think over time, the goal is that the S&I framework would help us populate this portfolio with some additional kinds of specifications and some additional ways of representing structure and transport, security and some other services as well.

These are the current S&I initiatives that are underway. The direct project is really in evaluation and implementation, it is part of the proposed, notice of proposed rulemaking. Transitions of care, there are some pilots that are underway, but we clearly are moving beyond that and trying to figure out how to align and refine this to meet some of the requirements of meaningful use. And the laboratory results interface as well, also showed up in an NPRM. So those are quite far along and we've gotten a lot of public comment and feedback about things. I'm sorry?

M

About your title, RI Test & Pilot?

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

Reference Implementation, testing and pilot. Yeah. So, the...

John Halamka, MD, MS – Harvard Medical School

On Google it said test in Rhode Island, so, I was...

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

Oh yeah, it's Rhode Island testing and pilots, you know, everything has to go through Rhode Island, it's a little small fact that we didn't know. Just to kind of give you a sense of what our process is, predisccovery is all about figuring out what the ecosystem is, what our target is, what the guardrails are and what success looks like; and understanding how an initiative fits into the other pieces we have. Use case is about scoping and figuring out a manageable piece of the puzzle that we can try to solve. Harmonization is making sure that what we have leverages work that's done in other places and so we have common representations of things like addresses and phone numbers and things. And the RI Test & Pilot and Evaluation is really part of that iterative process that allows us, once we've done that, that we can very, very quickly iterate back and forth with things.

So this is a list of all of the things that are out there, and I don't want to go too deep into those things. I will say that the HealthDecisions, which is about clinical decision support, was just recently launched. On the launch call, we had two hundred and thirty people who called in on that call, so there is continued interest in using this as a mechanism to accelerate consensus and to get some of the work done. So with apologies to my team, I am going to go through these, please ask if you have any questions, because it's the only time we're going through it. There, we're almost done. Are you getting it, it's more like a movie really when we do it like this, isn't it. So, LTPAC, we're going to...I want to make sure that they have a chance to talk, they were deferred last month and I want them to have an opportunity, so we're going to go through that.

So, I'm going to talk about three new initiatives, because you're going to hear about these. One is called PCORE, and Jaime Skipper is doing this. This is actually an opportunity for us to be able to support patient centered outcomes research. And the idea here is that as you start to look at Meaningful Use Stage 3, and the need to be able to capture structured data that will help support outcomes research. Is there a way that we can create a generic mechanism or container that allows us to put structured data that can then be captured by electronic health record. So, we're partnered with the National Library of Medicine. They're helping us identify what those common data elements might be, and working to coordinate across the NIH and the various institutes, to come up with a common way or a common way to look at common data elements. And then what we're trying to do is leveraging work that's been done at CDISC and some other organizations, to see if we can't describe the equivalent of a case report form or some kind of structured way of capturing information, but doing it in a way that's not restricted just clinical research, but to actually have it more generic, that you could capture quality information or other kinds of things in a structured way.

There's a second initiative, just under way, Pierce Graham Jones is leading this, around blue button. So this is in follow up to the Datapalooza that was two weeks ago, it seems like years, but two weeks ago, and some White House meetings that we had in association with that. And the idea here is that blue button is really as much an initiative to provide access to patients data, or to citizen's data, as it is a standard. And one of the things that you'd like is to be able to enhance it with more standardized ways of both interacting with the blue button, as well as capturing that data so that it can be reused. So the idea here is that we are going to set up three, and let me know if I get it wrong, three different workgroups. One that's going to look at two different use cases, a blue button push and a blue button pub-sub as a way of kind of interacting with the data, to try and to make sure that we look at identity, authorization and authentication as part of that; that's going to be important. And looking at things like OpenID and OAuth and other kinds of mechanisms. And then finally, to make sure that we structure content and make that aligned with what we've got within meaningful use, perhaps starting with transitions of care as a starting point, but then thinking more broadly about even administrative data and some of the X-12 transactions that would open up the door to some of the CMS transactions that occur as well.

Finally, the most recent...alright, second to last. Health eDecisions, Alicia Morton is running this, but this is really about clinical decision support, trying to get standards for importable, computable, knowledge formats and standards to access CDS web services that provide actionable interventions. So this is going to overlap with quality, because quality is sort of the if statement, right; if a subset of the population, and the then is these actionable interactions that may fit into an API or the like. So this is just getting launched and just getting started. There is one that isn't even on the list and that is, we're trying to develop, in response to the recommendations of the NwHIN Power Team from last summer. It was the second to the last slide, right before the thank you, in which is said, we would like to have additional work being done on RESTful interfaces as a way of transport. What has been developing over the course of the last month is that our Federal partners, through the Federal Health Architecture, have taken a leadership role here to be responsive to this. And we are working right now to do our pre-discovery work on a RESTful interface, that will give us something that is certifiable, in terms of how to construct that, again looking at OpenID and OAuth as mechanisms to support that identification piece. And then also taking a look at how to structure that, leveraging of course the work of the transitions of care, but then looking at how you might do that with say an hData format or the like. So those are initiatives that are coming down the road as well, that we hope to provide more information in subsequent updates.

So I think the thing is that one of things that we look at when we take a look at the S&I framework is that it's been a public platform where the community can build consensus around solutions to a standards gap that must be addressed to support health information exchange. Our goal here is to provide a platform for others to be successful, and so as we transition from all of the money coming through ARRA to a hybrid model in which we've got both others that come to the table and we provide a platform for success for them; I think that's an important thing that we're trying to do. We also want to use the S&I framework in the sweet spot to build consensus around solutions where there are existing standards that need to be sort of harmonized. And I think we want to help identify standards gap, provide flexible processes and dynamic tools, evaluate solutions that are emerging so that we can be very, very, sort of self-critical and improve what we do as we go along. And then, perhaps, figure out ways that we can serve as a repository for the products that come out of that, because there is this need to have a place to go to find the artifacts for meaningful use. And we do have some initiatives as part of the S&I framework to develop tools and repositories and to interact with things like Open Health Tools and the like, to make sure that we've got the right links and connections. So we've got some activities across the S&I frameworks, because we realize one of the things that we have to do a better job at is to make sure that we've got good coordination across our initiatives and that we can accelerate the process by leveraging and reusing things that were solved in one initiative, but can be applied in the other. And so we've got some work in what we call the clinical element data dictionary, and we're trying to take a look at that and see how we can refine that so that that can be reused across different initiatives as well.

So here's the money slide, and that is, what are the questions that we need to try to take a look at. So, we want to know...these are questions that we are sort of struggling with and trying to come up with answers and I think we welcome input, so that we can get better answers. What is the criteria for successful S&I initiative? I think we know what some of those criteria are, but I think we need to make it explicit and we need to be able to hold ourselves accountable. And if we don't reach success in an S&I initiative, we need to be comfortable in shutting it down or moving it to another place, or doing some other things with it, rather than just continuing to develop a bad solution.

What is the role of the HIT Standards Committee within the S&I framework governance? As we think about how we move forward, one of the things that I think is important is that, we need to take the artifacts that get constructed and you guys need to take a look at them and tell us whether we hit the mark or not. And that's why the work that Dixie's doing on establishing the criteria for good standards and the like in the NwHIN Power Team is so critical to understand what that success might look like. How can we convey priorities in the standards gap area? And this is a challenge because if you pay for everything, you can kind of set all the priorities; but sometimes there are things where people say, we're going to come with a lot of money and we're going to do this. If it's aligned, if it helps serve the nation's interest, if it's something that fits into our portfolio, I think we have to be open to providing an access point for that; realizing that there is some cost involved. But if there are other people that come to the table and have lots of money but it's not aligned with where we want to go, we also have to feel comfortable saying that isn't where we want to go, and we need some help with trying to figure out how to convey that as well.

What would you need as a committee, from us, to identify and prioritize standards gap information? So how can we provide information to you so you can make good decisions and provide us with good advice. And what kind of flexibility should be built into this? One of the things that we've been talking about is that we should probably have more explicit milestones so that we know if something is on track or if it's starting to veer away, and be able to either provide ways of getting it back on track or realizing that we've got a problem early in this. And what are the steps that we need to do to properly evaluate what it is that we're doing within the standards and interoperability framework? I think we've had some discussions with the working group co-chairs, and John, you feel free to comment on some those things as well, but I think one of the things that has been valuable is that people come to the S&I framework not because it's a perfect process or because we've got everything figured out; but they know that we listen and we know that sometimes these things, when well-constructed, can actually affect the industry in dramatic and important ways. And so I think that's one of the values that we come to the table with as well. So with that, I'm going to stop. I don't know, I did go over my time a little bit, but I did take ninety minutes and got it distilled in about twenty-five.

John Halamka, MD, MS – Harvard Medical School

We have eight minutes for discussion. Let me make three comments, and I think Mary Jo and MacKenzie we should T-up this as a very important discussion, to answer these questions at our next meeting. So first you highlighted a blue button initiative. One of the things the committee should know is, blue button is not the unstructured text scattered in random formats for various purposes. They are thinking of blue button as a brand which refers to patient enabled transfers of structured data like the consolidated CDA. Although text of course is fine and a good start, we don't want to think of unstructured text as a standard. So that was refreshing to hear. The RESTful discussion; Dixie and I and many others have highlighted the importance of a RESTful standard. The problem is, REST as the standard, REST as an architecture; so again, what they're looking at is how does one take such things as OAuth or OpenID, which are application layer authentication mechanisms, and incorporate them into a RESTful architecture so that the whole package is actually something you could certify. It isn't just an "Oh, I did a URL, therefore it's RESTful." It's much more specific than that, so that's quite good.

We'll talk as we go through all these criteria at our next meeting, about criteria for success and how to monitor your progress, what metrics we should use. But certainly adoption of standards has been something we've talked about in this Committee as very important, as metrics for success. And if you look at the Gantt chart, and I've drawn a line as to where some of the projects haven't gone into referenceable mentation, pilot test and adoption. This shows you, I think, the challenge that we have as we take standards from a nascent idea to actually getting them widely distributed in production. I would hope that we would declare victory only when we see a majority of our EHR users actually using the standards that have gone through the S&I process. But, I can promise you, we will have a rich discussion about how this committee will articulate with this set of activities and Jaime, I think you have one brief comment, oh, well, we've got three very, very brief comments, because we want to give John Derr and John Feikema their due.

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

Let me just respond, too. We are...a year ago we probably couldn't have a discussion around how to support implementations of the standards and the building blocks, because we didn't really have those standards and building blocks, at least identified. Now that we have that, we certainly are very keen to do the kind of crowd sourcing and government as a platform around implementation, as well. And so that's one of the areas that I think we really do need to focus on, that we have to not only support the consensus around the building blocks, but we also need to be able to support and learn from the implementations that are out there as well.

John Halamka, MD, MS – Harvard Medical School

Okay. So Jaime, Leslie and David.

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

So my question Doug is how you will build in and ensure stakeholder balance of different competing interests in the process, reflecting that one of the things that has characterized many different standards efforts, including accredited standards, so if you want accreditation for the standards, then it generally has to include a balance of stakeholder interests for the affected parties. That's also clearly in many other Federal...established in Federal law and processes, including HIPAA and the Technology Transfer Act and others. But I think frankly that's been missing from S&I as an explicit thing, and so I'd like to understand how that could be addressed going forward.

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

So I think one of the things that we, when I sort of said in my remarks, the things that come out of the standards and interoperability framework come to this group, which has a balanced set of perspectives and people that have different perspectives, right now that is our check that we have. We want to make sure that we have the ability to have this group take a look at it. It was...we had ongoing discussions early on about how we can encourage participants that were implementers, that had boots on the ground experience and those sorts of things, because that was an important part of the desires and the goals. But we have to be very careful not to exclude, in the effort to balance, just because that's not probably the role of government, to do that and Federal Advisory Committees and others have different kinds of authorities in which they can strike that balance. And so, you're absolutely right, we need to be able to have stakeholder balance. We've tried to address this with making sure that we've got the HIT Standards Committee involved, that we've got criteria for what success looks like and that we provide some degree of transparency. It's an important point.

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

My comment was actually within the S&I process, because by the time it comes to the Standards Committee, basically it's done or it's baked or it's not...I'm saying that within the process of S&I that was really my question.

John Halamka, MD, MS – Harvard Medical School

And as we talk next meeting, what my hope would be is that we could look at a candidate of possible projects and think about them here and hopefully advise priorities rather than being shown them after they're started or something. Leslie.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Quickly. I'm hoping that in our next meeting maybe we can get an idea of how much dollars really are at risk, what is the percentage that we're seeing being cut and maybe that can help us in our definitions of projects going forward. And then also, we've had so much success in the efforts you've outlined, and we're about to introduce new members, patients and their families, and when applicable, reuse of this work would be very important and very efficient. I want to make sure that that's in mind when we look at forward budgeting, that as we introduce these new players, they're not left out by virtue of lack of funding because we've met the commercial needs.

John Halamka, MD, MS – Harvard Medical School

David.

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

Yes, David McCallie. Doug, great summary. A couple of criteria that I think are implicit but that maybe need more discussion as we get further along is, which of the efforts of S&I actually are tied to a regulatory requirement; in other words, which ones have to be right in order for people to qualify for their meaningful use. I mean, those are ones that are obviously going to attract perhaps more attention, than ones that are, let's say voluntary or new and maybe incredibly important, but aren't really a part of a regulatory burden. I mean, that seems to be one of the waiting factors as to what to go work on. And second is one we've talked about from the beginning is just, not only is there stakeholder balance, whatever that means in operation, but are there enough stakeholders to actually do the work. There was one point where we were just overwhelmed with S&I activity, and it kind of got so diluted that there weren't enough of the experts available to put the time and energy in to actually get the work done. So there's some kind of a make sure you have critical mass before you take on a really important project, because if it fails because there's not enough critical mass, you may have missed an important project for the wrong reason. I think maybe that MicroData would be an example; there just wasn't critical mass for something which I think could still be an important project. And, you hate to call it a failure just because there weren't enough bodies available to...

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

It was a learning opportunity.

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

It was.

John Halamka, MD, MS – Harvard Medical School

Well thanks for all the comments and we will begin this discussion again, but we want to of course give our long term care folks their due, so, Jon Perlin...

Jonathan Perlin – Hospital Corporation of America

We set this up before. Today's entire discussion has been really prelude to the capability and to welcome both John Feikema and John Derr to a presentation that we've been looking forward to since last meeting. Thank you John.

John Derr – Golden Living, LLC

I just want to make you aware of what we are and what we're doing. I'm not asking for any decisions at this meeting. We are trying to position ourselves a little bit to be into Meaningful Use 3. I'm doing this in collaboration with Larry Wolf, who's on the Policy Committee and that's enough of that. I just want you to know what constitutes long term post-acute care. When I was a COO of American Healthcare Association and I used to review a lot of legislation, the legislation said LTC and LTC was synonymous with nursing homes and that's all it was. And so when we did the CCHIT certification, we came up with LTPAC, which is really not age limited. But those are all the different providers that make up this segment and our whole goal is to harmonize with the ambulatory and also the acute care sectors. We just had our...so, anyway, this is...you can see what we are, what we're trying to do. We're aligned with the policies here. In fact, in a handout I gave you is the 2012-2014 roadmap on long term post-acute care HIT, which is in harmony with ONCs thing, and that was just released; that's why I gave you a copy off a copy machine, it was just released Monday at our Eighth Annual Conference that we had. I must have skipped one.

Okay, this is...we're in the strategic plan, and these are the members that make up what's called the Long Term Post-Acute Care HIT collaborative. This began really in 2004, when I was at the meeting when they released President Bush's Executive Order and Secretary Thompson asked me to coordinate long term care HIT. Although Dr. Brailer said, "John, your third priority," and I said, "Gee, we don't like being third priority, but when you're ready to hook with us, we'll be ready to hook with you." And that's when we started doing different summits every year. We just held the Eighth Summit, where Judy Murphy was the keynote speaker and did an outstanding job. Leslie helped us out and we had over three hundred people at the summit. It was two and a half day summit and we released the roadmap at that thing and it covered a lot of different subjects, which I really don't have time to go through.

The big thing with us is this individual health. We're person centric. You can see this is the life cycle that we go through; with you guys, most of you are hospital oriented and it's acute care. And then they usually come into either the home care agencies or into SNFs and then we see people days, months, years and so we have to have longitudinal care and we're working on...HIT is so important to us because we can start to pro-act and prevent re-hospitalizations. You can see this is all the different types of providers that are involved into it, and we're actually merging a little bit into what we call care at home, not home care, because we understand what really is going on in that and we're very person centric and getting more so as the different providers start to have interconnectivity.

This is the big thing, and you guys have heard me say longitudinal care a lot and not just episodic, and so, I feel we're moving from a static, reactive, episodic health care system to a dynamic, pro-active and that's how we're going to do it, which is how I interpret and how the collaborative interprets the HITECH act. The collaborative I didn't go through, but it contains all the vendors, there...Agency has all the vendors members, it encourages all the therapists and includes all the providers and all that, and that's my resources. I say to you guys a lot of times, give me something to do and I've got a whole staff of people from all these different things. I think Leslie saw a lot of them at the meeting, that are willing and able, and I think Doug's seen what we can do on the S&I framework because we're very passionate about this because it's the best thing for our patients.

The other thing we concentrate on is chronic care, not disease management, but chronic care and co-morbidities, because that's what we have to deal with. This is the person centric, we're all getting to interoperability, interconnectivity, not only with the hospitals and with the physicians, but amongst ourselves to make sure that we really have person centric health care. One thing that didn't get mentioned during Leslie's thing is quality of life. In the S&I framework meeting, we have one workgroup which John will go through, that concerns quality of life. In fact, Leslie and I have talked about the advance directive, not only being medical, but also being quality of life. Like myself, I like to hike, I like to write books, I like to make movies; if I can't do those things in my retirement, my quality of life is not as good as I'd like it to be. And you can see, each one of us has a range of quality of life, and we have different episodics and if the physician, you guys can't bring us back to that quality of life range, we have to establish another quality of life range on top of it, and then the patient should have the opportunity if they can to say, I really don't like that quality of life and be able to make better decisions.

This is the ACO model, as we call it, and a lot in long term, post-acute care ACC or accountable care communities, that we're working and we really play a very valuable role in that. I'm not...you guys know what this...we're going through all these different phases of when somebody gets discharged from a hospital, we're really working on that thirty day re-hospitalization to help you guys out, we need the CC, the CDA and the summary and the problem list and many times we can't do anything until 48 hours has gone by, and that's why we need this. Because we get people at 4:30 in the afternoon on a Friday. This is the acuity, you can see the different acuity, you can read these slides. Medication management is very important to us. Many of you don't know that we have a consultant pharmacist that reviews meds in the nursing homes on a monthly basis, it's really somewhat of an unfunded mandate; it's paid out of the administrative costs. There's also a senior pharmacist group of people that are licensed in geriatric care and they are going to be very important in the ACOs and these different new types of models that are coming along and because they know everything about and can do poly-pharmacy and work on an individual basis.

The settings, you can see how many...there's only long term...there's LTACHs, which are the hospitals, inpatient or IRFs, we've got a bunch of acronyms too, and SNFs and then there's assisted living and ALFs which is assisted living, and those guys are becoming more and more attuned to acute care. Right now there's not enough beds in the SNFs to really take care of all of people, the 77 million people coming into this sector and so, the nursing homes are going to change a little bit to more rehab and through-put models and assisted living is going to pick up a little bit more ADLs and that. And the home care agency is going to do a little bit more care at home type of thing. We are all automated, that sometimes gets reported wrongly. We all have computers, because it's the only way you're getting paid with the MDS 3 and the home cares, the OASIS-Charlie and the rehabs and that have FIMs and IRFs. And the C.A.R.E., they call it CARE, but C.A.R.E. was another assessment form that was going to replace those, now we're using the data elements from that to make a better complete assessment, so there's not as many assessments.

We work with Floyd and NQF. You can see...in fact, they had a meeting this week of the MAP, the measure application partnership. You can see over on the right-hand side it says PAC and LTC, there's also some use cases being established now with home care and SNFs on quality. Because we have to harmonize quality across all the different settings or as Janet Corrigan and I used to say, somebody's going to be abnormal in one sector and then possibly normal in another sector, unless we harmonize the eMeasures. Certification. We have some vendors already certified under CCHIT, because we took the initiative to set up criteria so when we hook up with you guys that have certification, then they will be in harmony in that way, because our people then know what they have to do to do a CDA composite of that. It can stand certification. History of LTPAC HIT. We are in the enterprise thing, the EMR programs out there are basically enterprise type systems; There are a few vendors that do both home care, hospice care, therapy, pharmacy and SNF care. Others are very dedicated to either SNFs or one of the other providers. But there all moving...there's no pure EMR out there, nobody really does electronic lab or electronic radiology or anything like that.

Adoption. You can read these. We do have computers out there, although we don't have a...the MDS and the OASIS and all these assessment programs are a lot payment type programs and they have to be more robust to do what we want to do. In home care, this is the same thing. The one thing people don't realize, I call it bopping around a spectrum of care, we use the word spectrum because AARP did a study in 2000 where old people like me don't like a continuum of care, because it has a start and a finish, we like the word spectrum, because that means they're sort of moving around different care settings and all that, and we don't like the finish in the continuum.

I want to comment on the grants; really, really important part of our initiatives today is the S&I framework and the HIE grants. There are four grants, or challenge grants and we're working...the neat thing about the S&I framework is that's where everything's coming together; you know, the NQF stuff and MAP goes into the S&I framework, longitudinal care workgroup, the challenge Larry Garber up in Massachusetts is a part of that, Partners is part of it...the Maryland, we had all of them at the summit talking about it. And they're doing, each one of them, very good work of specific things that will give us interconnectivity and interoperability.

We've worked with Mark...but I started working with Mark I think in 2006 or something like that, to put nursing homes into Indiana with Regenstrief. We've worked with Jim over here at Geisinger to put in...and then I'm also working...we're working...I have a meeting next week in Minnesota and then Nebraska. So, we're becoming partners in HIEs and they love it, I'll tell you. I haven't seen Jim's yet, but I went to the first one in Indiana that was electronic exchange of information and the nurses just said, "my God, why didn't we have this?" And the first thing they started to do is talk about what they're going to do different with the patient because they have the electronic information. So now I'm going to pass it over to John, and, you there John?

John Feikema – Office of the National Coordinator

I am. Thanks very much John.

John Derr – Golden Living, LLC

You got it.

John Feikema – Office of the National Coordinator

So, if you can pull up the first slide on the deck that I sent ahead, thank you very much, back to the first one is fine, just the intro one, I'll sit there for just a second. I did want to introduce the fact that the LCC is a bit of an experiment in S&I. Doug talked about some of the different paradigms and talked about the fact that for us, the LTPAC is probably in between the limited and the strategic support models. We have called it a community-led initiative and it's different in that the ratio of volunteers to support staff is significantly higher than in other initiatives. It's an experiment that we're looking at to see how effectively we can stretch our resources across multiple initiatives, and I think we're learning quite a bit about it, I think there have been a few bumps along the way. John will probably attest to the fact that figuring out or helping community members get comfortable with a standard setting, standards development process takes a bit of work. These are excellent, committed members with great subject matter expertise, but they benefit from having practitioners who can help lead them through the process of how to take that understanding of a market and translate that into a use case that's very reproducible, that everyone can agree to, and then a set of specifications and standards and the like that can be rolled out. Where I think we're going to find that we need most support is around the harmonization and the IG development and we'll talk about that in just a couple of seconds.

I will say, I will echo John's comments that this is a very engaged community. I met the majority of them at the face-to-face meeting in April, the conference rooms that housed this group of community members and volunteers was always among the most packed and it's worth noting that we've often joked that it's the office of no coffee. We host a face-to-face S&I framework, we don't provide coffee, we don't provide lunch, there's water in the rooms, you pay for your own hotel room and your own travel and yet hundreds of people show up to participate in these projects. And this group is particularly noteworthy since they obviously aren't a part of the current MU framework. So, this is all about improving the quality of care for their patient community.

One of the reasons that we're doing this, and one of the reasons that we're so focused on this, was reemphasized at the summit this week, that this is projected this year to be a six hundred billion dollar segment, growing to 1.8 trillion dollars in 2026. So, everybody talked about growth in the baby boomer population and some of that growth in that segment is inevitable, but anything we can do to help bend the cost curve in this statement will reap big rewards for all of us. So, as we do that, we've looked at this space, we've looked at the set of challenges that are in front of us. John noted that they do have computers, but he also noted that there's a lack of a robust EHR system that extends across the continuum and given that there are spectrums of care where people bounce from setting to setting, that's quite important; the need for an interoperable longitudinal care plan is critical and noted. And we're certainly interested in seeing if there are ways that we can help influence what components are a part of Meaningful Use in Stage 3. So, you can see from this slide what our focus is.

On the next slide, is intended to just show that we've worked with this organization or this group of volunteers to organize into a number of different workgroups to help focus our activities and make sure that we're tackling the pieces that are most important. The longitudinal care plan sub-workgroup, a care transition sub-workgroup and a patient assessment, being the three primary working groups that help us focus those activities. In the next slide, the community has taken a look at MU Stage 2 and tried to map it against what some of the key areas for LTPAC are. There are certainly a lot of key building blocks that help get us toward the end-goal, but we notice that there are gaps, especially when it comes to care planning, the additional refinement in the consolidated CDA would significantly help this segment.

In the next slide we tried to highlight some of those; the next slide; by taking a look at within a longitudinal care plan, assessments, health concerns, interventions, goals and outcomes are all pieces that we think are critical pieces of it. And the community has helped identify our critical to this overall need and we think our enhancements to the current standards that are out there and things that this team is looking at, how do we go after and how do we enhance the tools that are available for this group to help advance care for their communities. In the next slide, really looking at what some of the additional gaps are and ways that we can help focus the workgroups, HL7 and others around creating extensions to consolidated CDA. And I think the largest one is highlighted and has to do with the care summary capability.

On the next slide, one of the things that we've been focused on is defining the requirements between these different settings, so that the interfaces between those movements is well documented. The patient assessment summary workgroup has been doing a good job in understanding how that fits into a lot of the other reporting projects that exist within the current settings, with CMS and others, and making sure that we can take advantage of the tools and data elements that are mandatory reporting today and use those to advance additional steps in the process. Finally on the next slide, there was an ONC roundtable that was hosted on May 3rd; it was attended by a significant number of people and we noted it at the meeting last month. A number of priorities were identified, they are noted here. I want to make sure that I leave time at the end for questions for John or for me, but, I'll let you read some of the additional details here. All of the activities that we're pursuing here are aligned with some of the feedback that we received at that.

And finally, the last point on this, the workgroup is working on a white paper and perhaps white paper isn't the right word here, but we're defining and laying out the landscape and the vision for what this group could be. We've currently identified use case one, which is focused on home care. We realize that there are lots of other settings, as John showed in his silo bubble at the beginning, that could be use cases, two through N and we want to use a white paper or a strategic document to help us focus what those future areas might be. And that would be an opportunity for us to come to this group and get some additional guidance on how we might pursue this longer term. This sheet shows where we are in the process. We've identified the initial charter, are well into the first use case around home care; recognize that there's a lot in front of us and a lot of different ways that this group could go, which would certainly stretch the bounds of our current funding paradigm. So, we have the option of continuing down the community led initiative, which while they're very energetic and met with lots of enthusiastic volunteers, take longer to develop perhaps than any of us would like and one of the things that we're examining is, are there are other ways to accelerate this, are there other initiatives that can plug into this to help us advance this. But frankly, we're at a bit of a crossroads as to how appropriately we could fund development in the LTPAC area. And I'll stop there and open it up for questions for John or for me.

John Derr – Golden Living, LLC

I just have...last..couple of days ago Victor and a couple of the other guys from the S&I group, we came up with a summary that came out summit, so I'd just like to read that because it makes it more concise of what our specific things...deliverables are going to do. "The S&I Longitudinal Coordination of Care Workgroup has three near term deliverables: One, expanding the data sets for clinical summaries and transitions of care to make them more meaningful for LTPAC settings. Two, the exchange of home health plan of care for skilled home care to set the foundation for ongoing work to define care plan requirements. We're working really hard on that longitudinal care and not just on episodics. Third, the availability of standardized, federally required patient assessment summaries, as example MDS 3 or OASIS-Charlie on transitions from long term post-acute care to emergency departments and hospitals and from LTPAC to LTPAC providers. These near term deliverables will support meaningful use, the noun, in that acute care hospitals will be able to meet meaningful use requirements by sending summaries to home health and to other LTPAC providers.

Longer term activities like the care plan will support meaningful use, the verb, and would be available in emerging models of care. The identification of these data sets and a mapping of these critical processes will facilitate the development of quality measures for these complex transactions. The S&I Longitudinal Coordination of Care Workgroup will continue to develop the functional requirements for interoperable care plan, building on the initial home health plan of care requirements defined in the baseline use case." And this will all be done with support, I know funding and all that, but we will do whatever is necessary to complete the work. I also would like to recognize Liz Hall in back of us, who is our ONC person that really helps us out. Next slide, and we're almost done.

John Feikema – Office of the National Coordinator

Yeah, I think we were at the end. Thanks very much for that John.

John Derr – Golden Living, LLC

I was going to go through more, but time doesn't allow us. So, questions.

John Halamka, MD, MS – Harvard Medical School

This is a brief comment. So the activities that you described in Massachusetts that Larry Garber is engaged in, illustrate the kind of standards that we need. So, we recognize the problem with long term care is there's often not a certified EHR that is going to speak the direct protocol. So, our initiative, our challenge grant, is to build two software components; one called LAND and the other called SEA; you know, grantsmanship is all about acronyms. LAND is a local application for network distribution, which takes a non-certified EHR, it could be simple as I'm running Microsoft Word, I mean, that's my EHR and gives the facility, the long term care organization to drop a file in a directory, for example, and have that then wrapped in appropriate envelopes, put into the direct protocol, effectively using an appliance that sits in the long term care facility, and makes them a direct node, even though their software doesn't support the direct protocol. The SEA idea, which is a surrogate EHR, is basically creating a lightweight, web-based application that allows consolidated CDA documents to be edited and sent and received. And so, basically what you say is, "John, I feel your pain, you're not part of the certification program, you're not part of Meaningful Use, but we're going to give you these components that will allow you, whatever you do today, and now participate in healthcare information."

John Derr – Golden Living, LLC

It's important for the moms and pops...the small independent ones out there. And Geisinger has worked up also where they have a program which is going to out where we can use, it takes elements from the OASIS and from MDS 3 and has interconnectivity in that. I get worried a lot about the independent guys in rural areas. I know we at Golden have one in South Dakota in a town of 500 people, where we're the only 24 hour care place in that town. So, it's important for those people, because I'm afraid with all this complexity, they might get left out.

John Halamka, MD, MS – Harvard Medical School

Right. So comments, questions. Jaime and Cris, is it Cris Ross?

Wes Rishel – Gartner, Incorporated

It's Wes.

John Halamka, MD, MS – Harvard Medical School

Wes, I'm sorry, and David.

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

So first of all, thank you John, nice presentation. I'm very supportive of the goals of getting the standards to support this area actually into Meaningful Use certification requirements and I do think that that specifically is something that should be done. And the reason is, so some of us here around the table actually participated in a symposium at the Hilltop Institute, University of Maryland last week in long term services and support. Looking around the room, I see several people who were there, and what that day-long symposium really highlighted for me was the number of different duplicative efforts that are creating new data silos for long term services and supports. In some of the most innovative cases, funded by the state Medicaid and so we heard there from South Carolina and Arkansas who are doing great work, but it's creating yet another silo that is sucking data in from their sources to support the smaller agencies and home health and so forth, that are supported at the state level. And this is creating, frankly, more of a patchwork more rapidly than I think even your presentation can acknowledge. So, I think the lack of standardization and the increasing development of silos is accelerating rapidly, so I would certainly support the definition of standards based requirements. I think that integrating those requirements into primary care electronic health record technology is completely appropriate and this is something that perhaps ONC could provide a very useful function by signaling a set of optional requirements and start the smoke signals now, because the fragmentation of silos is increasing rapidly.

John Derr – Golden Living, LLC

And I agree wholeheartedly with that because a lot of hospital groups, because of the re-hospitalization thirty days, they're starting with their own little programs and all that and it's just going to be a little bit of a mess in the long run.

John Halamka, MD, MS – Harvard Medical School

Great. Wes.

Wes Rishel – Gartner, Incorporated

Thanks, I want to address the two Johns and John...

John Derr – Golden Living, LLC

There's a lot of Johns...

M

Didn't used to be that way.

Wes Rishel – Gartner, Incorporated

I just want to know, deep in my heart, that somewhere in a document, way deep in the specification of header it's going to say, one if by LAND and two if by SEA....

John Halamka, MD, MS – Harvard Medical School

All right, okay.

John Derr – Golden Living, LLC

And I'm a retired Navy Captain, so I agree with you on that.

Wes Rishel – Gartner, Incorporated

I'm going to potentially commit a travesty here. I would like to say that those individual efforts, however their funded by Medicaid, whatever they are, are probably the most important activity that's going on. And while I would love the world to be optimal, and nobody do anything until they can do it in a common way, there are still...we all, I think, anyone who has ever had a family member who had a serious accident or who went through end of life, has a real gut level appreciation of the issues that we're dealing with here, and we all have this belief that information will solve the problem. We have such an experience though, where information was provided and didn't actually solve the problem, because there was some other obstacle, because there was some other this, some other that; that it is those programs that show economic benefit, it'd probably have to solve five or ten unanticipated problems in order to get to the point of an economic benefit, those are the ones that create the wellspring of support that gets it addressed at a national level. And we too often in standards try to anticipate the needs broadly and fail to anticipate the need specifically. I know that ideally what we'll be doing here is using those as experience towards creating a common spec. I just don't want it to get out that we think that those programs should in any way wait for the effort that's going on.

And that ties into my secondary comment which is that I think that in order for...this could be almost the perfect example of how the process ought to work, now that we've gone through some years of organizing it, we understand what it was about, we developed some trust, we developed some understanding; provided that those pilots that you had on your Gantt chart are pilots that go to the point of demonstrating economic value. And I just, you know, I've seen too many pilots that said, "yeah we ran it, we didn't see any problems, nobody actually tried to treat the payment by looking at the data, but we looked at it, it looked okay," you know, I think this needs to be much more robust in terms of solving the whole problem.

John Derr – Golden Living, LLC

In fact, at the summit, a lot of speakers had been doing pilots based on grants and I said to them, would you please, as part of your grant, white paper, whatever you write, tell us how we can justify our lie about spending the money because a lot of them were putting in home care monitors and different things, a hundred, two hundred of them. I said, those are expensive and we're mostly paid by Medicare and Medicaid, so please, write up how we can justify buying that with some economic five year plan. We did write a paper that you guys...it's not in that folder, but, on the cost of doing an EMR and what it would involve and this is done right now, today, there's a meeting of all the CIOs of most of the cares, about a hundred of them, NIHCA has it, in the folder I gave you is CAST. And so, they said for one single nursing home, and Liz told me it's probably not enough, that's hosting, is almost in five years is two hundred and eighty some thousand dollars. And if it's in your own, and you do it yourself, it's three hundred and some thousand dollars. And that's just to do an EMR. And we don't have that much money, so that the guys know it's better and they figure they'll get efficiencies and I just hope it doesn't reduce the reimbursements once we get the efficiency, so we can do more direct care. I mean, that's our whole ball game.

John Halamka, MD, MS – Harvard Medical School

David.

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

Yeah, thanks, it was a great presentation and I need to know...I need to learn a lot more about it, but one thing that strikes me is that it's easy to get misled by the name Long Term Post-Acute Care, it almost ought to be Post-Acute Long Term Care, in a sense that there's so much other post-acute care that isn't associated with long term facilities, and it seems like your attacking the information needs of a much broader setting than just the long term care facilities. You used the phrase dynamic care plan, I can't imagine a more complicated thing to go figure out than a dynamic care plan; but if you take the medical center at home, and the primary care physician as sort of some notion of locus of control, I almost wonder if you really should be centering these efforts around that model and long term care is one component of that, rather than focusing on long term care facilities, per se, because I think it may just mislead people, and say I don't need to pay attention to that, it's not me. But what you're talking about really is everybody.

John Derr – Golden Living, LLC

And also disabled who live longer. I'm a pharmacist for new meds and prosthetics and things like that, they live longer but they also crash pretty hard once their time is... there was a time it was called PACLT, but it's harder to say. So, and that, this eclectic group I put together to do the standards, the criteria for certification, is the one that really came up with the word. But, I guess I was always misled because all the legislation I used to read had LTC equals SNF and everyone thinks of long term as a SNF, and that's just not right at all.

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

And I think it could cause it to fall below the radar of the standards experts.

John Derr – Golden Living, LLC

Well, that's why I'm talking to you. I've been doing it for 37 meetings, and I appreciate the time that we've had on here.

John Halamka, MD, MS – Harvard Medical School

And consolidated CDA, transfers of care work, the S&I are really now bringing focus to all of your efforts. So, I feel like we have momentum and as Jaime said, I think we...many of us completely support...

John Derr – Golden Living, LLC

It will close the donut hole that you...

John Halamka, MD, MS – Harvard Medical School

Exactly. Long term care is part of care coordination in our community and should be included in Federal programs. With that Jon, at 2:55, we return it to your control, on time for public comment.

Jonathan Perlin – Hospital Corporation of America

Well thank you very much Jon. I hate to acknowledge this but, under my guidance we turned two hours of agenda into three, a 50% overrun. Under John's masterful leadership, 90 minutes was reduced to 30, so 66% improvement. Judge for yourself. So with that, one of the most important parts of the day is, of course, the public comment. I think today's meeting was particularly consumer and patient focused and I think that's terrific. Again, predicate of all the great work that's gone before. So with that, let me thank the Committee members for all of the work, presentations, very engaged discussion. I hope the guidance is helpful to ONC in advancing policy and fulfilling the aspirations John that you and John Feikema so eloquently described. Many thanks for that presentation. Mary Jo, let me turn to you to open the lines.

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

Thank you. Operator, would you open the lines for public comment and if there's anyone in the room who would like to make a comment, please come forward.

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 may press *1 at this time to be entered into the queue. We have no comments at this time.

John Halamka, MD, MS – Harvard Medical School

Okay, well, let me just say Jon is that like the Federal budget, I borrowed time from our next meeting, so it really wasn't performance (laughter).

Jonathan Perlin – Hospital Corporation of America

Well, we're going to work on that deficit. I appreciate all of the work that goes on between the meetings, that I know is so much a part of that. Again, many thanks to the Office of the National Coordinator, great work, all the support staff that behind the scenes do the work, technical support, many thanks. Thanks to all of you for being present today. We stand adjourned.

M

Thank you.

Public Comment Received During the Meeting

1. My concern is that meeting some of the Safeguard CTEs may be coupled to specific Interoperability CTEs. In other words, a particular Safeguard CTE maybe be a safeguard only if it is also known that a particular Interoperability CTE has been implemented. I guess that this is resolved by including the interoperability in the Safeguard CTE, rather than creating it as a separate Interoperability CTE. I hope that the previous comment will be associated with the discussion during which it was made, since it makes sense only in the context of the Governance RFI discussion.
2. No question... just a note that the NTTAA has further "expression" in OMB Circular A-119 (<http://standards.gov/a119.cfm>)