HIT Standards Committee
Final Transcript
September 28, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody. If you could please take your seats, we're ready to begin. Welcome to the 29th meeting of the HIT Standards Committee. This is a Federal Advisory Committee, which means there will be opportunity at the end of the meeting for the public to make comment. A transcript of the meeting will be available on the ONC Web site. Just a reminder for committee members to please identify yourselves when speaking for those listening on the telephone. Let's go around the table with introductions, beginning on my left with Doug Fridsma.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
This is Doug Fridsma, ONC.

Steve Posnack – ONC – Policy Analyst
Steve Posnack, ONC.

Mary Jo Deering – ONC – Senior Policy Advisor
Mary Jo Deering, ONC.

Tim Cromwell – VHA – Director of Standards & Interoperability
I'm not Linda Fischetti. I'm Tim Cromwell. I'm Director of Standards & Interoperability for VA.

Sharon Terry – Genetic Alliance – President & CEO
Sharon Terry, Genetic Alliance.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Walter Suarez with Kaiser Permanente.

Kevin Hutchinson – Prematics, Inc. – CEO
Kevin Hutchinson; Kevin Hutchinson.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Carol Diamond with Markle.

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

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker, SAIC.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Stephen Ondra – NeHC – Senior Policy Advisor
Steve Ondra, the White House.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jon Perlin, HCA, Vanderbilt University.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Beth Israel Deaconess.

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Anne Castro, Blue Cross Blue Shield, South Carolina.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff, Intermountain Healthcare and the University of Utah.

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy, Aurora Health Care.

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer
Marc Overhage, Siemens

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

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

Cris Ross – LabHub – CIO
Cris Ross, SureScripts.

Rebecca Kush – CDISC – CEO & President
Becky Kush, CDISC.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Martin Harris – Cleveland Clinic – Chief Information Officer
Martin Harris, Cleveland Clinic.

John Derr- Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living.

Kamie Roberts – NIST – IT Lab Grant Program Manager
Kamie Roberts for ..., NIST.

Judy Sparrow – Office of the National Coordinator – Executive Director
Are any members on the telephone, please?

Leslie Kelly Hall – Healthwise – Senior Vice President
This is Leslie Kelly Hall from Healthwise.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Leslie Kelly. And Dr. Mostashari will be joining us later. So with that I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, Judy. I want to take things a little bit out of sequence today. First, let me thank each of you for the incredible work. This was a very important meeting. It's a meeting that comes together in really not closing a body of work but closing a period of work that sets the stage for many things that are a possibility in terms of envisioning the characteristics of an improved health system and improved health in the future. You all have, in the body of what will be presented and discussed today, done tremendous work, our colleagues that you've worked with done tremendous work, have done a huge amount of public comment and please know how grateful John Halamka and I are for all of the effort.

I'll come back to a more formal introduction, and some of the topics of today's conversation, but I want to also take this moment to identify with all of you, and Doug, if you'd care to join us, another chapter. As some of you know, I had the great privilege of being in government service for the better part of a decade, and in my tenure there were certain individuals that one worked with that set the bar. We on this Standards Committee have the privilege of working with such an individual that sets the bar. A Federal Advisory Committee, or FACA, is just that, a federal advisory committee. It's meant to be the process by which government policy is informed by the wealth of knowledge that the public can bring forward. We are representatives of the public and as you know this process also includes looking to those in this room, and online a broader representation of the public. And I think that I have never in my entire federal experience seen a process that has been championed by someone who has not only assured the effectiveness of the process in terms of every meeting and all the work in between being so incredibly well coordinated, but the integrity of the spirit of the process, that is, the public input, not only from us as members of the public, but from the greater community.

And such an individual, I'm sure everyone here knows that we are talking about Judy Sparrow, who announced her retirement after a number of years government service, let the record show that she started when she was 12. But John Halamka and I on behalf of the entire committee, and we're joined by Doug and all colleagues at ONC, the White House I'm sure, in this moment I speak for all members of the Standards Committee in wanting to, on behalf of the Standards Committee, John, you and I, want to recognize Judy Sparrow. And, Judy we would ask you to come here and we thank you for your incredible and unequaled support. Please join me .... To Judy Sparrow, the standards bearer.

Judy Sparrow – Office of the National Coordinator – Executive Director
And I have the bowl to prove it, that I'm the standards bearer. But let me just say very, very briefly it's just been an honor and a pleasure to work with this committee and the Policy Committee. I don't think I've ever seen such generosity of time from a group of people. I have never seen such intellectual devotion to helping solve problems. And certainly I have never seen such civility among a group of people, all working towards helping make health IT better. It's just been fabulous for me to witness it and see it firsthand. And I think I'll borrow a line from Doug, "I'll still be very interested in the topic. I will be a first time caller, but a long time listener." Thank you all.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I want to actually read the full inscription, because it's on behalf of each of you. And it says "Judy Sparrow, the Standards Bearer Award in gratitude for your service for advancing health, the U.S. Health IT Standards Committee, Washington, D.C., September 2011." Thank you on behalf of all of us.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very, very much. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Judy, I just want to tell you that I did an analysis of my e-mail over the last year and I was ten times more likely to e-mail you than my wife. It is true that Judy has been the *real* national coordinator, so we thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John, and Judy, thanks for your work. I hope that in the spirit of what you've offered that we offer as recognition of that work the culmination of a lot of great thinking, of intellectual effort, and passion that Judy mentioned.

Let's dispense with our first order of business, the minutes from the last meeting, and I trust that everyone has had an opportunity to review. Are there any amendments, recommendations, ... changes that anyone would like to identify? Okay, hearing none let's assume consensus on that. Again, I think the ... recitation of the deliberations of this committee is again testament to Judy, and I know, Judy, you've also noted the hard work of the staff around you at ONC and want to recognize that.

Moving to today's agenda, what a remarkable moment. It is September 28th, two days from the end of the federal fiscal year, two days from the end of the year where hospitals and eligible providers will have had the opportunity to attest their demonstration of meaningful use. It's a pretty remarkable accomplishment. The work that's occurred has advanced the capacity for health information to support better care and better health in unprecedented ways, and that's remarkably notable. But it's really the beginning. In my ... colleague, John Halamka's words, the work that we've done, the work that we'll offer today as recommendations for the Office of the National Coordinator, which just to be very clear in our first order of business and remember the council is starting with what is the outcome of the first set of activities, to transmit with comment recommendations of ..., frames not what we can't do, but what we can. It's a beginning. It's a trajectory. It's a set of standards that begin to support a set of activities but do not circumscript a set of activities. They allow the opportunity for health information to be more standardized and more consistently transported. They don't define limits. They define beginnings. And in our deliberations here and understanding the role of the Standards Committee as the group that supports the policy intent of the Policy Committee and ultimately both in support of the National Coordinator and HHS, we have a set of standards that interoperate to some degree. They're part of a package.

And the process of coming to this package is one that by definition of the Federal Advisory process is one that I hope you felt has been very explicit and transparent, demonstrating trade-offs. It's not that one seeks imperfection; it's that the world is imperfect. And we make the trade-offs between maturity of the standard, adoptability, use in the health space, any number of different attributes of potential standards explicit. And then what is so impressive to me, stepping back for the role, is to look at the work of the summer camp and say here is a set of building blocks. They're building blocks that support the characteristics of the future system, but they don't define it. They don't define the limits. And just as we work with the Policy Committee to have discussion on the pace, and the pace sometimes being gated, sometimes being accelerated by the state of the standards of the metaphor of the escalator being fast enough for meaningful progress but slow enough to make sure that there's safe adoption, so too we talked about this balance between innovation and specification.

It's ironic that innovation doesn't occur in the absence of some degree of specificity and too much of the Goldilocks phenomenon also is problematic, and so as the standards come forward the set of possibilities don't foreclose what some have already done. In fact, what I think is particularly important is that we look to those public, private sector, federal and otherwise that have pushed the envelope and learn from how they created possibility as we provide building blocks that are available for all then they be part of the repertoire that has been used to date. There's been a lot of terrific work, for example, in the Continuing Care Consortium and Connect that have put together the possibility for communication. Maybe there's some approaches that are beyond what we can initiate as our recommendations today but are part of the set of characteristics that are the characteristics of the desirable health system of tomorrow. I say that because today as we move through the report from summer camp and all of the hard work I hope that we recognize this as something that we transmit to the Office of the National Coordinator as a set of building blocks that are useful to the future that don't constrain but define what can be supported and define only part of the characteristics, the characteristics of higher performance, health and healthcare being the greater goal.

So with that, I'm going to turn to my colleague, John Halamka, to go through the specifics of the different part of the agenda, but I wanted to be sure that we defined what our goal is at the end of this first session with great appreciation to the really remarkable and luminous work in between. John?

John Halamka – Harvard Medical School – Chief Information Officer

Thanks, and good morning, everybody. As you said, it's been a remarkable summer. In fact from April to September, as you'll see the statistics, we've met on average once every three days. This body of work today represents that culmination of April through September. The last month or so I've had a lot of visitors from foreign countries, and every one of them wants to talk about standards. They say the problem we have in our country is we can't actually articulate a standard until it's perfect, and it's never perfect so we just make no forward progress. How in the U.S. have you fixed that? I think the answer is of course we have our own challenges with perfection versus good, but very early on our implementation workgroup set up a set of principles as if a standard is good enough to move forward, if a standard is simple enough but no simpler, if a standard is implementable, if we measure our success by adoption and not by the volumes of documentation, these were some principles that have guided us.

So when we look at the work we'll review today, as you've said, it isn't saying, oh, we picked this standard but not that standard. We constrained the possibilities of the future. No. We were given a set of questions from the Policy Committee and we have come up with those standards that exist as of September 2011 that meet the Implementation Group's criteria of being good enough for primetime today. And in the future there are going to be others and it's going to be a continuous evolution, and today when I look at what I have to do locally I have, in Massachusetts, certain standards I want to choose for content vocabulary and transport and I will tend to choose those that we've articulated because they're good enough. And it does, in some ways, constrain in 2011 the things that I can do because I'll tell you we in Massachusetts just aren't ready for connecting everyone and everything for every purpose yet. But in 2013 we'll do more, and in 2015 we'll do more, and the standards will be there as necessary to do additional functions.

So as we look today at the agenda, we're going to start with summer camp review, and remember metadata analysis really comes out of the PCAST Report and asked us to figure out how we identify the patient and the provenance and think about privacy flags and an envelope, and we came up with a very simple set of XML constructs. We probably couldn't get a whole lot simpler than simple XML with name, gender, date of birth, demographic data, and a certificate for provenance and a very simple list of privacy flags. And the patient matching is not so much prescriptive of what you must do, it's informative, so you understand the sensitivity and specificity of what you might do and then you can make an informed decision in your implementation based on evidence. So that team did a really remarkable job of assembling best practices and evidence, and now enables you the flexibility to move forward.

On the Surveillance Power Team one of the things that I have written about, and I'm so proud that that team has done, is it effectively has chosen one standard per domain; not this or that, optional this, vocabulary that, no, one standard per domain, one implementation guide. It's very clear and unambiguous and the vendors and the users thank you for that. The power team on the Nationwide Health Information Network will I think occupy a lot of our discussion today and what's so very important and I think John and I will say this, Dixie will say this, Farzad will say this, Steve may say this, we'll all say this, that team was charged with something very focused and it is to say if we were to adopt today certain standards for nationwide use what seems to be directionally good enough for that particular narrow purpose? That isn't to say that's the only thing you can do, it isn't to say there won't be additional work. It's for nationwide scalability for a particular purpose are a set of standards good enough. And you'll hear a very thoughtful and objective analysis with that narrow question independently looking at a whole lot of different standards for their characteristics and you'll hear about what for today seems good enough and what seems like it needs further work, and it doesn't preclude future possibilities, by any means, it is just simply saying if you want to push something from point A to point B and you want to do it to scale today, oh, this seems to be good enough based on the experience we've had in the country to date. So that will be a rich discussion.

The ePrescribing of discharge meds, you'll again see a very nice description of what, given the constraints Jamie was handed, oh, Medicare Part D exists. Oh, hospitals use HL7. Oh, ambulatory areas use NCPDP scripts, what can you do? And it's a beautiful distillation of all those constraints being put into guidance. Then we'll hear from the Clinical Quality Workgroup Vocabulary Taskforce on transitions plans, if, again we want to get to one vocabulary per domain it's a goal. You can't just flip a switch and get there overnight.

So how can you, step-wise, enable the country to get to highly constrained vocabularies per domain, recognizing we have to go from the diversity that exists today to the future, and there are, again, a few restrictions that group has been given, like Meaningful Use Stage 1 exists, installed systems need to keep running. And we'll hear from Doug on the S&I framework, the important work that's been done on transitions of care, laboratories, and provider directories. And one of the things that's so good about the outcome of that, is that they were brave enough to make the conclusion that standards don't exist that are good enough. Rather than saying here are some standards that, they're untried, they're untested, we're going to force them on America. So actually what you'll hear from them is, oh, here are some things that we think could be good enough, where further pilot testing will advise us if they really are good enough. So he'll go through each one of those showing you how they constrained the possibilities, some look very directionally positive, others are going to be a variety of experiments and pilots that will inform future standards makers. The Implementation Workgroup will go through a very important discussion on certification criteria for meaningful use, and we did expand your time because we assumed that that would also be a rich discussion.

If we are successful in our work today, what we will have handed off is a set of summer camp guidance that will be recommendations that ONC can then, where appropriate, turn into a notice of proposed rule making, recognize that our, I wish I could say otherwise, but our work will never be done. I think from all the e-mails that have gone across the transom in the last 48 hours, it's teed up a whole other set of work. So I don't know, are you going to call that a Christmas vacation? What do you think? And of course then after our meeting we have a reception that has been arranged by the White House to thank you all for the extraordinary work that you've done, meeting one out of every three days from April to September is something to be absolutely celebrating. So I look forward to our discussion today. It will be a rich meeting.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John. I think that's a terrific teeing up. And we really need your help in going through a broad range of material, and again, remembering our role that we provide recommendations, not determinations, with thoughtful analysis and the object of our activity, particularly for the first session, the report from those one of three days of just terrific work is to transmit with the comments the recommendations of summer camp. I need your help. Let's keep the comments very focused. We can't redo the work of summer camp. As John said, it was every third day. I thought you said that Judy Sparrow was, because of your e-mails, needing more capacity on a daily basis, so it will be impossible for us to replicate, or try to replicate, the discussions of summer camp, but to really frame the commentary around the transmittal of the recommendations and all the hard work, the ... work from so many people behind that.

With that, let me turn to Doug Fridsma to really coordinate the set of presentations. I do know in some of the materials that we've gone through before it had been presented, one big note of those areas to reserve the bulk of the time for some of the material that's coming before the formal meeting for the .... Doug?

Doug Fridsma - ONC – Director, Office of Standards & Interoperability
Great. Thank you very much. Jon, I just have to thank you. You covered probably more quickly and more precisely what we're going to talk about with regard to the summer of standards, and so that will allow me to go very quickly through the slides, acknowledge the work that the committee has done, and then allow us more time for discussion of some of the other things. So I thank you on that.

Judy, did you want to –

Judy Murphy – Aurora Health Care – Vice President of Applications
Oh ... .

Doug Fridsma – ONC – Director, Office of Standards & Interoperability

Okay. We're going to talk about summer camp. The first thing I want to do is just to thank everybody around this room about the tremendous work that happened. At the end of summer camp usually you leave summer camp with something, so Judy is now handing out friendship bracelets to all of you because this is something to help you remember the service and time that you spent, and after the end of camp you have to find a friend who will then tie that on to your wrist. I'm not sure that we've coordinated at the White House, but I'm not sure that you can get in without the friendship bracelet, is that right? Yes, something like that. So it's just a way of me conveying to you just the importance and the value that we have. We also have camp whistles that people are going to get, but you can't use them until after the meeting, okay? But you can at least have that as well.

I'm going to just very quickly go through all of the people that participated, just in some sense to recognize people effectively on this. We have the Metadata Team led by Stan Huff, who in the course of just a couple of months were able to go and very quickly analyze three areas around metadata in response to the PCAST Report. That led to an ANPRM that was published over the summer, I mean, tremendously rapid and thoughtful work that they did.

The Patient Matching Team, again, led by Marc Overhage, took a look at the activities of what it would take in terms of data and certification, and quality of the data that you have, to be able to get to a level of patient matching, again, to help support some of the work that is going on with the PCAST Report and the need to be able to take data from different systems and match those things up effectively.

The ePrescribing of Discharge Medications Team, led by Jamie Ferguson, is going to report out a little bit later today on some of the findings that they've had as well. Again, a lot of folks have participated and supported that effort. A large group contributed to the Surveillance Implementation Guide, and as John has said, this is a tremendous opportunity for us to begin to converge on a single set of standards and implementation guides that I think will make it easier for vendors to be able to move forward.

The NwHIN Power Team, led by the power leader, Dixie Baker, who really I think has navigated probably one of the most important and thoughtful teams over the course of this summer, are coming up with really explicit criteria for how to evaluate different standards and implementation guides to provide a way of sorting those out and then providing recommendations that are both thoughtful, with the appropriate analysis behind it. And again we'll hear a lot more about that particular team as well.

I went back to April when we first charged the participants here in the summer camp activities, and just pulled these slides directly, and basically at that time we were looking at a very short time frame of work that needed to be done in which we needed to prepare for Meaningful Use Stage 2, identify gaps in the standards so that we could begin working towards filling those gaps, and then triage some of the standards work. And using hearings, the federal register, Wikis, the working groups, the S&I framework, all the tools at our disposable to be able to advance our understanding and what it is that we needed for Meaningful Use Stage 2. Part of the things that we wanted to do was to also do a refresh and a reload to take a look at recommended revisions to adopted certification criteria, and Judy and Liz will be reporting out later today on some of the work that they've started there. It's a big task. They've got a lot of work that they've been doing, which I think has been tremendous working with Steve Posnack on that as well.

We also wanted to analyze some of the meaningful use working group draft specifications, and so that was part of that work as well, to take a look at what we had received from the Policy Committee and very quickly turn that into what it is that we needed to do. I skipped some of the work because we initially tried to create buckets of work that needed to be done, and some of those things that we felt were already identified standards, some of the things that we felt needed some work in the working committee, some of the activities that required dedicated effort within the S&I framework, and some of those things that maybe we weren't ready for and we needed a functional assessment of those things.

And so we set up a timeline for the HIT Standards Committee to review standards, and I remember when I first put this up, the gasp that went around to the committee in terms of the amount of work that we needed to do and the amount of effort that we needed to devote to this. And we're right now in September, which is What I Did This Summer review, and that's kind of where we are right now. I am so

delighted and humbled by the amount of work that's come out of this group, the amount of dedication and effort that has gone into it. We really hit just about everything on that list in terms of being able to thoughtfully analyze that. We had essentially six summer camp power teams. It's hard to know what was part of camp and what was summer school or whatever, there were ongoing sets of work that continued. There was at least 39 public meetings and hearings over those 20 weeks, and we were meeting about once every three to four days, and I'm including the weekends when I do that calculation. If you don't include the weekends then it's even more frequently than that. But I think it just is a testament to the dedication and the work and the commitment that the people around this table have. And I don't think we could have done any of it without the leadership that we got from this group. In addition to the six summer camp power teams we had six S&I initiatives and projects that were started, or that are in the process of starting. Some of them have essentially completed some of their work, and we'll be hearing a bit more about those later. Certainly we have got work on certificate interoperability, the Transitions of Care team, working very closely with standards development organizations and HL7 actually took the transition of care work and in the course of six months had two cycles of ballots. Now, remember this may not seem like much, but it takes about 24 months to go through that whole cycle. And with the dedication of the team here and the thoughtful analysis that they did, this week it has been approved as a draft standard for testing and use out of HL7.

The laboratory results initiative is right now doing an off cycle ballot that will complete in the course of the next couple of weeks. And again, through the efforts of the team and the people around this table, we anticipate getting some feedback with the ballot, and this is something that if successful will become, I believe, a normative standard because it's actually building on an existing standard with an implementation guide.

The Provider Directory Project, we'll hear a little bit more about that this afternoon and some of the work that they've done and the sub-projects that have launched out of that to get clarity around what we should do with regard to finding certificates, finding services, and finding people, the Yellow Pages, if you will, on the Web. You all know that in the last couple of weeks we've launched a project called Query Health, which is really about not so much taking the data and bringing it to the question, but taking the question and bringing it to the data, figuring out ways in which we can empower providers out there in the communities to have the same kinds of analytics and the tools that big organizations have all the time to be able to apply to their work. We've got a project that we've been working with SAMHSA on, and Joy Pritts has been leading, on data segmentation. Again, part of that portfolio of activities that I think will help us get clarity around the PCAST recommendations and some of the approaches that they have there as well, how can we protect the data that patients have entrusted the healthcare system with and how can we make sure that that is used in appropriate ways and in compliance with the way in which both the HIPAA statute requires, as well as what the patient preferences might have as well.

I just have to applaud and sometimes be humbled by the amount of work that has been accomplished over this summer, and to thank you all again personally for all the efforts that you've done to advance this. I want to just very, very briefly highlight some of the completed work, again, not so much that we want to reopen this and to discuss it, but just to provide you a full packet of the work that's gone on. There are some other activities that we need to finish today that we'll have some additional discussion on, but I wanted to make sure that we at least had an idea, or remembered some of the things we've talked about over the summer.

The Metadata Analysis team, they identified metadata elements and standards for three categories, patient identity, provenance, and privacy; made recommendations that were aligned with HL7 CDA header elements, with some modifications, looking at things like URIs as opposed to oids and some other technical details. But the thing I think that's remarkable is that this team was able to provide clear recommendations that allowed us to be able to publish an ANPRM and continue that process of getting public feedback about the best ways for us to move forward. We are currently reviewing public comments from that advanced notice of proposed rule making, and we should be able to then analyze those with the Office of Programming, Policy, and Planning. You can tell I was up late last night. And we'll be able to then incorporate that and then come back to this committee and others with the analysis that we have.

The Patient Matching team created some baseline assumptions, got a lot of feedback about sensitivity and specificity and the need to align patient attributes for matching. I think one of the thoughtful things that this particular committee was able to do was to realize that to be successful with patient match it isn't just about the standards. It's about the way we certify that technology. It's the way that we collected data. It's the way that we make sure that that data is of high quality, and all of those elements together provide a mechanism for getting appropriate patient matching.

We'll hear just a little bit more about some of the additional value sets and some discussions that Cris and his team have done in terms of converging on a surveillance implementation guide. Again, I second John's comments in terms of the success of this team in really converging on a singular standard and a set of clear implementation guides, giving us public vetting of what's gone on and continuing to drive towards simplicity and specificity in the value sets and the attributes that are needed to be included in that.

And so, again, there's a whole host of things that they've been able to accomplish, and I think it's also important to recognize that they also wanted us to be cognizant and forward-thinking. And so one of the things that they also included was to make sure that we don't get our blinders on in terms of these kinds of recommendations, that in fact we can move forward with a singular standard, we can ... some of the ones that are not there, but we should keep our eye on some of the other things that are out there, for example, work within the CDA architecture to see if that is something that could be helpful for public health reporting as well. So we'll need to continue that, we'll have to take a look at that in the future, but I think that that's wise guidance as well.

This is, I think, let me just take a look here. I think this might be out of order. This is actually the summary recommendations from the Patient Matching team, so these slides are a little bit out of order but I can talk about some of the things that they took a look at. With regard to the patient matching, identifying a base set of attributes, making sure that we improve data quality, including the patient in the cycle to make sure that they're empowered to verify and validate the information that's there; making sure that if we've got queries that we follow specific kinds of information models or particular formats that allow us to represent these things consistently with patient attributes and metadata standards, and to make sure that we don't return information that was not asked for within the original query, some recommendations about how to do that. I think that that's been, again, very, very helpful advice.

The last thing that I want to talk about before I turn this over to the people that have really been doing the work over the summer and to get them to be able to report out, is to talk a little bit about something that I wasn't quite sure where to put. I've actually got the slide in two different places, and I'm going to talk about it here just so that we can essentially get it out of the way. But we didn't know whether this was a working group or whether this was an S&I initiative, but this we thought really was an effort to support the work that Dixie Baker and her team on the NWHIN Power Team were working on. That is, we've been taking a look at all of the specifications that we have out there realizing that one of our goals is to create this portfolio of solutions that work. So when we think about what we do in my office, the Office of Standards & Interoperability, there's really three things. We enable people to come together to solve common problems and come up with shared solutions, and that's really about the S&I framework, it's about the working groups, it's about bringing people together to help us identify things that work.

The second thing is that we try to ... a portfolio of activities. And the Modular Specification Project, that was led by Avinash Shanbhag in my team, tried to take a look at the NWHIN Direct specifications and some of the NWHIN Exchange specifications. And there's a whole host of different kinds of specifications that we have there, authorization framework messaging platform document submission, there's administrative things, patient discovery, a whole host of things, and our goal was to get input to work very closely with Dixie and her team to develop feedback that would allow us to create more modular specifications, to tease out those things that people felt were tremendously important and foundational, and those things that were part of the process as well. We've really not completed our work just yet, but we've got this notion of secured transport specifications, we've got some of the direct-based secure transports based on the SMTP and S/MIME standards. We've taken a look at Exchange ... secure transports, looking at their Web services over HTTP associated with the security framework there as well.

I think we've been trying to do this so that we can begin that process of developing a portfolio and putting the pieces in place that are going to be foundational, that can be assembled to help us solve problems as we go forward. I want to thank, again, the teams led by Avinash that have been able to work at creating some clarity there as well.

Now I'm going to turn the mic and the rest of the presentations over to the other groups that are going to be presenting. We're going to hear from the Biosurveillance Power Team, we've got the NWHIN Power Team, led by Dixie Baker, ePrescribing, the Vocabulary Workgroup, and the Implementation Group work. John, I think has summarized a lot of the activities that are ongoing within that and I want to, again, thank you all for the tremendous effort. This is something that I don't think that we could have accomplished individually, but collectively we have tremendous expertise and strength and I'm just humbled by the amount of dedication that this team has had.

So with that, I'd like to turn it over to Cris to talk a little bit about the work that's gone on there. I think, is Taha here, or is he going to be on the phone?

Cris Ross – LabHub – CIO
He's there, yes.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Oh, there he is. Good.

Cris Ross – LabHub – CIO
Thank you very much, Doug.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Thank you.

Cris Ross – LabHub – CIO
Let give just a very brief introduction then Taha is actually going to give us the details. As we presented the syndromic surveillance information we pointed out that the implementation guide was incompletely specified but was anticipated to be more completely specified very soon. Well, it has been. The short version is that a lot of reference information that I would characterize as information about treating facilities that could otherwise be found by reference is recommended to be removed from that exchange, which I think is eminently sensible. So Taha is going to give us the details on that point.

Taha Kass-Hout – Centers for Disease Control and Prevention
Thank you very much. I'm Taha ... with the Centers for Disease Control and Prevention. A really quick summary about the findings from the work that we've been doing over the last year, the CDC has been working very closely with the International Science ... Surveillance, ISTS, on a committee approach to this. Core data elements have been identified and are meaningfully useful, have been vetted with syndromic surveillance practice, and the public health community through a consensus process approach. This is the floor, not the ceiling, with 17 core elements in addition to 16 optional. It is an alignment, this whole process was an alignment with the S&I framework but also prior work by surveillance minimum data sets, namely the AHIC biosurveillance MDS, the NHIN biosurveillance use case, the HITSP biosurveillance interoperability specification version 3.2, and also looking at an environmental scan of the current landscape for health departments, where they are looking at the experience we have distributed over 50 jurisdictions as well as BioSense with over 20 age restrictions and ..., as Judy Murphy would know.

We have a messaging guide that's being based on these recommendations and also being revised given the stakeholder input received ... public comment on the federal registry. We've been working very closely with ONC over the last three months just on this process, to finalize these 17 core elements and 16 optional. In the handout I have full detail about the elements and why we can – and we also provide a chart to provide evidence for why we wanted an element or evidence why an element could be optional. And I'm happy to address any of those, if you like.

Lastly, on the health department side, health departments are ready and be able to receive these elements from providers, if they opt to, starting November 15th this year. The BioSense 2.0 roll out is on November 15th and will provide a ... and the environment will be hosted in an Internet cloud that's governed under ... health officials where state and local have ownership and control over their own data. We endorse the recommendation by ... team and I'm happy to answer any questions.

Cris Ross – LabHub – CIO
I just want to summarize, the salient factor here is that some options that were previously required but could be blank are now recommended as optional. And in fact, those elements really bear on the treating facility, things like address and other metadata about the treating facility. Although the treating facility identifier remains required, it was the opinion of the group that because the treating facility information as an identifier is required, that other metadata need not accompany each and every transaction but could be accessed by reference from other sources. So it seems a sane simplification of the surveillance implementation guide.

Taha Kass-Hout – Centers for Disease Control and Prevention
Yes, over these 17 core elements we have six, what we called administratives. These are required for data management, quality control or for a health department to be able to reach back in case they want to have follow up on a patient or on a case or an outbreak, for example, and also to take into account whether this hospital, for example, ... health department or is going through an intermediary, like an HIE.

These six elements, part of the 17 core, 6 administrative include: the facility identifier, the facility visit type, report date time because we want the report of the origin not of the intermediary, the unique patient identifier, unique visit and ... and diagnosis type. Diagnosis type, just from our experience in the public health practice you need to be able to see is this a working diagnosis, if it's a final diagnosis. For a real time sensitive information system that element is really important. Aside from that, the rest are really just the usual suspects. You get the essential demographic information, chief complaint, as well as some initial diagnosis criteria. From our experience with H1N1 we opted to, in consensus with the community discharge disposition was important as an early indicator of severity of illness, so there was a lot of debate around measure of temperature, should that be optional, should that be required. We did a study and actually a patient saying they have a fever was more sensitive than measure of temperature. Measure of temperature was very specific and having temperature did not increase the sensitivity from that point. This is why measure of temperature should be optional as opposed to required. We really tried to be very, very methodological in every single one of these elements to get to the core floor, which was pretty much 11 syndromic surveillance practice and 6 administratives. That makes the 17 elements.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
... good morning.

M
Good morning.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Optional is a four letter word, and I'm curious how you defined optional. The typical situation with anything optional in an interface standard is that it becomes up to the receiver to define whether it's required or not. Unless there's a clear compliance statement that says all receivers must accept the message with any combination of optional fields not populated, we have not really created an interoperable specification.

Taha Kass-Hout – Centers for Disease Control and Prevention
That's a good point. We want to make sure that the barrier is really low for providers and at the same time be able to run the current syndromic surveillance systems in place or be able to maintain syndromic surveillance for a situation ... . Initially we had 32 elements that were required and the majority of them were "are required but can be ..." Then the discussion with ONC was we really have to come down to what is the absolute required over here. But at the same time since the consensus approach many

health departments conduct ... currently that accept and receive some of these elements, but when you look at overall what makes truly a required, that's where we came down to this 17. But without losing knowledge there we ... the others as optional in case the receiver or the provider can work together on the data that they need and there's a message guide and clear FAQs to support this.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I didn't understand the answer. Are you saying that any sender that sends any combination of the optional fields, including none of them, will be judged as being compliant both in certification and in actual operation? Or are you saying we have left it up to the public health departments to say which things are required?

Taha Kass-Hout – Centers for Disease Control and Prevention
The required will be the 17 elements. That's the required.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So there's no case where a public health department can reject the message because some 18th element is not –

Taha Kass-Hout – Centers for Disease Control and Prevention
Exactly, yes. The required is what the attestation will be against. Additional elements, we want to make sure that they're there and there's a message guide to support them in case the relationship between the public health department and provider can allow for ... .

Cris Ross – LabHub – CIO
Let me address that one briefly, Wes, because it is an important problem. I actually raised a red flag on the optionality question and I became persuaded, upon examining this more carefully, that as a practical matter the recipient here is public health, and as a practical matter virtually all public health organizations can accept this content, including the optional fields. The expectation here is where is the difficulty and the cost in generating the data, and that was at the provider side. So there are really three options here logically. One is to persist with them being required fields, but everybody winks the eye because it was permitted informally that many of them could be blank. That was not a very rational setting.

The second option, which is the one that was chosen, is that these previously required fields that were tolerated to be blank would just be made optional. The reason why there's a value in that is because there are some organizations, particularly with the oximetry data and the temperature data, that are able to provide it and it does have utility if it's available, so there was seen to be advantage to keeping some of that. The rest of it, the administrative data by reference, we could quibble about that.

Then the third option of course logically is to simply delete those fields from the implementation specification. I could see rational argument about deletion, particularly for the information that's available by reference, however, there is information in there specifically, as I said, the temperature and the oximetry, that was deemed to have value when it is available.

So we went for door number two, which is to declare optionality, recognizing that the usual cost of optionality is a requirement to have this dual obligation. If it's optional for one team it's mandatory for the other, that is, the recipient in this case. The recipients are capable of accepting this information so we thought that the pragmatic impact of retaining them as optional was trivial, if completely negligible and there was potential benefit for those organizations that could provide it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I've got no problem. My concern is that there will be a public health department that says, gee, it would cost us this much to change our system, for example, to get the reference data. But if we just say it's required then we don't have to change our system. And they will say that if you want to send data to us, you must include this optional data. All I'm looking for is a clear performance statement to accompany the spec that effectively gives the providers something to point to, to say you can't do that to us.

Cris Ross – LabHub – CIO

This reminds me of the Halamka theorem or ..., and if I'm understanding you correctly, Wes, that the optionality creates ambiguity, that in the implementation of one element creates an obligation in another element. So then what does optionality mean, is really your point.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm trying to avoid the Halamka theory here by a clear statement of optionality.

Cris Ross – LabHub – CIO
In terms of the content, this is where we might in terms of our discussion transmit the recommendation that this creates an ambiguity around the optionality of optionality, and that may be something that is inelegant or incomplete but may be difficult for us to resolve here. But I think the point is very well taken about the ambiguous nature of optionality which has been a point which has come forward a number of times around standards. Doug, did you want to comment on this and we'll go to David and Carol?

Jonathan Perlin – Hospital Corporation of America – CMO & President
One summary comment, and that is, Cris, is this really what we're saying here, for the purposes, let's say, of Meaningful Use Stage 2 if I send a message which has 17 core elements, it is conformant and if it turns out that by mutual agreement my public health department ... "a database of temperature would be cool," well, we have a way to do it, again, the conformance, Wes, is the 17 core elements. They can't tell you to do more. You can't do less. But if you want to go beyond that and by mutual agreement do something cool, you have the option to do it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I don't want to belabor this, and I already am, the issue is that whenever there's a spec written like that unless there's a clear accompanying statement that says, in this case, a health department cannot refuse to accept data, if it doesn't contain some of the optional items, then it becomes a negotiation because, yes, here I am, I've got a system that's completely certified and I'm populating all the data in the system, I can send all the required elements, but if the public health department won't accept it, it doesn't do me any good. I'm not going to ... meaningful use criterion.

M
If I may, this really gets at the purpose of an implementation specification and conformance to it. I submit that the specification is unambiguous about what is and is not optional. I don't think we need to add additional statements. I think, quite honestly it's there. What you're suggesting is that some public health agency would ignore the Standards Committee implementation specification and write its own specification. That's essentially what you're saying. I don't know what more we can do in the context of writing a specification than to write in English what we mean, and that's what we did. If an organization chooses to be non-conformant, and I'm referring in this case of your scenario of requiring mandatory fields, then I submit that's a conformance issue that needs to be addressed through whatever standards resolution processes we have. But it doesn't seem on the face of it that the implementation specification is opening the door for that kind of behavior. Quite the contrary, I think we are unambiguous, forgive me, this discussion about ambiguity in the spec is not germane. I think we are unambiguous about declaring the optionality of these fields.

M
I also just want to remind you, this process was a consensus process, this is what public health departments and the practice have agreed, these 17 elements. I have been through this so many times in the HIPAA context, in every other context, where there wasn't a clear statement what optional meant in terms of conformance, it just said "optional," that I have no reason to believe that your saying the word "optional" is unambiguous. If there are statements in the specification, so be it, that define the conformance requirement associated with it, but this is a pragmatic matter that has come up in inter-enterprise interfaces since day one.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What I would suggest, to move this forward, is we said we're going to forward our recommendations with comments, and that the comment that was circumscribed this one is, it is the intent of the committee that

the 17 core elements represent conformance with the standard for the exchange of data for certification of products and their meaningful use and that the Policy Committee should know that these optional fields were put in specifically to allow additional function should it be desired. But they are outside of what is a conformance message.

M
... agreement with ... statement because I think that honors the process that led to the recommendations and identifies the complexity, not intended, but about the word "optionality" in general which has been issued ... . On this point specifically – Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I would propose a more direct language that would say no entity shall require other than the 17 required fields, period. I think Wes is right –

M
... practical. I think we would have to remand that to ONC.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
That's fine.

(Two parties speaking simultaneously.)

M
... that if it isn't that specific –

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I'm happy to write some proposed language for you to consider in constructing the transmittal letter, and we're pretty close to it now.

Laura CONN – CDC – Associate Director for Science
Hi, this is Laura Kahn from CDC. Can you hear me?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, we can. Please go ahead.

Laura CONN– CDC – Associate Director for Science
I just want to remind you that in the actual objectives and written in the regulation that there's a phrase that says "in accordance with applicable state and local laws and practices" and that's I think where this negotiation back and forth between the sender and the receiver really allows for this optional elements to be discussed. I feel like that covers the question, but that's a conversation it has to have before sending can occur. But it wouldn't necessarily apply to compliance of how the guide is implemented.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's stick on this topic specifically. Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
I think I understand Wes' point. It can't be optional in the sense of for everyone, because if it's optional it has to be required for the public health organizations. If it's optional for them and someone ... the information and they're not able to receive it, so aren't we saying that all of these elements are required from a public health entity, it's optional from a sender not from a public health. They're all required for public health, correct?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris, do you want to ...?

Cris Ross – LabHub – CIO
Yes, I can address it. The 17 is what the community has consensus that all these 17 will be acquired. The additional elements, 16 elements, there's varied agreement there. Some people say I want ..., others say, well, you know I can get away without it. So this is why we have to base a lot of that. Also we have to look at the body of evidence we have collected over the last ten years and ... other things where some of these elements were useful, others were not for the public health practice. But others have, for example, there was one element that three health departments wanted but the rest I can get away without them.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
This is Chris Chute. But I think the answer to the question is yes.

M
Thank you.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm sorry, but I don't understand what that means at the level that this comes up in implementation. Is it required to use it, or only to accept it? If there's a field that's listed as optional, that some provider wants to send, then it should be fine for the public health department to say I'm not going to reject the message that's there, but I don't have any intention of storing it in my database.

M
... perspective we're saying it's required for public health to receive. I think from a meaningful use definition it's outside the scope of the discussion.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Exactly. This is where I think we're trending to the policy, and that's why I think we need to provide some comment back on the meaning of optionality. Kevin, I think you provided a scenario in which what is the practical implication of something that's optional. From the health department standpoint that implies a requirement to be able to receive. I don't know. In the interest of that, that seems likely at one level, but the conformance is around the specific required elements and I understand the ambiguity that it creates to describe optional elements. On the other hand, I think the script has put a bit of thought into trying to telegraph other potential data that would be of value. I get the point on the ambiguity around that. Let's transmit what the challenges of the concept of optionality are to the Policy Committee in terms of the practical implementation. It sounds to me that the implementation specifications are restricted ... required elements definitionally. David, do you want to weigh in on this topic?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
No.

Jonathan Perlin – Hospital Corporation of America – CMO & President
A different topic. Anyone else on this topic? Walter and Carol?

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Yes, on this specific topic I think Wes is very right. The problem with optionality is that we have 50 states and we have 3,000 different county and city level agencies and any of them can establish state laws or jurisdictional ordinances that convert, that turn one of these data elements from optional to required. That little key that says optional in the implementation guide, they might turn it as required and so at the end we would have a multiplicity of situations where in some states or some jurisdictions this particular element is now required to be submitted as part of the message, even though in the actual implementation guidance it's optional. In HIPAA, I'll go to Wes' point, the standard transactions don't use the word "optional" they use the word "situational." And situational means there is a rule that defines

when that is either required or not required. So there might be an opportunity to be very clear as to whether, first of all, jurisdictions like states and locals can have the ability to turn an optional data element in implementation guide into required, which the recommendation would be no. Or alternatively, actually in the next version of the implementation ... convert all these optional elements into situational elements in which there is a specific rule that defines when the situation is positive and then is required.

M
It defies logic that there wouldn't be situations when – you've defined 17 core elements and 16 optional elements that in the context, as our colleague from CDC indicated, of state activities. The state may define things beyond this. I think that the point that I take away from this discussion is the specificity around the core elements and categorical challenge with the nature of optionality that then may be difficult to resolve. That said, I cannot imagine a scenario in which a particular state or municipal health department may not ask for, or negotiate for, other information given a situational issue. Let's go to Doug Fridsma, because this spans areas that are beyond the standards ... the policy and certainly the ONC requirements.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I just wanted to highlight some work that's been going on in some of the other power teams and other work, and that's this notion of Internet robustness, Postel's Principle is what it's based on. What it says is that when you send something you should send it conservatively, which means that there should be conformance to the standard. Realize that what we want is we want the technology to have the capability of sending that information in a fully conformant way, and that probably involves making sure that you can send it with the optional elements as well. Now, from a policy perspective or from a particular area you may not need all of those, but we want to empower providers and healthcare physicians and whatnot to have the technology to be able to send conservatively.

The other part that's really important is that we have to make sure that the CDC and the receivers receive liberally. What I mean by that is that if you expect to see an element and it's not there, you can't reject the message. You need to have a way of still accepting it. Or if you see something that is unexpected that you didn't anticipate, you need to, again, not break when that happens. Those principles have held very, very solid when it comes to being able to progress over time and maintain interoperability, so when we think about this discussion, this notion of making sure that we certify that technology has the capability to send fully conformant messages and that at the same time we work very closely with our federal partners to make sure that they can receive liberally and not break if there's something unexpected or something unanticipated.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think that's good counsel. Let's go to Carol and then David, and then let's bring this ... to closure, because ... strong consensus around the core national of optionality, which is generically worthy of discussion in many contexts, not just here. Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I'm less concerned about the optionality from a technical standpoint than I am from a policy standpoint. ONC has adopted fair information principles generally which talk about purpose specification and data minimization, which in a nutshell says collect only what you need. Say what you need, specify the purpose and collect what you need to accomplish that. I think this whole conversation about collecting stuff that may be optional, somebody sending that you're not using, is a slippery slope, that the answer to what should be collected is what's needed, period. Now it's fine to say on the data system side that there's going to be standardization for a whole set of elements depending on what's needed, but I'm less comfortable with saying then everything gets sent every time it needs to get sent regardless of whether or not it's used.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific points to make sure that ... are transported back to the Policy Committee, and I appreciate that input. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David McCallie with Cerner. My question is on a different angle, which is it seems like some of these data fields are likely to become available on different time frames, including some of them like coded cause of injury could conceivably take days before they're available. So my question is whether the standard is contemplated with the service level expectation from the sending system as to how timely the data has to be captured and sent. Is it possible to send a message more than once if subsequent data rolls in? How is that approached?

Cris Ross – LabHub – CIO
That's a good question. In the guide we do provide instructions about when these data elements – so for example they can be empty if it's not available at that time, but their time can be backfilled, realizing some of these elements might take several days. A lot of that language in the message guide came from the current practice, so we'll look at currently how long does it take to get certain elements, and we take that into account.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Is the assumption that a department provider or institution might send more than one message at a routine case?

Cris Ross – LabHub – CIO
Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So that complicates the required field even more, in a sense.

Cris Ross – LabHub – CIO
It's complicated –

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

Cris Ross – LabHub – CIO
... building to accept it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Okay. Just to make sure that's accounted for.

Cris Ross – LabHub – CIO
We've been dealing with this for about a decade in BioSense, for example, and a lot of health pharmas are right now, where on the receiving end it's also really complicated. But there are ways on how we deal with it. But also at the same time, for example, we need an initial diagnosis, and it's a working diagnosis but later on might be a final diagnosis, and that's where the current practice is. So multiple messages will come and then their receiving system is designed to process those and update them. This is why when we look back at the administrative elements we'll want to make sure that we can go back and update the same record as opposed to –

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Okay, thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, well a very robust discussion. I appreciate that very practical point that has policy implications as well as very pragmatic elements associated with it. As mentioned at the outset, the incent here was to transmit with comment and I think the comment, David, the two issues that I hear are the issue of the timing of the reporting and OS thrift discussion on the nature of optionality and unintended consequences. So as we transmit, those will be the areas of comment and we'll work to capture the robust discussion around the concerns that optionality creates. Do you want to hearken back that we're trying to bring

forward a package of elements that facilitate, doesn't constrain, but good feedback back to the Policy Committee and to ONC, so are we in agreement on that process? Good.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
There's one question.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jim, sure.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
It's probably just my own clarity, so when we say, normally if you say it's required then that would mean they're not going to accept that if you don't fill the field in, but that isn't what this means. What "required" here means is that sometime in the course of this episode, and it could be days, they're required. So it isn't required for transmission, which is I think the normal meaning of, or at least one normal meaning, it's required in another way which can be accounted for, but it's not the normal way we talk. And I don't know if that's part of Wes' concern, but at least it seems unclear to me.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's forward that with our comments, because I do think that's a very important practical consideration. Cris, was there any contemplation of that concern that you'd want to communicate at this time, or shall we forward it –

Cris Ross – LabHub – CIO
There was ample discussion about the notion of required but blank. Evidently this is common practice in this particular use case, and we were trying to actually diminish those numbers of fields, specifically the administrative fields that could be obtained by reference. Jim raises an interesting question. You can get into deep philosophical issues about what constitutes requirement. I think the expectation is that if the information is available then it's required. If it isn't then it's blank. And that's really the extent of the intention on the face of it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, and then the inquiry around the no value in the essence of information ... an appropriate response would be helpful. So we'll capture those three points. Others? Okay, that's terrific work, great discussion. I appreciate the challenge to assuring that the logic is completely intact and thanks to all the members of this particular team.

It's my pleasure to, before we go into the next component, to welcome Dr. Mostashari, who is living the ONC pattern of hard work and little sleep, I understand in from a Red Eye from the west coast, and circling above Washington, so thank you for being here ... . Farzad?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
Thanks, and sorry I'm late. I have been talking about this, I've been advised the most important Standards Committee meeting maybe ever, so I knew I had to be back. I was over at Health 2.0 back in San Francisco yesterday, and I think some of these comments have already probably been made in the preface to this, but I'll just repeat them. When we talked about the escalator and ambitious but achievable and moving the country in a step-wise manner towards the goals, we need an explicit expectation that Stage 2 was going to be much more rigorous in terms of exchange and interoperability, and I think we're at a critical juncture now in terms of whether we step forward or we say, you know what, we're just not ready to take that step, or how big a step we take forward. I just want to share with you the perspective that I'm getting out and about as I talk to folks.

The first is, I think there is an under recognition of the progress that's already been made, that Stage 1 really did set an important foundation for the work that we're continuing today, whether it's around the messaging or around the vocabulary and terminology. But somehow that is lost, and I think that somehow has to do with the exchange part. The lack of transport standards has meant that many groups say, sure, the EHR can produce a CCD, and yes, it can be more specified, yes, there can be more code,

yes, yes, yes, but it doesn't help us because there's actually not exchange happening. And what exchange is happening is still either HL7 or proprietary information exchange formats for the most part. And particularly if we're looking at the Policy Committee's recommendations that Stage 1 be extended for an additional year, I don't think we can afford not to move ahead on exchange of information, on transport standards, for another five years. I don't think we can afford that. So the question then becomes what do we do in the face of no standards that are perfectly ready that we have absolute confidence in both their maturity as well as their adoptability, much less evidence of adoption. I think what we have to gird ourselves to is to recognize that, yes, it's going to be imperfect, but that's okay. That we're going to need to move ahead but to do so in a way that is in the right direction, that does not create either undue burdens nor lead us into dead ends. I think that's the most challenging part of this policy decision, where we are with this.

In general, my request to you is to push, to take that step forward. A CEO of a mid-size electronic health records company came to see us, and like many others he echoed what we really need are more interoperability standards, and then he said, honestly anything. At this point we don't so much care what it is. Now I think that view is not universally held. I think there are still folks who are concerned about the path and where it leads and so forth, but there is a sense in which not moving on anything is a greater risk than moving forward on things that may be imperfect. I think that's just, in general, my plea to you is that at least out of the gate, this is going to go through rule making, we're going to hear plenty of feedback on feasibility and alternative approaches and so forth, but moving forward I think, being forward leaning, being action oriented, being brave on putting out there what your best guess is, is going to be important for us to make progress, because we can't afford to waste another five years before we have exchange in this country.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you for that charge. I think it's not just right and inspiring, but it does remind us of our initial conversation that I need your help. We need to be able to meet this unique opportunity to accelerate the health information. There are many elements that in aggregate form a package. We can't have an engine without wheels. I hear that the engine is the emerging environment of electronic health records, the ... in the personal computer revolution, we've got to move to the Internet revolution to really be able to honor the intent. That's why I'm actually charged by the last discussion. Yes, some pragmatic issues, but the intent below that is not just directional but specific in terms of particular standards are recommended and that helps to meet this requirement for moving this forward, again, as a recommendation that will be subject to further deliberation and in fact not determination, and with feedback to our colleagues at the Policy Committee, through ONC, through the secretary's office, rule making and so forth. So in the spirit of that, let's keep adding to the package of tools, the resources that don't define the limits, but define really the base of possibilities that can be used, don't constrain those we're already doing, but support those that need to really make use of pieces at this very moment.

With that, Doug, let's go back to you. We've got I think tremendously fascinating work that we're going to hear about next that in fact takes us to that area of transport and information exchange in the broadest sense.

(Background conversation.)

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. For those on the line Doug Fridsma and Dixie Baker are at the table and going to present on this next topic of NwHIN.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
As I said in my opening comments, I just want to thank this particular committee, and in particular Dixie and the leadership that she's demonstrated in bringing together really work that I think this committee can be proud of in terms of articulating a way of assessing the various different standards that are out there, expanding the clarity in which we can move forward, and really I think tackling head-on some of the thorniest issues that we have. I think in large part the committee is going to be able to come up with

recommendations that will actually satisfy some of the charge that we've gotten from Farzad and others as well, so with that I'm going to just turn it over to Dixie and let you do your magic.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
All right, thank you. I would certainly echo what Farzad said, that people definitely do care about transport standards. The power team has gotten a lot of feedback already from the public where we've very grateful for that feedback because it's been very, very helpful to us. So if someone can tee up the slides, please.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Here, you've got –

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Oh, I've got control and didn't even know it. This is the members of our power team. It's been a real pleasure to work with all of these individuals. Our power team did represent both people from the federal government organizations, Tim was on the power team, and we certainly appreciate the input that we got from both the VA and the DoD. It was really, really valuable. As I said before, I do want to thank the public for their interest and their inputs as well, as those inputs have been very helpful to us.

I wanted to remind you of the context and the tasking for this power team. The ONC has defined the Nationwide Health Information Network as: "The set of standards, services, and policies that enable the secure health information exchange over the Internet." This is the definition that Doug presented to us I think a couple of years ago at this point, and in support of that definition of the NwHIN the power team was asked to assist ONC in defining this set of standards, services, and policies and they ask us to go about that by first evaluating the specifications that have been developed for the exchange and direct pilots that have been underway with respects to their usability and their scalability to support nationwide health information exchange. I want to stress two points in that, one, our focus was at the national level and especially on the scalability of these standards. And secondly, I want to stress that each specification was evaluated individually, there was no comparison among these standards or even among the sets of standards between Exchange and Direct.

Secondly, ONC asked us to recommend those specifications that could be integrated and deployed to support the secure transport and exchange of electronic health information at a national scale and to identify where further work may be needed. As Doug has made clear to us since the beginning, the outputs from this work were intended to help inform ONC decisions regarding future investments in additional NwHIN pilots and specification development. Obviously the ultimate goal is to enable and facilitate the exchange among federal, state and private health organizations. As we all know, the majority of people on the NwHIN are organizations ... federal agencies. The CDC, the DoD, the military health system are certainly key players in the NwHIN, as well as private healthcare organizations.

The focus, as I said, of this work is that the national level we did not address or have a single conversation about the use of these specifications within enterprises or among partners within a regional health information exchange or for community use. The power team evaluated each exchange and direct specification independently against a number of defined criteria. These criteria are defined in the glossary of this presentation, and also I'll go over each definition as we look at that particular criterion.

There was no comparison or selection between the specification set for Exchange or Direct and we recognized from the outset that each of these specification sets was designed for a different use case and to fulfill different needs and in fact each can serve a role in the NwHIN. In fact, we know that a number of organizations and EHR vendors have already implemented both Exchange specifications as well as Direct specifications. This is a list of the specifications. There are ten specifications that have been developed for Exchange and there are two developed for the Direct pilot. I have the URL for each of them there, and we looked at each specification.

I do want to note that the Direct, because this seems to be a common misunderstanding, the Direct specifications include two specifications, the Direct pilot developed two specifications. The first, which has a rather odd name, applicability statement for secure health transport, that is the core transport for Direct. That is the specification for the use of the Simple Mail Transport Protocol, SMTP, and S/MIME, Secure Mail – I don't remember what MIME stands for, but it's secure e-mail and that's the core specification.

The second is XDR and XDM for direct messaging. I do want to stress that XDR is the IHE profile for reliable cross-enterprise document exchange. XDR uses Web services to push data from one enterprise to another and it was included as one of the Direct specifications to provide a reliable means of allowing Direct users to exchange documents with Exchange users, so that XDR and XDM for direct messaging is not only one of the direct specification but it also serves as a bridge between Direct and Exchange.

The methodology we used, and I'll go over this on this slide and the next slide, first, we evaluated each specification generated by the Direct and Exchange pilots on these six factors shown here, the need for the specified capability, the maturity of the specification itself, the maturity of the document itself, the maturity of the underlying technology that the specification depended upon, deployment and operational and administrative complexity, the breadth of industry adoption, and the availability of alternatives. The scores that I will review with you in a minute here were initially recommended by the ONC with inputs from the NwHIN Exchange coordinating committee and the National Institute of Standards and Technology, NIST. Then the pilot team provided review inputs to those scores. We worked very closely with Avinash Shanbhag and his team, and Avinash was an invaluable resource to us.

Secondly, we identified those specifications that provide capabilities for which the business need was evaluated as low.

Third, we identified those specifications that are in the early or moderate stages of adoption and that use technologies that are in the declining phase of their technology life cycle.

The fourth step was to identify those specifications that introduced significant deployment, operational and administrative complexity and that have low industry adoption. After we finished evaluating each of these specifications we considered the availability of alternatives. To do this we created a smaller team within the power team that identified standards and solutions that have been broadly adopted in healthcare but are not either Exchange or Direct specifications but are used broadly in our industry today. We also looked at other industry standards. Any of these alternatives we used the same criteria as we used in evaluating Exchange and Direct specifications, although I would note that further evaluation of these alternatives is needed. We looked at alternatives primarily as do they exist, what are they, how broadly are they used in our industry, then we subjectively assessed whether any gaps remain. And finally, we formulated the recommendations that we're presenting to you today.

I hope you have this as a handout because it certainly isn't easily seen on the screen here. There are two slides here that present the Exchange specifications and then there's one slide that presents the Direct specifications. You'll notice that on all three of these slides we assigned a low for industry adoption for the simple fact that none of these specifications have been broadly deployed beyond the pilot. And so we just said well, we really don't feel comfortable saying anything other than low, because they haven't really gone beyond that at this point. The need for all of them on this slide is either moderate or high need. You'll also notice that there's some blue font on there. I want you to ignore that. That just earlier indicated a new change, but it really has no meaning at this point. Next slide.

You'll notice that on this slide they are two that we judged having low need. One is the NHIN Access Consent Policy specification, and this spec describes the content and format of access consent policies that are associated with the content that's exchanged used the query and receive specifications, and just the way it's used and the functionality as described in that specification was judged low. The other one that's judged low is the NwHIN Health Information Event Management stack, HIEM, which allows a single node to subscribe and unsubscribe to various classes of content and ... . I think those are the only two things I wanted to point out on that slide.

The third, this is the two Direct specs, as I mentioned earlier, that applicability statement for secure health transport is the core SMTP S/MIME spec, basically that describes how you do secure e-mail. And the XDR and XDM for Direct messaging is the spec that uses Web services to facilitate the exchange of documents between Direct and Exchange.

Okay, looking first at the need we define this criteria, along with Avinash and his team at ONC came up with these definitions, it was a subjective judgment, it was either low, moderate or high, and it focused on whether the specification is needed for meaningful use, federal agencies, and to meet other national needs, plus review inputs from us. The factors we all considered were for low we could find as it lacked specific and compelling needs, if it's needed for meaningful use, and this was either moderate to high depending on the other three factors, federal agency need, other health information, technology needs, etc. And as I've gone over before too that we had assigned a low need score were the NHIN Access Consent Policy Spec and the HIEM spec.

The next two criteria we considered were the maturity of specifications and the maturity of underlying technology. The maturity of the specification was a subjective assessment judged low, moderate, or high. The initial scores were assigned from a survey that the ONC conducted with the NwHIN Exchange Coordinating Committee and they also solicited inputs from NIST and added their own ONC inputs. Then the power team added our own inputs. The factors considered were if the specification was still in development it was given a low score. If it's clear and unambiguous it was moderate. If it's testable, maintainable and fully tested and piloted, it was assigned a score of either moderate or high.

The maturity of the underlying technology was a subjective assessment and the four categories were emerging, maturing, mature, and declining. These are basic life cycle indicators, life cycle within the technology life cycle. This was an assessment of the maturity of the technologies used and the specifications with respect to this complete technology life cycle and it was assigned by ONC with inputs from the power team. The factors included if it was a new and unproven standard and industry support for it was still building, it was judged emerging. If it was still gaining market adoption but less than 30% of industry adoption it was judged maturing. If it had attained mainstream adoption across the industry it was judged mature. And if the technology were experiencing a decline in its use, it was judged declining. Here are all the specs that based on their specification maturity on the Y-axis and technology maturity on the X-axis you'll see that really only one used technology in its declining phase, and that's the NHIN Web Services registry specification. The thinking behind this particular assessment was that if a specification was still not mature, it was still in development and the technologies that it depended upon were in their declining stages, then it may not be wise to invest further in that specification because it was dependent on technologies that were really in their declining phase of maturity. And that's what we see in the case of the Web Services registry specification.

Next, we looked at deployment operational and administrative complexity. This was a subjective assessment judged low, moderate, or high, and it considers how easily the specification is to implement to begin with, how easily it is maintained through ongoing operations, and the administrative complexity has to do with the complexity that exists across organizations as they interact using that particular specification. If it can be handled with ease by IT support it was judged low if it did not reach the other levels. If it needed moderate administrative support for deployment and maintenance over time it was judged moderate. If it needs substantial ongoing IT investment to support the service it was judged high in complexity. And if it introduces administrative complexity that spans multiple organizations and requires a high degree of federation and a high degree of complexity with respect to the projects used to implement it, it was judged high.

Industry adoption was assessed at low, moderate or high relative to the market segment that the specification was developed for. The initial scores were derived from responses to objective questions on exchange usage, and the scores were reviewed by the power team, who concluded that since neither the Exchange specs nor the Direct specs had been broadly deployed beyond the ONC pilot we judged all of them to be low. Here are the scores shown on this grid of deployment, operational and administrative complexity on the Y-axis, and industry adoption on the X-axis. The three specifications that showed both

high complexity as well as low industry adoption were the NwHIN Authorization Framework specifications, the Patient Discovery specifications, and the Web Services Registry specifications.

Moving on to our conclusions and recommendations, the first conclusion that we reached fairly early is that architecture is important and the set of standards, services and policies that comprise the NwHIN must be deployable within an architectural framework capable of supporting the secure exchange of health information at a national scale. You'll recall that we first started out looking at let's come up with a bunch of building blocks, and it became clear that those building blocks have to fit and operate within an architectural framework. We also wanted to note that the standard services and policies, they need to address the transport, the security, and the clinical content using standards for clinical documents and controlled vocabulary. Structured clinical documents and controlled vocabulary should be equally valuable regardless of what secure transport you're using. Whether you're using a Direct transport, an Exchange transport, or some other transport down the line, the use of structured documents and controlled vocabulary is really, really important to interoperability. And we felt that any NwHIN secure transport should support the full range of health information exchange from unstructured data and possibly incomplete data, to structured, coded content. In fact, we had a discussion a little earlier today about the importance of being able to accept incomplete content as well. So we heartily endorse all of the work that Jamie's team has been doing.

The second conclusion is that neither the Exchange specs nor the Direct specs had been proven at large scale in production environments across a broad range of healthcare organizations. The scalability of the underlying architectures and the inherent impacts to workflow needs to be better understood. Once these specs have been deployed at a much larger scale across a broader spectrum of healthcare users they should really be reassessed against the criteria that we used in this exercise. The third and fourth recommendations here has to do with Exchange, our conclusions with respect to the Exchange specifications. The fifth conclusion has to do with our assessment of the Direct specifications.

We heard testimony from two development teams who had been directly and intimately involved in the implementation and deployment of the Exchange specifications for the VA and the DoD, and we're extremely appreciative of the insights that they provided to our team. And where you see on the slide, you see quotes, those quotes are from that testimony that we heard from actual implementers. Our conclusion is that the Exchange specifications are highly complex and they're designed to support a complex architecture that may not be appropriate for all healthcare organizations and that may not scale to nationwide deployment. I would add to that that the Exchange specifications were never intended to be appropriate to all healthcare organizations. They were intended to be appropriate for certain types of organizations. So the first thing that was pointed out was that there are too many layers and debugging is very hard due to the complexity of the layered approach. We asked whether layered protocols in general tend to be complex, so is this a problem with the layering or is this more complex than most and we were told that these specifications are more complex than other layered specifications they've encountered.

Version skew among these layered protocols made it hard to manage widespread deployment of these specifications. What we mean by these layered protocols, these are standards that are embedded within the specifications themselves and they're standards that are externally specified, so they're specified and maintained by another standards development organization. The NHIN query for document specifications poses operational challenges. There's no agreed upon way to query for specific items such as "Show me the most recent ECG," which forces the download of large chunks of a patient's record from multiple sites, which is an issue that I know Carol mentioned earlier today, about the minimum necessary. They don't handle images well, and this is largely due to under constraint specifications on how to handle extremely large files. Then the C32, the Continuity of Care document, definitions are not precise enough to allow for seamless importing of external data elements.

NHIN retrieved document specifications method of accumulating query results may cause, and has caused, long delays, huge messages, and frequent timeouts. In fact, with respect to this, we heard this in our testimony but we also heard from another large organization who has implemented the Exchange specification and they told us that they had solved this problem by running their queries overnight. I don't think that that may be a realistic approach for everyone. NHIN Patient Discovery specifications, this

perhaps was our biggest concern. We believe that this specification is at risk of being a real show stopper for the Nationwide Health Information Network Exchange, and that's primarily due to serious policy issues that drive an architecture that performs poorly, disrupts provider workflow, and poses a serious challenge to scalability beyond the limited pilot.

The results from this study present opportunities for simplification, so we're certainly not saying toss all these specifications out the window. We are suggesting that these opportunities for simplification be considered. There are two specifications that address needs that are judged low in our analysis, as we covered these, the access consent policies and the HIEM specifications. The NwHIN Web Services registry specification is a moderately mature specification that uses technology that's in its declining phase of the life cycle, as you saw in our assessment. And I would also note that the S&I framework team is also considering alternatives to this specification. The NwHIN Authorization Framework specification is also highly complex and there are alternatives that could be considered, such as the OAUTH standard, that's Open Authorization Standard.

The NwHIN Patient Discovery specification is highly complex but it's highly needed as well, and the NHIN query for document specification has operational and workflow challenges. We need a more scalable architecture to support patient discovery. Patient discovery, we talk about this in this committee all the time. This is really, really important to achieve the objectives that we're all striving for. The Query for Documents Patient Discovery and Retrieve Document specifications are usually implemented together, and so we're recommending that any alternatives should be considered within this context of all three of these specifications.

Our conclusions regarding the Direct specifications, although the Direct specifications have been in pilot usage for only a short time, they started in January of this year and they've not been deployed widely beyond that pilot, the underlying transport standard, SMTP for e-mail, is well understood, widely deployed, and has been proven highly scalable. The security standard, S/MIME, fulfills the EHR certification requirement that already exists for an encrypted and integrity protected link, and that reference there is to the standards and certification criteria regulation that currently exists.

The Direct specifications do introduce some new approaches that have yet to be fully deployed and proven beyond this pilot itself, and particularly around the validation and use of organization level digital certificates and the use of the domain name service for certificate discovery. Given the current ONC initiatives to address these risks and recognizing the potential benefit of having a simple, easily implemented solution for exchanging EHR data within the framework of existing standards and certification criteria for transport we would support and encourage broader deployment and use of the Direct specifications, including XDR.

The sixth conclusion is we discovered that some areas are underspecified in the current specification set and we learned this primarily through our testimony. The specifications to support Exchange or remote viewing of large images are lacking. Specifications are lacking for the discovery and retrieval of individual data elements, such as a lab result outside this document context and there's a need for more granular query capability for patient records, such as "Give me the record with the most recent ECG." We note that addressing these needs may present opportunities to consider the PCAST model for data discovery using indexed metadata combined with the retrieval of desired data element or object. The PCAST model also may be more scalable to patient discovery as well. You'll recall our talking about the President's Council of Advisers on Science and Technology report from December that introduced a brand new model where you just searched the metadata to find where certain types of data, data records exist, and then you go to where those data reside to retrieve them. So this may be an opportunity to explore using that model.

I mentioned that our power team conducted a small study of other Exchange methods that are broadly used within our industry and one of the methods that seems to be more and more broadly used is the use of the REST architectural style. So we observed that the industry is trending toward more widespread use of this REST architectural style in designing network systems, and we feel that this presents an opportunity to develop a new specification for restful exchange of health information. REST is not a

standard in itself. It's a style that uses the HTTP, the normal Web protocol standard to provide a simpler alternative for Web services accessing than the SOAP standard uses. But not all RESTful implementations are implemented in the same way. In fact, even in our discussion of various alternative transports that are used in our industry we had a little debate on which was really RESTful and which was really not RESTful. There's a lot of use of that term and nobody really has a specification that they can go back and say, oh, here's what we need by RESTful. Also REST is not inherently secure, but it can be secured using the same standards that the Exchange specifications use, which is the transport layer security and open authorization, the Exchange specifications don't use that, but they do use PLS.

We feel that the last of the specification for the REST style and the last of a specification for how you secure REST presents risk associated with the use of the RESTful style in healthcare organizations. So we believe that developing one or more specifications for secure, RESTful transport for healthcare exchange would provide healthcare organizations assurance that when they see RESTful implementations they know that they'll be able to assume that it's implemented in accordance with the specifications, and so it would be predictable and they would know it would be secured.

And with that, the rest of this is the glossary, so let's open it up for discussion.

John Halamka – Harvard Medical School - Chief Information Officer Thanks, very, very much. I am sure there will be many comments. But I just want to frame up, because I think a lot of people in this room have exchanged hundreds of e-mails as we've gone through these various drafts, and it's just so important to put what Dixie has said in context. As I said in the framing remarks, one of the things she was charged with doing was looking at the state of standards as specified and implemented today to determine what's basically good enough for national scale use. It isn't to suggest that's the only thing we're going to do. It doesn't say that you can't use them locally or in any other context. They didn't even ask that question. It doesn't make such assumptions as oh, well, Dixie, in point five you said Direct seems to be low risk, does that imply other architectures that we might imagine in the future are now not possible. Well, no, right? So it is just again what is today looking good enough, and actually I think it tees up a variety of future work so that as we together start asking, well, Farzad, I show up unconscious in the emergency room and you want to pull my record from all the places that exist in America, we need to be able to do that. It's just the standards as they exist today don't support that to scale. So, guys, as we talk about this, that's really the context. What is good enough to move forward with today and what is future work that still needs some polish. So, hey, Wes, you were fast on the card.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I bring a spring so I just let it go and it springs up. I just have several comments. First of all, I think that Dixie did an enormously, and I think the right word is "powerful" job of organizing this conversation, structuring this conversation to meet the charge that we had, as opposed to meet what people often wanted to talk about. It's occasionally troubling, particularly in the round of e-mails and discussions last night, that there's a perception that Exchange is about structured data and Direct is about e-mail. I think that we did not assume that in a committee, and it's important to recognize that any rational set of standards should have sufficient modularity so that structured data can be sent by various transport means as opposed to the transport means be identified with structured data or not. I'm mindful that we put a high standard, if you will, on our report, we were given a high standard to report to, which is suitability for scaling to a national level, by which we mean a million providers, plus or minus. It's many degrees of magnitude better than most current networks. I'm also mindful of Farzad's comments this morning, which were on the order of we need whatever works well enough soon as opposed to we need what's best later. Is that a reasonable statement? Okay.

I personally feel, and I'm completely in alignment with reports, that the particular stack of standards and protocols that were developed for the NHIN trial implementation include a number of elements that are both unproven and probably extremely difficult to implement at scale. They were included I think for good reasons, the way the problem was ... to the people who did it at the time. It wasn't just frivolous, but having a full role-based access control capability, a number of things, having a constrained patient lookup capability, have created problems in terms of the ability to adopt that stack in situations that could be important to meeting meaningful use requirements yet not be a full nationwide health information network.

It's important that we be consistent on that because one of the claims for Direct has been that it's useful in a community context long before all of the full framework that makes it useful on a full million provider national context are there. So there was a communication last night in e-mail that suggested that there is in fact operational use of a different stack built out of many of the same protocols that are used in the NHIN trial implementation specifications, a different statement of the use case, which avoids many of the policy issues that created the complexities in the NHIN trial implementation's profile, and a claim, which I can't confirm or deny, I just don't know, but I'm not trying to either demean the statement or support it, I just don't know, that it's been used by a number of vendors interoperating across their EHR systems. Given that we have on the one hand the comment from Farzad this morning, and on the other hand a potential that there's a plum out there to be picked from a low branch, I think we ought to look at it. It's no fault of the power team in not having looked at it. We had a very explicit charter which by itself was challenging. If we'd added a more open-ended thing we'd still be on defining our terms, but I just think going forward we should take a look at what's happening now, to what extent these vendors operating among themselves as opposed to through the standards organization have managed to select a path through the complexity of that complete protocol stack that is easy to use and in part, as is almost always the case in getting something done pragmatically in interoperability, they did it by sharpening the use case in a way that would be acceptable for community usage or broader usage of things like that. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
A couple of things that Wes said that I just want to highlight, because it's so important that we communicate this very well, is that Direct decouples transport from content, and that is to say, as Dixie has said and as you've said, Wes, if you want to send structured data via Direct, go ahead. If you want to send unstructured data, go ahead. That's the reality of a transport that can be used for any package we wish to send inside that transport. So if people say, oh, well, I hear Direct is e-mail, no. It is a transport mechanism based on the SMTP and the Secure Multipurpose Internet Mail Extension protocol –

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I knew the multipurpose part.

Jonathan Perlin – Hospital Corporation of America – CMO & President
... that is used for sending X12, NCPDP, C32, CCR, whatever you wish to send. Now, Doug, in some of the discussions you and I have had about the S&I framework you've mentioned that there's ongoing work in the modular specification to look at a SOAP mechanism that is separate from other specifications that Dixie's team has reviewed because, Wes, in all of our e-mails last evening that there are certainly SOAP approaches that have worked and Dixie has highlighted issues of certain complexity or scalability. Any comment you'd want to make on that modular work you're doing?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Sure. I think one of the things, as Dixie was going through her presentation, realize that over the course of this summer we've had a number of activities that have all been performing in parallel and so things like the challenge of the layering, a lot of the work that was done in the consolidation project was an attempt to smooth that out and create better implementation specifications that have lessened direction. There were issues around the C32 and the complexity there and the transitions of care project is something that, again, in parallel has been going on. I think the other one was this notion of trying to create more modular specifications. It's been a challenge because we have implementations of the specifications that have made particular implementation choices that have added to complexity in the tools that people use. We have implementation specifications that isn't so much modular as substitutable that it's hard to take one piece out and put it in another piece. You have to buy into the whole stack or not at all. Then we have this conversation about architecture.

So one of the things that we've tried to do in this modular specification project is to take a look at all those specifications, figure out what are the core elements, and can we get to the point where we've got a clear specification around transport that is somewhat substitutable, if you will, with some of the other parts of the specifications that we have in the stack. That's hard work. We've only just started that work. But again led by Avinash Shanbhag and the people that are participating, that's something where we're trying

to get that public input, understanding how we can tease this apart to what are the essential building blocks that then can be used to compare different approaches, whether it's SMTP, whether it's a SOAP, whether it's an HTTP, however it is, and then be able to say well, is it easier to implement but harder to integrate. Is it easier to integrate but harder to implement. There are some trade-offs there. So that's ongoing work. I don't think that we've completed that. I think in large part it has been so helpful to have the public conversations that have been happening with the power team to help guide the way in which we've looked at that as well.

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Just again it's so important that this is ongoing work exploring ways in which some of the issues that Dixie's team has raised can be addressed in the context of standards that are still evolving.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Let me say just one other thing to that. I think it's all part of what has been articulated in the ONC strategy this notion of a portfolio, we have things that have to go into that portfolio and part of the modular specification work is to help tease it apart so that we can figure out what are those fundamental building blocks, what are the things that need to be in our portfolio as we go forward, this notion of making sure that we've got the right tool for the right task and that we've got the right sort of articulation. It's not a one size fits all, but that in fact we want to make sure that we have the ability to start on that escalator and move people along to better opportunities for new operability.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great. Marc, you were next.

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer
Thank you. I have several things, but I want to start with one, which is I think we ought to do a process check here. My guess is, based on the e-mail traffic and discussions that have been happening around that this is going to take a considerable amount of time for discussion and to get to closure, and we might want to think about how we want to do that so that we don't force ourselves into a box and not get a complete discussion of this topic. Then I'd like to ask a couple of clarifying questions, if I could.

John Halamka – Harvard Medical School – Chief Information Officer
From a process standpoint I think what ONC is asking for is a set of recommendations that are our observations that there are many other processes, as Farzad has outlined, that will result in the creation of rule proposals with further ongoing refinements and discussion. Farzad, maybe you can comment about what is your expectation given it is September and you have certain deadlines, of how we today should be most helpful to you.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
I don't think we should try to force consensus today if there's not a very specific recommendation in terms of what should be in the NPRM. I think the power team's presentation does a good job of making observations and statements where they felt comfortable making them, but I think accurately reflecting a lot of the discussions that have been happening in the workgroup and, frankly, very much in the open, not for this e-mail traffic. All these issues have been discussed in the workgroup in the open, and I think you've done a good job of saying where we feel we can agree on these are the recommendations and the observations on a go forward basis. I think the one piece that I still feel would be helpful, and ultimately there's going to be a policy call that's going to be made, and that's okay. You've given us what you can give us. One piece that I still see a little bit, I wish we had actually more information, is there seems to be still some uncertainty about the facts, about the extent to which there are various aspects of, for example, Web services, so SAML approaches to information exchange are actually being used or not being used, whether it's within proprietary EHR systems or within information exchanges. I think the members of the committee are very knowledgeable, have in-depth knowledge of the field, but there still seems to be some discussion about that. So that may be some facts finding that we need to do further to really understand that.

The other point that I'm hearing discussed but maybe could be taken to the next step is Wes' comment about we're not really comparing apples to apples. On the Direct side we're just talking about transport and on the IHE stack we're talking about a literal stack and I'm sure that if we start building up that stack on the SMTP approach, to try to do all those same things there would be all sorts of problems too. But on the Direct side we're saying, look at, let's start somewhere and we understand the workflows piece hasn't yet been developed and so forth, but there's a reasonable confidence that those could be developed in turn. And I wonder if on the same side if we take a step back there isn't the equivalent SOAP SAML nugget of transport that we can isolate or whether that is, by necessity, brings along with it all the problems of the stack as it currently is. I don't know that we've had that fact finding yet about whether there's an equivalent true transport core on the SOAP side that could be bridged with XDR. I don't expect part of this process. I don't expect from you to achieve forced consensus today on a very specific recommendation, but I do find the discussion to be helpful in particular in highlighting not just perspectives but areas where there are gaps in knowledge.

John Halamka – Harvard Medical School – Chief Information Officer Just to reiterate my comments at the beginning, we obviously cannot recreate, nor should we attempt to recreate the entire work of the summer camp for which many individuals at the table were a part of. I think Farzad raises a great point, that there are facts that will inform the recommendation and our goal is to transmit with comments the recommendations of the work. The comment absolutely can include the need for further fact finding and clarification.

M
David?

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer
... my question, now that you've addressed that. The first one, Dixie, I think many of us would benefit, and I understand we can't recreate the discussion, but I think it's important as committee members if we're going to support a recommendation we need to understand the facts on which it was derived. I don't understand the patient query issue as you've described it, there are certainly many issues around it. But it would help me to understand that. And then the second thing, and this goes a little bit, Farzad, to your point as well, is I'm struggling a bit with, and this goes back to Wes' comment a bit, I do struggle with this apples and oranges sense, and there was a comment made about well, let's not boil the ocean, and I'm a big fan of boiling the ocean, and let's not worry about the unconscious patient in the emergency department. I'm absolutely okay with that. But I think it's important that people remember that that's not what it's about. In other words, the need to, for example, be able to draw data from a number of places is not primarily driven by those scenarios, but rather by the date today I need to do a quality measure. And the patient's data to do that quality measure doesn't live in one system and I'm suspicious it never will. Today on average we draw data from 27 different systems for each quality measure we compute for each of 5.6 million people in Indiana on a monthly basis. It doesn't come from one EHR, for example.

So those kinds of things are the use cases I think are the primary drivers for the need to be able to query, and yet I struggle, we've got the unevenness I feel in this analysis of we've got a set of use cases and criteria, and we've said, well, it's tough to meet this one and we haven't met it very well and then we've got this use case where, well, we don't know if we've met it very well or not, but maybe it's okay and we can bet on the ... for a very limited use case. And I'm struggling with that unevenness, at least as I understand the presentation and analysis. So those would be the two things I would start with.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
We wrestle with this a lot, Mark, in our debates. We were handed a basketful of fruit and asked to evaluate the fruit, but we really weren't asked to evaluate one fruit versus another, which was better for you or healthier or a wiser choice. And I think that the two core exchange models, I think you can risk some oversimplification, but there's a push model and a pull model, and the push model is carved out as directed exchange. It's understood simplified consent requirements. It satisfies the use case of moving data from point A to point B, and you know in advance that point A knows they need to move. The pull case is much, much harder. It's much more complicated technically. It's more complicated from a permissions and consent management issue. And we were given a push specification, Direct, and a pull

specification, Exchange, and we evaluated them under the same criteria. But they really are very different worlds. It is possible to go forward maybe with a push model because it's simpler, and to defer on a pull model until we've studied it better, or it would be possible to go forward on both of them. But I think they really are two separate questions. And, Farzad, to your "Is it good enough" question, really the question is, is a push model good enough. If we just did that, is that going to meet the needs for meaningful use? That to me is the debate that we really ought to have. And if the answer's no, that's not going to be sufficient, then I think we have more work to do to figure out what the right pull model is, because the majority of the concerns we raised were on the pull side in part, that's just what we zoned in on. It was the core of our mandate. But is push good enough, and if not then I think we have a push solution that is plausible to go forward with in Direct, do we need to also include a pull model. And if so, what do we include.

M
When we say meaningful use, I assume we're saying Meaningful Use Stage 3 and beyond, not just Meaningful Use Stage 1, which we've artificially, if you will, constrained based on where we thought we could go.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I'm just reacting to Farzad's we need to move, so whatever your definition of why we need to move is, is a push model adequate? Or do we also need a pull model, and if so which pull model? Are we comfortable with what we've got? Do we want to use the more constrained profile version that Wes mentioned, or do we in fact need to go back to the drawing board and rethink our whole approach to pull models a la PCAST, which is a pull model of a completely different color.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
David, I'd just like to say something about that, because I think, speaking of apples and oranges, I think that we really need a definition of what we expect out of a nationwide information exchange network versus what we expect from a national health system, because you talk about how, we've talked about how Exchange is different from Direct, they were developed for entirely different use cases, sets of new use cases, and I would add I wouldn't put PCAST out there as a third. PCAST brings in, you have Direct that's push, you have Exchange that's push/pull, you have PCAST which is push, pull and analyze, and we have to decide what's part of the network versus what are components of the health system. I would say that there are multiple pieces that are in meaningful use that are way beyond the network that are part of our health system, and I think as we addressed the network, we addressed the nationwide health information network, and what's ready for primetime for that exchange component. We did not address all the PCAST options, the ability to do analytics on metadata. We didn't look at any of that. That's the health system. Nor did we look at meaningful use. We looked at these specifications with respect to the network. I would propose that there be a definition of, besides services, standards and policies, what do we mean by network? Are you using the term "nationwide health information network" equivalent to the "national health system?"

M
Any comments that you would like to react to before we gather ....

M
It's a good point that through policy, through business practice one can layer on top of a number of different models of exchanging information and probably we're going to be heterogeneous. There is going to be heterogeneous ways in which information is exchanged. One can layer on top of those any number of services that provide the analytics or quality measurements through a variety of means. And I agree with Dixie, I think is what you're implying, that there is a need to focus on the transport and the simple how does data move aspects of the network as a core requirement for what we're responsible for, or you're responsible for in your power team, and not to try to put everything on top of the committee.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The network.

M
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think we need to define what we expect out of the NwHIN.

John Halamaka – Harvard Medical School – Chief Information Officer
To give you an example from Massachusetts, just in the way we've tried to think about the network versus the system, what we said is we know there are a lot of stakeholders, there's your providers and they need to communicate, and then we have your payers and there needs to be transactions of them, and there are patients, they need to get their data, and there are registries by which we are going to measure quality, and there's public health that needs to receive a variety of data. So we looked at all that and said well, what are the transactions the network can support based on the policy and technology we have today in 2011. We said, boy, we're going to need a pull network, no question, in the future to do all kinds of great things, but for the moment the State of Massachusetts said you know if we could push summaries to public health, and summaries to registries for quality, and summaries between PCP and specialists it would make the system a whole lot better. So that's the first goal of the network. It's the first of many, many goals but we felt like the standards in the policies exist in a mature enough fashion today to move that forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think for our work, just to simplify the expectations, I'm looking at the consensus around the point, at least the body language is pretty positive, that the system has infinite use cases. I think our comment ... are best directed to the ... specifications that allow transport on network not system ... . I think the other is just beyond our scope and will allow us to be more focused. That's not to say that we're insensitive to or devoid of reflection on implications, ... we get to the things that we'd want for public and personal health, but let's constrain and we'll capture that as such in our letters. It's a really good point.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
To include not just the transport but also the structured and unstructured data of course, but allow multiple use cases.

M
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

M
Cris?

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer
Can I get my questions answered first, the clarification questions?

M
What was the scalability of the patient query?

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer

No, the ... specifically, elaborate on the issue about the patient query and what the policy issues are because I think that's relevant to what we were just talking about. And we talked around but I don't think we addressed the issue of the unevenness, if you will, in this, that we're apples and oranges and how do we attack that, because I haven't heard ... either of those.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The second question I thought I replied to but we didn't compare. We didn't make any effort to compare. We attempted to independently evaluate the specifications. That's what we were asked to do. We didn't decide to do that that's what we were asked to do so it's not a matter of—I mean you know I can evaluate an apple and an orange independently. Tim, in our Power Team you did a really good job of articulating the patient query issues. Would you mind repeating?

M
I don't do …

Tim Cromwell – VHA – Director of Standards & Interoperability
In this committee to all of the discussion mark—but basically the statement about being a showstopper, patient discovery is a showstopper is relevant in the notion that right now VA is interoperable with 11 health information exchanges, and each of those what we need to make sure is that we have securely and correctly identified the right veteran, and to go through that process 11 times with 11 unique identifiers, potentially. Not every veteran has gone through the country and gone to all 11 of these HIEs but we do have veterans who are seen in multiple VA Medical Centers throughout the county, and so our requirement is to securely identify them and to make sure that if they are in multiple HIEs that we've got the same patient every time, and the process of doing that patient discovery is not scalable when next year there are 50 members of the Nationwide Health Information Network. That's basically …

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer

The … though is how does Direct fix that or address that and the answer is it doesn't. It simply says, "Mr. Doctor you get it right or Ms. Nurse you get it right." Because there is a patient identity matching requirement no matter how you do the exchange. It's absolutely necessary and what you're doing is say, "It is challenging to operationalize when you decide to create a policy in a process that sets a certain expectation for how that gets done and what happens." So using Direct for example—I just want to make sure I understand, Tim—So if I ask you to send me that Veteran's record with Direct would it be any easier or less onerous or less of a showstopper?

Tim Cromwell – VHA – Director of Standards & Interoperability
I'm not going to comment on that because our patient discovery specification was around the exchange specifications.

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer

But the point was it's a policy issue. It's not a technology issue it's a policy issue and process in that if you chose when you use Direct to ignore how that happens and assume that somebody does it right that's okay. I mean but that's what you're getting at fundamentally.

Tim Cromwell – VHA – Director of Standards & Interoperability
Yes, I mean because this comes to the question of scalability and what we were calling administrative scalability so by design in the direct discussions when we were kind of trying to decide what it was we had a debate, do we require an MPI that spans both systems that are participating in Direct, and within a few nanoseconds we concluded no because that would make it an unusable protocol, and the vast majority of provider care today is delivered by messages that arrive without a structured identifier and the office maps it to the local patient registry and care gets delivered. They do it today with fax machines and telephone calls and it works very scalable, so Direct is an attempt to just make that process better. It doesn't solve for the case of which of the 50 gateways has my veteran been seen at so that I can deliver care. That's a completely different problem that, of course, requires better mastery of patient identity. That's not solved for yet. That's what we discovered. The scalability of the solution for nationwide discovery of patient identity is not addressed by the current exchange specification. Direct just skips it and

says, “On a one-to-one exchange with PUSH you don’t need it.” We have a scalable solution today. It does make mistakes but it works today, so it’s solving a simpler problem and it’s not trying to solve the harder problem. The question is, is that simpler problem sufficient to move forward with or do we need to step back and readdress the harder problem with a better approach to patient identity discovery and I personally think we should address the harder problem but—

John Halamka – Harvard Medical School – Chief Information Officer

The answer to your question is both, which is to say Direct is going to, as a simple transport mechanism between two points, address several of the requirements, let’s say in Stage II, of how do I get that piece of data to the public health entity or how do I get that data from PCP to specialists? But it doesn’t address many other things that may be goals of the health system, and so I think all we’re trying to do in Dixie’s initial analysis and what she was charged is here’s what we got, as it stands on its own not comparing one to another, how do these things fulfill their intended purpose? I think what we’ve heard is there are some things that need some additional policies and some things that may need to look at, in other forums, which there’ll be many, additional opportunities to solve some of these other problems.

M
I just want to make clear we are committed to solving both problems. We need to solve for both problems. The question, as John said, is what are we ready to solve through rule making, when.

John Halamka – Harvard Medical School – Chief Information Officer
I know we have many other comments but let me just try to get in Chris Ross and then Jamie and then we’ll go back to Mark.

Cris Ross – LabHub – CIO
Thanks, John. So I think the email communication about this even before the report was presented suggests that this report presents kind of a blind man and the elephant problem that seven people looking at this report will come to seven different conclusions about what it’s saying, and I think that’s somewhat inevitable but I think some context is really important. There are some reasons why that happen. Number one, obviously we’ve pointed out the transport is not at the level of things like vocabulary, for example. They’re not a codification point. This is still a pioneering space in almost every respect. The second is that our exercise, in some ways, was artificially constrained. To use David’s metaphor, looking at this basket of fruit we weren’t asked to come up with what’s a balanced diet. We were asked to assess an apple and an orange, hand-to-hand exchange in Direct, and I think during that process Dixie and the rest of the group have tried to, where appropriate, broaden that slightly to include let’s look at some other patterns that are working in health care from a practical perspective, and that’s been inserted into this analysis. I think the third thing is I don’t think that we were asked specifically to come up with a set of recommendations that would be exclusively limited to meaningful use Stage II requirements but this was intended to support a broader range of other things that we might do to advance the industry and I see Dixie nodding. I think that’s something that was really important that she kept reminding us about. And then the last is I think there may have been some expectation that the purpose of this may have, in fact, been to perform a bake off, Direct versus Exchange, which it was, again, not, but I think there are some thoughts out there.

So it seems to me given the kinds of conversations we have it feels like we are now at the point where we’ve got an immature set of specs and an industry that has not put them in use, and it feels like we have three ways to move this ball forward. One of which would be to force fit by more analysis and more precision this is what the spec is going to be come hell or high water. Let’s just pick something even if it’s imperfect. Number two, we could constrain the problem set and we’ve talked here about why don’t we just focus on PUSH and that might be reasonable but I think there’s a third way that really was also underlying a lot of our conversations, which was to put the specifications in use to force rapid iteration because I think the underlying idea of meaningful use was use in a meaningful way not go by boxes and we’ll pay for them. It is prove to us that you are using this technology and I think we should remind ourselves this is probably the best, one of the exemplar places of where use is really important to advance this industry. And Doug said can we get to a clear specification for transport, which a lot of people are asking. I think

the right question is can we have a clear process for iterating towards a specification for transport because clearly the disconnect between vocabulary and package and content and all the rest from transport is crippling meaningful use too far as Ed's comments and John's at the beginning.

It feels to me as though if there is anyway within the statue and the regulatory environment that ONC can see fit that the Meaningful Use II Spec and III Spec around transport might focus on behavior and outcome as opposed to implementation of a specific plug, which imperfectly might get us some place, I think would be incredibly useful, and let the marketplace in this particular instance iterate through solutions. God help the person that has to write the regulation. That's all I can say.

John Halamka – Harvard Medical School – Chief Information Officer So, Cris, let me just comment. I did have a very funny experience. It was played out in my blog in the … blog where we had interpreted the regulations—wonderful regulations, beautifully written—as you say, well, just get it from point A to point B, and what we learned in the FAQs was if you do it via FTP, HGDP, FMTP, that was okay but if you did it via DVD or thumb drive that was not, and so one would hope you could constrain this in some fashion.

Cris Ross – LabHub – CIO
Of course. I mean there are clearly ways we can constrain it and still leave room for iteration but it just feels like this is a classic problem we've talked about a bunch of times of do we try to move the industry more quickly than the underlying maturity of the specs? That's the fundamental thing that Dixie brought to this analysis. Her answer was no so the question is, is there something that we can do to help foster maturity and I think ONC really does have some leverage here. It's a very, very hard task. It's harder than trying to say let's do some bake-offs where we can and make some tough choices. This one really has to be about fostering an industry as opposed to making selections it seems to me.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, I think you had a comment.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I just wanted to sort of echo one of the points that Cris had made earlier, and thank you so much for those comments. This is the beginning of a conversation. I don't want us to lose sight of we asked Dixie and her team to come up with a series of ways of analyzing and making explicit that ways in which we evaluation the kinds of specifications that are out there, and so, as you said, it wasn't intended to be a bake-off. It was really intended to sort of figure out how do we take a look at this broad— all the different factors that come into the complex decision making that has to go forward with regard to recommending how we're going to achieve interoperability, and I think just talking a look at the thoughtfulness that the committee—the process that they went through to sort of thoughtfully take a look at maturity, declining standards, emerging standards, those are all things that a year ago we didn't have a vocabulary to talk about and now we do, and I think that's a tremendous step forward in our ability to be more nuanced and more thoughtful about how we do things. I want to make sure that we don't lose sight of that as we think about things. One of the things that we really wanted to get out of this analysis was that vocabulary about how we talk about these things, and I think that we've just started the process. We need to apply this to larger and different kinds of context, and we will probably over the course of months in this committee continue to refine that but Dixie and her team have given us a vocabulary in which we can talk about things so that if we have to compare apples to oranges at least we have a way of doing that whereas before I don't think we did.

John Halamka – Harvard Medical School – Chief Information Officer
Farzad has a comment as well.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
It's always refreshing to step back and think about the outcomes based approach, right, and let the outcomes be what we push, and then let people build to that. My one question for you in terms of your third way approach is does it matter if most of the exchanges are local or national? Because if most of the exchanges that people are going to be pushing themselves to work together to get exchange to happen if

most of them are local then there is more of a concern on my part that those local urgency to figure out ways to exchange information will lead to national progress as opposed to one-off proprietary patch and other non-scalable approaches.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So I guess to offer an opinion I'm not sure that national scale introduces a new dimension of complexity more than say large complicated institution and small practice. Those two together I think surface—

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
I'm not talking about the complexity issue as I am about the likelihood that it will drive towards national standards.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Got it, I get your point. I'm not sure we know. I think the more likely thing is—I think we heard from some folks. I'll use one example, which is you can push perfectly well using Exchange, which is true and you can push perfectly well using Direct and you can push perfectly well using a set of rest styled Web service APIs. Again, I think ONC has a really difficult challenge to it but if the specification was supported in a way that you need to be able to move in a secure fashion data in this kind of package from this place to this place may be the core of what you do. The challenge, of course, is then how do you get the … piece in place so that when I send you'll receive and those kinds of challenges. I think we could continue to do a lot more specification and work around this. There are a lot of questions about will all this be done peer-to-peer or will there be orchestrating entities that provide the step up and step down between entities? I think the market has not shaken itself out. Many of us are deeply engaged in that market right now trying to figure it out and it seems like it changes on a weekly basis.

John Halamka – Harvard Medical School – Chief Information Officer
I think Jamie is the one person who hasn't had a word yet.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Wes was next and then I—

John Halamka – Harvard Medical School – Chief Information Officer
Okay because you haven't had a word yet so you got—and these other guys, of course, we'll go back to.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Thanks. So I want to just get back and actually focus on the report itself for a minute, a couple aspects of it. I think that my organization has been in the production status using Exchange specs for over two years now, and I just want to note that I think Dixie said that the Exchange was mostly a Federal thing but in fact there are 19 production participants today and I think only three or maybe four of them are Federal Agencies so clearly a large majority of the production participants representing thousands of providers and millions of patients are non-federal, and correct me if I'm wrong but I don't think you've received testimony or heard of the experience from any of those.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes we did from one, yours in fact. We received inputs from yours.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay but there was no—I mean I really have to disagree with that. Certainly there were informal conversations but—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right, it was not formal testimony. We received—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So there was really no opportunity to interact in the same way with any of the non-federal participants, and I have to say the same thing about the Coordinating Committee. So the Coordinating Committee,

which governs the Exchange, was not consulted. I understand that you go input from some organizations that have membership on the Coordinating Committee but I believe I've attended every meeting of the Coordinating Committee and this was not discussed.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We did not hear testimony from the Coordinating Committee but … himself worked closely with the Coordinating Committee at the outset.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
But I think that certainly the experience of my organization is not reflected in your report and I think that's likely to be true of the other non-federal participants and if we think about in particular some of your comments about the complexity of implementation while I think you talked to the DoD and they had complexity of implementation but they have the most complex systems environment probably on the planet, and so I think that there's a confusion frankly about the complexity of the specifications versus the complexity of implementing them in a complex environment in the DoD and that's, I think, a different issue that was not experienced by the non-federal participants who you didn't hear from. So I think unfortunately the input that you got, frankly, from whatever the process was, and I know you were under tremendous time pressure, but I think it was so skewed that it really is not representative of the experience of the majority of the participants in the exchange, and so I think it really calls into question just that one recommendation number three.

John Halamka – Harvard Medical School – Chief Information Officer
Now, Chris, you haven't had a chance to speak so—

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I'll build very briefly on that and that is in the Southeastern Minnesota beacon where we are actually implementing NwHIN Exchange on a peer-to-peer basis we have found the implementation to be—well, trivial is too strong a term—but not a great barrier mostly because we are using an appliance model provided by Mirth actually, which was essentially NwHIN in a box. Now, it's true we have to interface from our organizations to that box but the horror of implementing Exchange is not large in our experience.

John Halamka – Harvard Medical School – Chief Information Officer
So let us go back to the three cards that are up, and then come to a conclusion for today. So, I think, who had their card up first was, I think, Martin, you actually put your card up …

Martin Harris – Cleveland Clinic – Chief Information Officer
I guess the couple of closing points; one is that I think my fundamental worry is that we fragment the energy in the market. There's only so much energy for people to implement stuff, and as we bounce around in different directions and there's uncertainty, people do nothing in the face of uncertainty, and … back to the CCR or CCD dialog in its many incarnations and what that does to implementation and progress, so I think that's one of my fundamental anxieties here, and in particular given the specific limitations of a push strategy and where that gets us and it builds worry. Is it a dead-end? Is ePrescribing isolated applications a dead-end or will people get to full born ePrescribing? It's that same anxiety I think. Translating that into a practical issue I guess the fundamental, and maybe I was overreacting to this but I think one of my fundamental challenges is as you look at the conclusions and recommendation 0.5 and it says, "We would support and encourage broader adoption use of the direct specification" and in Exchange it says, "May not be appropriate for all health care organizations. It may not scale nationwide deployment." Stop. The implication of somebody reading that could be directive the thing to move forward with Exchange, eh-huh not so much, and I don't see the evidence in the report or in the discussion that would support that, frankly. They're all rated in the same quadrants especially given the very fuzzy ratings. I would, in fact, argue in some ways that the NwHIN specifications are sort of further down the road because they have been through the fire a little bit more and that's why they're uglier and more complex because they're dealing with these practical pragmatic issues, and so is the intent of this report to have a differential perspective on these two that were analyzed separately but with same criteria?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

No it was not the intent and it's actually—I'm sorry it was miscommunicated but there is a whole—item four is all about what we recommend further work is done on the Exchange specifications. That's everything that's in number four. It doesn't say, "Stop working on them or through them away." It says, "Here are your opportunities for simplification." Maybe we weren't clear but what we were trying to say is, "We suggest you explore these opportunities for simplification."

Martin Harris – Cleveland Clinic – Chief Information Officer
That is different than saying we support and encourage broader deployment. If we intended that I don't think we said it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, I think that we weren't to the point where we would say, "We think simplification is needed before there is universal deployment."

Martin Harris – Cleveland Clinic – Chief Information Officer
So if that's the case then what is it—I guess a) on what basis because these are all in the same quadrants, right, in terms of—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We weren't comparing them.

Martin Harris – Cleveland Clinic – Chief Information Officer
Well, I understand you're not comparing them but they're all in the same quadrant so what's different about them that leads you to make a stronger recommendation in one case, and second, even there this challenge when you talk about nationwide deployment of certificate management I think it's still an unsolved problem, so what is it that makes you so confident in the recommendation that Direct—that we support and encourage and in the other we say, "Explore and learn"?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It's primarily if you go back to the grids and you look at the complexity scores and it's—

Martin Harris – Cleveland Clinic – Chief Information Officer
They're in the same place. Show me where they're different.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
In the direct specifications we gave moderate complexity and the Exchange as whole we gave moderate to high, and that was really the primary reason why we didn't go that additional step but we certainly do support further work on simplification. I'm sure ONC and … certainly knows that. He worked closely with us he knows that's what we were saying.

M
And so I want to make sure we emphasize this point. This isn't a bake-off. This wasn't saying one is better than the other. It was—

Marc Overhage – Siemens Corporation – Chief Medical Informatics Officer

But we do.

M
So the intent was to look at them separately and so say, "Based on objective criteria what should we do next?" And I think what Dixie's report concludes is that on the Exchange standards there are some improvements that we should queue up as part of the SNI framework that are actually already being worked on and those will make it a better set of standards for its intended purpose and that there are aspects of Direct that are appealing and that SMTP and … is widely understood, DNS is widely understood. It seems to make to low-risk for further broad implementation.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology
Let me see if I can—this is my understanding, Marc. I get a sense of your passion and I appreciate it. The reason why, as you helped frame, the reason why it's an apples to oranges is because they're trying to meet two different use cases, the push versus the pull, and the pull, I think by necessity, has more parts to it. You're trying to do more things in a pull. It's got more pieces, it's more parts to the stack. Now, maybe there don't need to be so many parts to the stack but the way it's currently formulated each of those pieces may be in similar quadrants but there's just more of those pieces and some of those pieces are in different quadrants so taken as a whole stack— and, again, this is where it gets into the apples versus oranges—taken as a whole that whole stack and what we're trying to do with pull is more complex and has more, not only technology and status but also policy challenges. The question that I'm looking for guidance on here is if we assume that yes we do need to have a portfolio of approaches I don't think a single approach to this is going to solve it. I don't think a pulled approach on its own is going to solve all the things we do need to have like you said ePrescribing. I don't know that there is a pull scenario where you need to do ePrescribing in a pull way where the pharmacist says, "I'm looking for any prescription …" It doesn't fit the use case so I think we do need a portfolio of approaches and the question that I'm looking here for guidance from the committee broadly is, is there a whole apple or part of an apple that we could move forward on and is there a whole orange or part of an orange that we can move forward on each of those different use cases respectively, and I don't think we should get into our coats of armor and do the battle between apples are better oranges are better. I don't think that's productive.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And I'll segue on that even though there are a number of things I would love to talk about but in hopes of keeping it focused I think a good fruit salad has a couple of slices of apples and maybe a couple of slices of segments of orange, and it's a mistake to say it's either or, push or pull. It may well be that it's pull locally and push on a larger scale or the model that I actually prefer personally, it's pull locally and push to the consumer and then the consumer scales nationally by having a PHR if they think they have enough information that warrants to be shared across regions of care. There are lots of combinations of these things that may make sense and it's over simplifying to say it's one or the other. It's going to be some mix of both but perhaps at different scales.

M
Very good.

John Halamka – Harvard Medical School – Chief Information Officer
Because I think the intent of what we're trying to accomplish today, and this is, Mark, to your point about process, is we are just trying to give ONC some guidance of some of the best thinking of everybody on that team and in this room as to where we currently are, and hopefully that guidance will enable you to create some options, some building blocks that will allow, as you guys have said, some market testing, and I worry if you say nothing we will run into the problem I have today and that is I just can't get data flowing because the end points can't agree on what to do. Massachusetts is talking about creating a public utility that is a pipe and we're just going to pick something and it happens to be Direct with an NDR onramp and off-ramp. That's just what we're going to pick for now. There could be other options but that seems like a reasonable choice.

Well, Wes, I think we want to give you—oh, and, Jim, do you have your current up—we just want to get these two final comments in and hopefully just talk about next steps because I know there is a presentation lunch, so yes, Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So I'll start off by talking about fruit salad being a … as opposed to being a smoothie but what I hear is that there is significant observable use of some group of specifications that strongly resembles the NHIN trial implementation specifications. So we got the Beacon communities. We've got these 12 HIEs that Kaiser interacts with and so forth. What I don't know—I suspect—I can assume but I don't know is the degree of which they really implemented XACML to the level that you would have to talk about implementing XACML if you put this out as a national standard. Whether it's being used for controlled use

cases like only sending the data overnight because we can't find a way to make it happen during the day, and I don't know maybe it's different in Beacon, maybe it's not, I don't know, but I certainly think that ONC has a decision, we're advising them on what is feasible with respect to pulling data, and that ONC's decisions come in multiyear groups as regulations are issued and ONC will, as everyone does in that situation, make due with what's available and usable in the timeframe that they have to write a regulation for. It is clear to me that we have not fully explored the possibility that there is something resembling pull. There is a pull option out there that we don't know for sure about. I'm not sure whether it's limited to the case of the patient says where they've been seen and you go ask them or whether it's really a nationwide search. When I was working on the … standards we never contemplated the nationwide search. It was too creepy, to close to the third rail about patient identification to talk about. I think that if we have room before ONC cuts and runs we ought to look at the information from the Beacon grant. We ought to look at the 12 other implementations. Where they're using in appliance, what are the simplifications that went into the appliance? Did they cutout whole levels of the protocol and things like that? But our goal should be to find a way to do pull in the next round of regulations rather than find a reason not to.

The other thing I wanted to comment on was this … philosophy that came up and went by pretty quickly about the difference between the certification requirement and a meaningful use standard. So right now in labs we have a certification requirement for a certain format and we have a meaningful use requirement to get structured data. We don't have a meaningful use requirement to get at using the standard that you have to be certified for. It's really good that we don't because most of the EHRs that have been getting labs for some time would have to go back and redo it, and what we don't want to do is write regulations that say, "You have to go back and re-plow the same field just in order to get your meaningful use money." But on a broader basis it allows us as a committee, ONC as the policy making organization, to really live up to the idea that standards aren't created they're adopted. That we can encourage their adoption through certification, and if we find the adoption then maybe we can mandate more adoption but rather than just set meaningful use criteria that are standards based set meaningful use requirements that are interoperability based.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Wes, I thought you were going somewhere else, which is to point out that the only tool that we have, even on regulation, is not electronic health record certification, and there may be requirements around intermediaries and governance of intermediaries for which the pull, for example, requirements may fit more into the existing implementations of the Exchange stack and the Pull use case where it may not be an individual doctor's electronic health record that's been stalled in their office that responds to a pull query but it may be their network. It may be Quality Health First that is the one that needs to respond to the request. So I just want to also put on the table that we don't only have one hammer. We have at least two hammers and probably more, and to say that we have to think about—we're talking here about meaningful use and certification for electronic health records but there's also the issues around conditions of interoperability and trust for intermediaries that's going to become, again, as part of the governance rules and other potential leaders as well.

John Halamka – Harvard Medical School – Chief Information Officer
So, Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
So this is Jim, quickly, Dixie, thank you, you and your team. This is spectacular work and an incredibly well presented report, thank you. I want to reflect on it as a communication tool and reiterate to some extent what's already been said, but if you read three, four, and five it sounds like there is field evidence that three is overstated. It is clear that four and five read differently in terms of the warmth of their embrace of the two things, and I know this wasn't intended as a bake off and that was no part of what you tried to do and that's totally appropriate I think, but this does—for the people out there trying to read the tea leaves and figure out where things are going I think it could create not quite the message that we're after.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

That's clear, thank you.

John Halamka – Harvard Medical School – Chief Information Officer
So in the interest of bringing this discussion to closure, Jon Perlin has written a couple of sentences for—your sense is that they capture what we have tried to do this morning.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, John, thank you, and thanks to everyone for a very robust discussion. It's really interesting to me that in this conversation what I really take away is, first, an eloquent explicit framework in which to evaluate. Clearly there are some … aspects but the consideration that was given was fundamentally explicit. You can agree or disagree with the framework but there it is and that is absolutely terrific. Second, there are a set of building blocks, and, Wes, I haven't been thinking of a smoothie or David a fruit salad, but really a fruit basket and a basket that contains elements that are usable today but importantly a basket that doesn't constrain entities that are already doing advanced work and that's another fundamentally important piece. Third, there's clearly the need for data and I think we have to commend to the Office of the National Coordinator the requirement to get some of the data from those implementations across the entirety to be able to form subsequent decisions, and thus it's really in the spirit of this conversation as well as really the compelling need to be able to support ONC and their fundamental charge that we come to consensus that we transmit with comment the evaluations framework and communication of this Summer Camp activity. So I want to be very clear, our role is not determination. There are many policy elements that have been raised. What we put forward is this consideration, the thoughtfulness of it, and contextualize with the comments of discussion that requires further work and I'd actually love to see that work come back here. Is that something that's agreeable to everybody? Great. Well, I thank you and Dixie and team just extraordinary work. I think …

John Halamka – Harvard Medical School – Chief Information Officer
I was going to say, Doug, we do have some time constraints but wondered if we could slip in the work that Jaime was going to present, and then it may very well be that the S&I framework activity in the afternoon won't take the full hour and a half because we've already touched on many of the topics already so maybe we could move the vocabulary stuff to after lunch.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I think maybe if we have a short lunch and try to convene back here very quickly we can do that, and then I'll just try to talk really fast.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Anyway, so we want to go ahead and move forward with the ePrescribing of discharge meds and then take a quick lunch, and then we can come back and work fast.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. I will try to be fast and get us back on track to some degree at least. So just to reflect that back we're revisiting an issue that was sent back to the Power Team following our report in the July meeting. So the charge for this Power Team was to recommend standards for ePrescribing for discharge medications, which has two primary scenarios. One is where the medication order is filled by retail pharmacy and the other is basically the take home meds where the order is filled by a hospital inpatient or outpatient pharmacy.

So back in July our previous recommendations were to align essentially with the Medicare Part D standards for ePrescribing using NCPDP script for the retail pharmacy scenario and allowing the use of HL7 for the hospital pharmacy scenario. So what we were sent back to do was to be more specific on the HL7 messaging so that it would be able to achieve the level of specificity required to be included in certification because the Part D language is just very vague, but in fact we worked with NIST and Ken Gebhart in particular. Want to thank him for helping us to walk through the Part D regulation text in order to interpret and to understand how NIST would interpret it in order to create certification test scripts based on that, and what that analysis came back with was that any valid HL7 Version 2 prescription message defined as Version 2.2 through 2.5.1 would meet the requirements of Medicare Part D ePrescribing for

the use of HL7 in the hospital pharmacy scenario. And so we then looked at well what are the required elements? How is an HL7 Version 2 prescription message defined, and so the testing for the segments that are required to define a valid prescription message turns out are identical in all of the versions 2.1 through 2.5.1 so certification is not, frankly, that much of a technical challenge.

Now, we also considered what would be the impact if we wanted to recommend a single standard, say, for example, 2.5.1? Now, it's probably true and one of our considerations was that if we were to pick a single version like 2.5.1 that might make future hospital systems integration easier but at the same time a single version like 2.5.1 would put meaningful use in EHR certification out of sync with Part D regulations, and it would also, frankly, raise a big new barrier for meaningful use for hospitals that are already compliant with the ePrescribing under Part D.

So another aspect of the analysis that we did was—and by the way, you're not supposed to read this eye chart. This is just to demonstrate that we did the work. Although if you want to read it that's great to—it shows that we sought to ensure comparability of the script messages versus the HL7 messages that would be used in certification. So in other words, that there was a similar level of rigor and content and that there wasn't a big material discrepancy in terms of the different messages that are allowed under the Part D Reg. Having completed that then, we're recommending amending the previously approved ePrescribing standards back from the July meeting to incorporate HL7 Version 2.2 through 2.5.1 and we can enumerate, I think it's, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.5.1. I think those are all the version, and so instead of adopting only the exact language in Part D, which doesn't have quite that level of specificity, if the committee agrees with this then we'll modify the draft transmittal letter that you all reviewed two months ago and we'll add this specificity.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jaime and I had an important email exchange on this topic that he's reviewed, which is there are so many of the other standards we could—one implementation guide, one version, and I think what you've heard from his comments today is he recognized Medicare Part D has actually a set of requirements that make it okay not having just one, and I think other statements have been made about what is being used today and how putting in one implementation guide can actually do some harm to what already exists. So question for the Committee is based on what you have heard as alignment with what is necessary to support the workflow, what are the standards that exist today? What is Medicare Part D? Does this seem like a reasonably good enough recommendation? Wes, you have a comment?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Oh, that was left up from before. I'm sorry.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I was assuming you had a comment.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I forgot to reset the spring. Just were there somewhere being documents that say, here's what you need to do to qualify? It can be anyone of these end versions— I don't know how many versions there are between 2.2 and 2.5.1—as long as it has these particular fields filled out.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, so long as the—let me go back. So basically any HL7 Version 2.2 through 2.5.1 message that contains these segments would be deemed a valid prescription message to meet the requirements of the Part D regulation.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And, Wes, one of the things that Jamie and I talked about was the validation tool because one of the things I like about—oh, it's a 2.5.1, here is the implementation guide. It has no optionality. It's very easy to validate. Well, he pointed out to me that given this is the constraints to validate it's quite trivial to have a validator which passes an HL7 message and notes that those segments are pressed.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And I'll just add one other thing and that is that also in our analysis that we did with Ken from NIST we took a small number of specific prescriptions that were written by a pharmacist and tested them to how would the data fields actually be filled out and how would it work just to make sure that it was workable and practical.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm still not clear on where the document is that says you can have any one of these versions as long as these particular data items within these segments are filled out.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So the document would be the transmittal letter from the Committee I believe because the enumeration of those versions is not spelled out in Part D. That's the interpretation of Part D for the—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
The transmittal letter from us?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
From us.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So it's a recommendation, it would end up being in a regulation—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, I think it would end up being in the EHR certification, in the standards for certification, and then just exactly the way you laid out previously just because you're certified to that doesn't mean—I mean I don't know what that means, frankly, in terms of the meaningful use measure for ePrescribing, and I think overall the issue that we had with this and the reason why we had to go back, actually based on your request, to do this work to add the specificity is that to measure ePrescribing of discharge medications you have to account for both of those scenarios so if you're going to measure ePrescribing for discharge you have to account for the retail pharmacy scenario as well as the hospital pharmacy scenario.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So we already have a problem that then there's self-developers trying to implement, have to sort through a stack of documents to understand what they have to do. All I'm concerned about is that we've just added another level of complexity. I suppose if it's the NIST certification scripts and requirements that's the ruling document then that's okay.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And I think that's where it would come out under this recommendation.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any other comments? Yes?

Kevin Hutchinson – Prematics, Inc. – CEO
The only thing I would add is, and 100% agreement with this, is on the Medicare Part D is the fact that they could amend that based upon backward compatibility of future versions of this particular standard so right now we're at 2.5.1 but they could very easily determine that 2.6, 2.7 is backward compatible and that's going to expand the ability to use that particular standard. I'm not a big fan of versions getting implemented other than for specificity but in this case that's the way it is. It's a Federal law so it's not like you can change that at this point.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Sounds like a friendly amendment. Okay, very good. Well, any objections of us moving forward to the mission—

M
Inaudible

Jonathan Perlin – Hospital Corporation of America – CMO & President
Oh, sorry? Your card was at an angle so I couldn't see it.

Steve Posnack – ONC – Policy Analyst
This is Steve Posnack. I don't know if I'll steal some thunder from Judy and Liz, so we had a bit of a discussion because this is obviously one of the meaningful use stage II recommendations from the Policy Committee, and we are charged with developing—I'll say we, we're all we—as the implementation workgroup coming up with certification criteria to address these new requirements, and one of the things that this raised, which we haven't delved into in any level of detail from a policy discussion standpoint, is the internal versus external question, and it's a question whether for certification one would certify that you can always generate the electronic prescription and for internal you have to specify that it be done according to a particular standard for within an organizations communications and always require that NCPDP script is used for external transmission. That's I think a question to the committee because the point that Wes, I think, made, you make them go back and get certified to reconfigure a system just to meet any of these HL7 versions. If we're convinced that all of these HL7 versions would work and all hospitals use those, that range of versions, that could be a discussion but, again, it's a question just regardless do you go and specify the standards used within the organization?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Again, it was our intent as part of our charge to align these standards with the Part D regulation, which allows all of these versions of prescription messaging so it's true. I mean I think Kevin's point is well taken that Part D could expand and so there would need to be a rethinking but, again, if you're going to have standards that are then used to support the meaningful use measure of ePrescribing of discharge medications then this is how to align that with Part D.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Judy?

Judy Murphy – Aurora Health Care – Vice President of Applications
This is Judy Murphy. Just to further elaborate, so one of the questions was how do we define internal versus external? You had one way of defining it when you were going through your presentation. We've also used the term internal/external so that's kind of a little bit—I think that's got to be … but probably the more important point is as we get into thinking about allowing this there's a lot of vendors who have ePrescribing software who have never thought about using HL7 so is this a gee, you can or is this a gee, you have to. Because in some cases from within the hospital even if it's going internally they would choose not to use HL7 and use the existing NCPDP standards just because that's how the software works. If, now, there's an organization that wants HL7 are we then requiring that the vendors have to go back and provide that standard as well? So it becomes kind of when you're certifying is it a one or the other or a both, again?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So just, again, to the point of aligning this with Part D, I think that for Part D prescribers the use of anything other than HL7 or NCPDP Script does not comply with the regulation, I think, pretty clearly.

Judy Murphy – Aurora Health Care – Vice President of Applications
Well, let me ask the question more clearly. So if you were certifying a vendor would you require them to do both or just one?

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

Well, it would depend on which of those two scenarios I needed to use. If I were only sending all of the discharge prescriptions to a retail pharmacy then I would only use Script but if I had both scenarios I would require both.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
This is Liz Johnson. So if the region pharmacy is inside of your organizational boundary you require both?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That's the answer then. I mean—

M
You're a vendor you're not a user.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Well, that's why we're asking. That's why this is on our list of questions.

M
... the physicians will have to do both, right?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That's already …—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, I think, again, it depends on what capability their product has. If the capability—

M
… category for regional only or internal only. We only have a certification category for ePrescribing so the answer is they'll have to do both.

Judy Murphy – Aurora Health Care – Vice President of Applications
If that's true. As … described that …

M
Every time we say or it means and. I mean just to be clear.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
… compliance is situational depending on whether—under the Part D regulation it's situational. When it goes outside the organization, as ambiguous as that is defined, the NCPDP Script needs to be used.

M
And you certify again to—you're not certifying them in … you're certifying them for all the places they might be used so that means "and". That means you have to be able to do both, right? I mean I'm not against it I'm just—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think in most cases that's true. I can imagine that if it would be possible for a vendor to say that, "This product can only be used to send prescriptions to a retail pharmacy," and then they would only pick one.

M
But how are you going to give the ATCBs or whatever they're going to be called by then the discretion to—

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, because the certification does usually have capability check boxes like with quality you didn't have to certify to do 44 you had to just pick these three. I would imagine if you had—let's just pick a piece of software, if Dr. First—It is used for ambulatory ePrescribing to retail pharmacies. You wouldn't ask Dr. First to be HL7 complaint. I wouldn't think.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
This is Liz Johnson again. I think the quadrum we ran into in the certification group, and we did have many discussions around this issue, was organizational boundary so I want to be real clear here I believe the is "and" now. I believe the word as we are describing it for approval is you would have to do both, and the organizational boundary if it happens to include a retail pharmacy you would need to be able to do both, and I just want Jamie to confirm because we did go—there was a strong contingent that had feelings about we have excluded organizational boundary as not being subject to these recommendations in the past. We are now coming inside the organizational boundary for a specific instance so we need to be clear about what we're saying.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that's right and I think generally you're all right, it is an "and" although—

John Halamka – Harvard Medical School – Chief Information Officer
So … comments. I think, Jim Walker did you have a comment?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Quick question, in the slide that has the various fields is there a cancel field in HL7 2.5.1 or any of the others?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'd have to go—can I answer that offline because I don't know the answer to that?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Sure. Great.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And Nancy?

W
Just as an organization who's thinking ahead to clinical decision support I think the "and" is probably the right answer because you want to be able to use the medication information between applications or into a mark or against a protocol or something like that, and we are building that with those other attributes so I'm thinking from my perspective I would be looking for applications that could do both.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Objections then to moving forward with these recommendations and forwarding them to ONC? Well, very well. No objections being seen I think it is now time for lunch. You happen to be the keeper of the schedule. I think—that's right … open question of counsel and Kevin's points on backward compatibility in Part D compartment and terrific, thank you. I'm going to be very brief on that. It is 12:34. Let's come back at 1:00. Revised schedule put up the Quality Workgroup 1:00 to 1:45. S&I will be shortened and go to 2:45, and then very important at this time and a lot of data at the Implementation Workgroup in terms of certification. So 1:00 o'clock sharp then. Thanks, everybody, terrific discussion.

Judy Sparrow – Office of the National Coordinator – Executive Director
I think we're ready to begin if everybody could please take their seats and, operator, if you could open the lines, thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great. Many thanks, folks, for getting back together. Thank you even more for the very robust discussion this morning. Let's turn immediately to a continuity of this morning's conversation, and a pleasure to

introduce Jamie Ferguson who will be leading the Managing Transitions the Center for Vocabulary conversation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much, Dr. Perlin. I think you all probably recall last month in our virtual meeting we went through and had a number of recommendations on the long-term target vocabularies, and those recommendations were approved and we said we wanted to then come back because we had identified six different areas in the quality data measures set where transitions would be required for a variety of reasons. Among those reasons the use of alternative vocabularies in measures that are in use in Stage I of Meaningful Use, for example, and so we're back here now with a report on managing those transitions to the standardized vocabularies. And I think overall just reflecting on this work and the work of the joint workgroups on this we really sought to try to balance the need for standardization with flexibility and the needs of implementers. And so in terms of the background you'll notice we really were trying to minimize the burden on implementers of migrating to the standard vocabularies, and I think it's also important to reiterate that the recommendations are not intended to apply beyond the quality measure reporting. I know we had some discussion last month about the potential of using, for example, problem lists in other kinds of requirements but here we're limiting this strictly to the transitions from interim and alternative vocabularies to the long-term standard of standards that were adopted or that were recommended by the committee for purposes of quality measures.

Then, looking at the effect on stakeholders we put number four in a different color because frankly CMS as a stakeholder has a different set of requirements as a result of these recommendations if they're approved because for CMS all of the "or" become "and" and so this is a case where just like with our previous discussions here today we're recommending that alternatives to the standard vocabularies could be used in the quality measures. CMS would have to be able to receive them all and process them all. I also want to highlight the effect number two on the list here. There is no requirement here for certification so we're not saying that these vocabularies should be part of certification.

Again, this comes back to our report last month where we identified the six different areas where primarily transitions to SNOMED and LOINC were required, and so we've identified a number here of transition vocabularies including those that are used—and this was mentioned in the report last month—including those that are used in the Stage I measures. So in considering these kinds of transitions we wanted to look for subsets and value sets that are used in the quality measures. Again, no certification issues were identified. We looked at the mappings that are available that would be used potentially by care delivery organizations, by measure developers, and by CMS, and we considered final dates of the transition period, which in some cases are set by existing regulation and in other cases, as you'll see, we developed essentially an algorithm to make a recommendation that we came to consensus in the workgroups on recommended final dates. So this is that algorithm and for determining final dates for transitions you can see we looked at whether essentially there's an existing law or regulation that sets a date. We had broad discussion in the workgroup about when organizations could use the targeted vocabularies. We tried to understand the existence of both value sets and mappings, and I'm going to come back to mappings later but this was a key part of our discussion.

I'm going to go through this by each of the transition vocabularies so ICD-9 both diagnoses and procedures are actually very similar in terms of the recommendation. In terms of the cross maps I want to emphasize we've listed some existing sources of available cross maps but these cross maps, remember this is not generalized cross maps from ICD-9 to SNOMED, for example, it's constrained to the particular values that are used in the measures for meaningful use, so these are 40 some odd measures, and so it's a very constrained set and a numerated list of values that have to be mapped for this purpose. So in this case the final date for ICD-9 obviously is set by the current final rule for ICD-10. It's the same thing for the ICD-9 procedures. On each of these slides as I go through the transition vocabularies the italics below the title list the data domains where this is currently used in measures so this is which of the quality measures use this. Then, moving into ICD-10, again, this according to the current final rule this would be for use after October 2013. We found that because it's not used yet there aren't any existing subsets and value sets so that's not relevant, and the source of the mappings doesn't exist yet either but, again, that

depends on the measures and so that's going to depend on how measures use ICD-10 as for which values cross maps would be required.

Now, this is the first transition vocabulary where we have a final date recommendation, and so I want to say that this is a suggestion that's made with humility, and so we're not certain, frankly, about this but at the same time there was strong consensus across the joint workgroup that this was an appropriate date, That one year after Meaningful Use Stage III is effective would be an appropriate date to target for the transition for the final date. And then, again, so very similar for 10-PCS, and again you can see the particular QDM areas where this would be used for inpatient encounter interventions and procedures. Again, the same identical suggested final end date.

Now, for CPT this is another one that would be limited to the existing measures where it's currently used in the Stage I measures, and so we have a list of existing value sets where this is used. In terms of mappings there are some gaps in terms of the cross maps, and, again, the same final date with the same set of caveats.

Now, moving into the HCPSC then, again, very similar in terms of its existing use. No mappings currently identified.

So that's the list of transition vocabularies that we identified in the group. In terms of next steps I think that actually HCPSC is something I'll bring up. In terms of this point here of monitoring and the need for tracking changes to other vocabularies that may need to be used in quality data measures and the reason why I picked on HCPSC is that the FDA is preparing a notice of proposed rulemaking. They've held several workshops on this for a unique device identifier that could potentially—I know that the NCVHS is discussing this and is, I think, planning hearings on this—the potential for the FDA's UDI to replace HCPSC in some of the HIPAA code set usage for device identification. I'm putting that out as an example of monitoring that's going to be needed going forward because as the UDI or other vocabularies and coding systems come into existence as those regulations are promulgated in other related agencies then it's going to be very important to maintain alignment and to maintain some degree of flexibility in terms of how these things are used.

A second next step I'll add that's not on the slide here is that we—as you saw as we went through the slides—we identified several gaps in terms of both the existence and availability of the cross maps that are needed for the transition periods, and so I think one of the big questions that we wanted to get committee discussion and input on is who's supposed to be responsible for developing authoritative cross maps? Who's supposed to be responsible for publishing authoritative cross maps and what support resources will be available to implementers' and software developers through the transition period for the use of cross maps and related needs? So this is something I know we covered this in previous year actually in terms of vocabulary hearings. We made, as a committee, a set of recommendations that there should be a single central Federal office or agency with these responsibilities but frankly it doesn't exists yet, and so I was hoping to get some committee discussion on this point whether it's appropriate to talk about this as a role for MLM or whether there's some other place—if we just wanted it to be a place so we're at a point now where there are needs for these transition support tools including the cross maps that's becoming now more urgent with the transition of meaningful use as it progresses through the stages, and we don't have the central point of authority yet.

Jonathan Perlin – Hospital Corporation of America – CMO & President
First, let me thank you for the presentation and the ongoing work since the last update. Let me just ask if there are any comments on the general topic first, and then, if not, any comments on the stewardship that Jamie's alluded to? Okay, let me introduce Dr. Marjorie Rallins and—

Marjorie Rallins – AMA – Director, CPT Clinical Informatics
Marjorie Rallins here for Karen Kmetik. I did want to add, Jamie, one comment about—and maybe to the group as well. We can queue that up—for the one year recommendation, the recommendation that you made with humility, the one year after the effective date we may want to sort of think about adding some

additional language that says, “Contingent upon the experience” because we don’t know what that experience would be. So I’d like to sort of throw that out for the committee to just think about.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I’m always sensitive about making sure that we don’t tread into the policy committee’s work and timing and the guidance there from ONC would be welcome but I mention there must be an issue with the mapping that would be helpful in terms of finding clarification, Jamie, on the …

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, exactly. So I think we need to understand the timing, I think, for the existence of the cross maps, how long they need to be supported for and so forth.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes. Okay, David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This might be an ill posed question but I wonder if there is a distinction between cross maps that have been developed for the subset of codes that are relevant to measures versus value sets specified by the measure developers that include the respective choices of vocabularies, and what I mean by that is that the measure developer probably has a better idea how to resolve the ambiguity of an inexact match than an office that’s simply looking at code sets in the abstract. And would it make more sense to have the measure developers actually develop complete lists of codes from all other allowable vocabularies during the transition period then to say someone else should specify cross maps for those very measures.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. So if you recall part of our previous recommendations in terms of having this central office or authority was that this would be a point for information distribution and not necessarily the single office that would actually do all of the cross maps so that in that case, for example, measure developers, CMS, CDC, and other agencies could also create the support resources that are needed including the cross maps but that there would be basically a single place to go to get the information.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So then in terms of a recommendation would you be interested in a recommendation about who should actually be responsible for creating the knowledge or who’s responsible for distributing the knowledge?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think it’s who’s responsible for ensuring that that support resources are created and are distributed.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Not sort of an administrative responsibility.

Betsy Humphreys – National Library of Medicine – Deputy Director
This is Betsy Humphreys, I’m sorry when this was moved after lunch I missed the beginning of the presentation but I just wanted to make a comment on this point. It has always been our view that the selection of a value set from a vocabulary to represent a particular set of meanings for a measure really needs to be an activity in which the experts in the content from the point of view of the measure and the experts in the content of the vocabulary or code set pretty much both have their place and have to work together to make it come out right. We’ve seen some strange and not useful results in both directions when that doesn’t occur.

Marjorie Rallins – AMA – Director, CPT Clinical Informatics
This is Marjorie Rallins again. I think I would agree with Betsy’s comment in that any of those mappings I would believe should be ruled based for a particular use case so localized per user.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Well, appreciate, Betsy, you're joining, and it does seem that the recognition of the role of national library medicine does make sense there and appreciate the mapping and the counsel to ONC. If there are no other comments on this area we will move forward into the S&I framework with much appreciation for your … presentation. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'll have to go after lunch next time to.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We're going to break for lunch earlier next time. All right, let's turn back then to a continuing discussion and appreciate Dr. Doug Fridsma leading us through conversation about the work of the S&I framework. John, anything you want to … introduction?

John Halamka – Harvard Medical School – Chief Information Officer
So some framing remarks on this and that is one of the fascinating things Doug gets to do in his day job is run multiple activities in parallel and yet making sure there are appropriate intersections among activities, and we heard in our last meeting what the work of the S&I framework has been, where it has been complimentary to the work of this committee, and today, I think, what we'll get is the special September deliverable to ONC a sense of what you guys have done over the summer, where it is ready for primetime, where it is ready for pilots and how it will intersect with our future work. I have to say I have great respect for the S&I framework because one of the interesting aspects of doing standard harmonization and many of us in this room have been doing this for many, many years, is it's very often the case that the standards we find in industry aren't quite perfect but harmonization means picking from a list of imperfect standards and hoping it's good enough. Whereas what the S&I framework has been able to do is go a bit beyond that, and actually not only identify what is but think about what might be and how to get there. I do think this combination of S&I and ourselves working in parallel can work very well.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Thank you, John. I'd like to just spend a little bit of time going over some of the S&I framework activities. There's going to be a little bit of a review, sort of what our charge is and what are the kinds of things that we'd like to do, how this fits into some of the other activities that we have within ONC, pose some questions that I think help guide the work that we do and that I hope we can have a conversation about, and then dive in a little bit deeper into sort of what those STBs are, kind of where they are and the work that they're doing as well.

So one of the things that I think is important is that the S&I framework fits into a much larger ecosystem, if you will, of activities that are meant to support achieving interoperable health care systems, and so we need to enable stakeholders to come up with simple shared solutions when they have problems that they share so that we don't have everybody solving the same problem in different ways. When we identify that we have to sort of curate the portfolio, and we had a very good discussion, I think, this morning about the importance of having a portfolio of standards and services and policies that accelerate information exchange. And then finally, we have to make sure that people are following the ways in which those standards and services are described or hubs are implemented so that if somebody passes a test and says, "I'm compliant with the transitions of care document" then somebody who also has passed that test will be able to have some degree of information exchange. This fundamentally drives much of the work that happens within my office. We've talked about the portfolio this morning. The S&I framework is really about enabling stakeholders. I think it's one way of doing that. There are lots of other ways that ONC can help with that. I think this committee here also helps by creating the impotence to enable stakeholders to come up with common solutions.

Again, reviewing a little bit into place and context some of the things that John has said, I think why the S&I framework. For certain problem domains meaningful use specifies multiple or ambiguous standards, things that we need to do some work to get to a better place. We've got a whole series of recommendations that have come out and we want to have this sort of parsimonious set of standards that fit into our portfolio and enable us to exchange information, and so the S&I framework was sort of set up to, as John described, do some real work to actually go and try to get real world experience, try to create

focused initiatives that if there's a gap in what it is that we do then we can try to fill that gap, and if there's not a good standard to select to actually explore is there a better one that we can start to build towards. Maybe we can't build it all but we can build towards that, and it's important to recognize to that the S&I framework is here in large part to support a lot of the recommendations and work. I mean one of the things that you sort of recognize is that if there's an existing standard that we need to weigh them or we have to come up with a criteria by which we can assess them. Dixie Baker has demonstrated in the work that she's done that this is a good group of people that can come together and answer those kinds of questions and kind of create that framework for decision making and sort of provide a much broader context, but part of it is that Dixie's group can't do modular specification. She can't sort of tease apart the pieces and kind of do the heads down work, and so the S&I framework is here to sort of support the HIT Standards Committee and the work that you do so that we've got some real world experience, that we've got sort of the heads down work and that's in large part how we'd like to frame some of the activities that have been going on.

So the context for the current initiative that we've got, much of the work that we have within this started at the beginning of this year and we had some recommended Meaningful Use Stage II objectives, and in April, of course, we had discussions within this committee about how we can converge and provide more specificity in some of the Meaningful Use I criteria, and then also think ahead to what we might need in Stage II and Stage III and is there work that we have to do now that will help us have an easier time of things when we get to those decision making points?

We had the PCAST recommendations that talked about a universal exchange language, and we had a presentation back in December of 12 potential S&I initiatives. We posted them on the blog. We got feedback. We had some discussions in January and we picked some of those to begin to move forward particularly the transitions of care and the laboratory projects. Those were launched in January in response to the work that this committee had done and the recommendations that they had provided. We also had some additional recommendations around provider directories that occurred in June and that included trying to make sure that we have kind of the broad prospective on different approaches to doing certificate discovery, service discovery, and identifying people with the yellow pages.

So the kinds of questions to think about is as we think about this portfolio and we think about sort of an incremental iterative and value based approach to identifying and working on these particular standards we need to think about things like, if it's not perfect does it represent some of the best work that we have going forward? Does it point us in the right direction so are we directionally aligned? Does it support our policy objectives? Does it represent sort of the next incremental step in refining our standards and implementation guides? Do we have an existing community outside of the S&I framework that can help us update and maintain and sort of perceive through the standards development organization, and does it really represent a path of least regress in terms of how we want to sort of move forward?

So this year is in one picture a lot of the work that has happened over the summer. We have listed here all of the working groups and sort of what kinds of activities they were working on. We had folks that when we think about the interoperability stack we have the semantics that are captured in vocabularies and terminologies in the code sets that we recommend. We have packages of the content structure about how we would put all those vocabularies and terminologies together to make sort of a cohesive set of information, and then we have transport and security standards that allow us to move that around. In addition, there are, what we've termed here, access services or services that help enable those other three things to occur by providing certificates or by providing directories or providing other pieces of the puzzle that let this all happen. So this isn't a perfect diagram but it's our attempt to sort of see where people are working and you can see that we've got activities over the summer that have happened in all of these areas. There's nothing sort of magical about sort of the vertical lines except to know that transitions of care looked at content structures and vocabularies as part of their work, and the laboratory results interfaces also looked at that. The NWHN modular specifications sort of looked at transported security and how we might do that, and then we had work on the certificate interoperability and provider directories that looked at some of the access services as well.

All the things that are listed, the six boxes that are listed in sort of the tan color, represent S&I initiatives and the things that are listed in sort of the purple/blue represent activities within the working groups, and this really defines a lot of the work that has happened over the course of the summer and how they're complementary to each other as we kind of begin putting these building blocks together. We talked about the modular specification project. I included—as remember I told you I was going to include it in both places because I didn't know the right place to talk about it but we've already talked about this. This is sort of an ongoing process to try to begin to tease apart these various exchange and transport specifications.

So I'd like to sort of get into the meat because I'd rather get through this and make sure that we have ample time for discussion, and this is our diagram that tries to use some of the work that Dixie and her group had done to try and kind of have this notion of extensibility and flexibility and things like ease of implementation or degree of interoperability, and so the way I want to sort of frame this is that we have the CDA as a standard that HL7 has developed, which is highly extensible and highly flexible but had scores sort of low on ease of implementation and sort of getting things out there and degree of interoperability. If you have lots of optionality it becomes harder to sort of constrain that. CCD helps us by creating something that was a little bit easier to implement and that was able to sort of constrain what it was that we were doing a little bit, and what we did in the transitions of care project is we sort of took the CCD and the C32—the C32 and the CCR were both part of Meaningful Use Stage I and we've always said that part of our goal is to not have multiple standards to do exactly the same thing but to begin to converge on things that make sense, and so we brought together the CCR and the C32 community and what has come out of that really represents the product of the transitions of care initiative. An effort to get to a point where we have a standard that looks like a CCR in terms of being easier to look at from an implementation perspective but at the same time has a lot of extensibility and flexibility as well, and so we're trying to drive towards that upper right hand corner in terms of where we want to go with some of these initiatives.

One of the things that we've got, and I just want to mention this, is that there is an initiative that's ongoing that's called the Green CDA, and there's, I guess, just as the blue buttons there's no, I think, significance necessarily to green except that there is this notion of being more environmentally friendly maybe it's when you print out the specifications it uses less paper. But one of the challenges that we have is that when you have a CDA template a lot of times what it'll say is it'll say template ID equals FXYZ nonsensical set of numbers and it's much more intuitive rather than saying template ID equals something to actually put laboratory results as the tag for that, and so the notion of the greening of the CDA changes things that have template IDs and pointers and sort of this notion of a template ID equals something to just saying this is laboratory results sections. That's what it looks like. So one of the things that transitions of care document project has been doing is moving incrementally towards a collection of templates and modules that can be put together in a way that makes sense for transitions of care that you can say for a person who is being seen by their primary care doctor and needs to see a consultant here are the templates that you should put together and here's the standard way to describe that, and we're going to use language like lab results rather them template IDs as a way of sort of describing that, and so we are incrementally moving towards more business friendly, if you will, or domain expert friendly tags that are applied to those standards in a sense to help us be responsive to the criticisms that folks have had about the C32, and the reasons why the CR is active is because of the sense of having those names be appropriate.

And so the initiative was started back in January and February. We've had about 150 active participants and have come to really broad consensus about things. There's an existing base of CDA knowledge, expertise and tooling that's been created by vendors who are supporting and who are trying to meet Meaningful Use Stage I, and we're trying to work very closely with NIST and others to develop tooling testing educational resources through the S&I committee that will help both support the implementation of a transitions of care initiative as well as to support this pathway that we have to simplifying some of these standards.

So the pilot process was guided by the implementation community in a very sort of direct and community focused way trying to figure out the clinical relevance of transitions of care clinical information model,

trying to work to develop an information model to help support this, and we're working very closely in collaboration with the State HIN Beacon Communities. They're working on a tighter timeframe than what we had within this particular community. It's hard to believe six months was too much time but indeed there are some things going on in the states and the Beacons that I think are very forward-thinking. We've tried now to try and take a look at the … the consolidated CDR templates and we have commitments from the HR vendors to pilot and test these new test templates in the course of the next couple of months, and our goal is to begin working towards going from where we are now in a transitions of care document to something that we call sort of Green CDA. This notion of getting to those more business friendly terms as well, and we've been working very closely with HL7 and some of the other SDOs to make sure that we can have a path that creates those simple documents as well.

I'm happy to say that there has been, through the transitions of care project, two valid cycles in the course of six months through HL7. So those of you who are familiar with the HL7 process will recognize really how remarkable that is to be able to move through this process, and we have reached, I think, 60.5% concordance in terms of our balloting. You have to hit 60% to become approved for a draft state of … and use and so the transitions of care initiative has sort of met that bar and we're going to continue to resolve those ballots as well as we move through this. But I believe that we've been able to move from a standard that was adopted within meaningful use. In fact, two standards and beginning to converge now on one that takes the best of both worlds. That has the complicity of the CCR but the power of the CDA architecture, if you will, to maintain sort of semantic consistency. We have got more work to do in terms of pilots and testing but we certainly are on our way.

The second initiative— and I'll go through all of these and then at the end we can have some questions— the second initiative that I want to update you on is the laboratory results interfaces, and very similar to the other projects in which we had two existing sets of standards and we needed to kind of converge we had a similar result within the laboratory results interfaces. So there was a common standard across this and I think it's important to recognize that we have a common standard across all this work and that standard was the HL7 2.5.1 standard for how laboratory information gets exchanged. But we had two different kinds of implementation guides that served slightly different purposes. The first was an implementation guide that was developed by HITSP and it was designed to satisfy a very broad set of use cases. It had lots and lots of bells and whistles that would allow us to do lots of kinds of laboratory exchange but as a result given that flexibility was harder for us to sort of test. It was harder to implement and there were some challenges that we had been hearing from the states and the Regional Extension Centers that laboratory interfaces was a challenge for them in terms of information exchange.

There was also another implementation guide that was developed called ELINCS and this was designed for a much newer use case really the information exchange between say a laboratory and an outpatient primary care provider or the likes. A much more constrained set of uses, and so our goal and where we've sort of landed with the laboratory results interface project is we are still using exactly the same standard that was adopted as part of Meaningful Use Stage I, and we've taken a similar approach to transitions of care in the sense that we have this extensible base with a required profile that kind of helps make it easier to implement, has a little bit more flexibility to broaden the number of use cases that it has, but we've also tried to take a look at vocabularies and terminologies to constrain those down as well so that we can get more interoperability and more easier to test sorts of criteria. Again, leveraging what we've learned in other initiatives within the S&I framework and within Direct we've got approximately 90 active participants that have been guiding this effort and we've had very strong participation from the laboratory communities, from the vendors and the like. So we had clinical laboratories, EHR vendors, industry associates, government agencies, other clinical and technical experts that really represent that broad range of proponents both those that have implemented it and used the ELINCS implementation guide and those that have also looked at the HITSP implementation guide.

It's important to recognize that we're trying to get this sort of ease of use with this so it's based on an existing standard that has over 200 current deployments. We've had the laboratory results interface initiative reviewed by vendors for clarity and implementer friendliness just to get sort of broad consensus on things. We are going through—I mentioned earlier this morning—an off cycle ballot so that we can get even broader input from the HL7 community that we've not made mistakes, and, again, like all the other

initiatives that we have within the S&I framework we've been trying to pair the development of our specifications with consultation with NIST so that NIST is at the table as we're developing these things so that we can look down the road and make sure we're not creating things that are going to be difficult to test or that aren't going to achieve the objective that we had, and I just want to thank NIST for that participation. I think that's been tremendous.

We anticipate some pilots over the course of the next quarter to obtain further feedback on bugs and things, to focus on the implementation group and the consensus vocabularies around LOINC and SNOMED, and we've also raised the issue, although we don't, I think, have a solution per say, that we need some longer term evaluation of things like UCUM or … or other things that are going to be important parts of those messages because we don't really have good evidence about what's the right way to do it and what's the uptake that we might have within these communities. So that's kind of where we are right now. In the transitions of care we've got that going, so HSL that's been approved as a draft standard for testing and use. We will have another ballot with the HL7 community around the laboratory results interfaces but these are all examples of continuation of existing standards from Meaningful Use Stage I that we have really tried to make more implementable, easier to use and something that provides greater specificity and standardization.

The third initiative to talk about is the provider directory work, and this is something that we have had discussions within this community around how best to do the kinds of discovery that we need to do to enable information exchange to occur, and so the first one that we wanted to take a look at has to do with certificates, and we need this because we need to be able to find certificates to help support secure directed exchange. And we've got a lot of different ways we could do this none of which have sort of been tried and true, and so we've got about 63 active participants, a lot of other folks that attend the calls and the like, and so the consensus that they've reached is sort of a compromise. It isn't necessarily the final end all and be all and I think we are going to be moving towards something but this is an example of one of these incremental steps that I hope will provide us the ability to get information flowing, and then we can continue to refine it over time. The idea here or the recommendation is that the direct project … uses the domain name server as a way of finding certificates and if you can't find the certificate because somebody isn't able to implement that or that's not part of what your DNS is able to support we need to find another mechanism to also support that. And so one of the things is LDAP, which is a particular protocol that if you use outlook in your organization or if you have a kind of organizational directory there's a good chance that directory is being supported by an LDAP infrastructure. LDAP was never meant to be federated. It's truly supposed to be within an enterprise but the idea here is if you can't find the certificate using DNS, which is a broadly federated approach, you can actually query to find out where that LDAP server might be and issue a query there to try and figure out if you can find the certificate, and so this is directionally where the S&I framework is looking to go is to try to resolve this certificate discovery problem in the short-term by using the direct project … around DNS but to have a fall back if that becomes an implementation challenge so that you could then use something like LDAP as a way to discover that information.

DNS uses a backbone. I think we've sort of just talked about LDAP used for certificates of discovery in a significant number of organizations, and if we put these together we hope to have an incremental solution that sort of makes that next incremental step. So we're going to be, within the S&I community, updating the implementation guidance. The direct project … group believes the work required is minimal and complimentary to kind of creating this kind of infrastructure, and we've got two direct project communities that will be piloting this over the course of the next couple of months to see if this particular approach will work. The S&I framework community around the provider directory suggests that this solution be considered given the value and interest of implementers' and that we do have to have pilot testing and continued evaluation but this seemed like a good compromise that would get the ball rolling and at the same time allow us to work toward the more permanent and a more robust solution.

Now, there's also work that's gone on and I know that much of this work has also been presented in August. It was a report that was given to this committee during that timeframe, and this is to try to figure out how we can figure out about services and how we can figure out about that yellow pages, finding the provider directories and the like, and so querying for electronic services basically is asking questions like

does this organization speak direct? Do they speak Web services? Do they speak …? What are the kinds of things they are capable of doing electronically with regards to Exchange? Right now there are a number of different standards that help support queries but there's a limited deployment right now. We don't have any sort of nationally recognized set of standards that are out there, and before we can recommend anything in particular we really do need to do some work, real work experiences to be gained and evaluated as part of that. Some of that means taking a look at things like querying for a particular service and then saying, "Well, what are the kinds of information, the data models that you would want to have that would allow you to ask the right questions?" Without sort of a consensus around that one of the things that we have to do is we have to begin identifying the minimum set of data elements that might be necessary to ask the question about which services are there and to get back responses about what kinds of provider information that we have.

There are groups out there, for example, IHE has an HPD profile that provides a data model about what kind of information should be contained within these directories, and certainly, I think—Dixie, was this you again as well? Like did we give you all the hard problems, I guess? Dixie actually had worked on some of the recommendations around provider directories, and one of the things that came out of there was that the data model around HPD was something for us to explore and look at. We've also taken a look at some of the work that's going on in X12 and essentially tried to figure out a way that we can look at those different data models, and this is some consistency there. So as we work out the technical details of things we know that the data and the kinds of questions that we are going to ask are likely going to be similar regardless of whether it's in an LDAP directory or a micro data format or if there's an HPD directory services. We think this will help vendors who are looking at implementation solutions now to be able to facilitate innovation and as we sort of begin to hone in on different approaches at least have some consistency in the data that gets taken care of for that as well.

Again, this is one that we are having an ongoing push to get real world deployments so that we can then report back to this committee the results of those implementations realizing that scalability and the other things that Dixie has in terms of evaluating these various profiles will need to be applied but seeing if we can get more information about what that minimum data set might be, whether or not this incremental path with the DNS and the LDAP approach can work, and whether we can get those additional services out there that will, I think, enable us to begin the process of getting information exchange to occur.

So this last page is just really a summary of the findings. The transitions of care, we have significant convergence around consolidated CDA … and the community has really, I think, come together to help us on that incremental path from the C32 and the CCR to this transitions of care document that uses consolidated CDA templates and the recommendation from the community is to use the implementation guide for CDA release 2.0 based upon a consolidated CDA template. That has just been approved as a draft standard for testing and use within HL7. The second summary is that the laboratory results interface, again, has broad agreement on this new implementation guide and the vocabularies around that. That will, we think, aid in the implementation and the ease of use. It doesn't change the underlying standard but provides more specificity around the implementation guide, and that is currently in the ballot process, and we will know more as we go along but we certainly need to continue to monitor and pilot these sorts of things but the recommendation is that implementation guide pending the balloting process within HL7 is probably the right next step in this incremental path that we have towards standards for information exchange.

Then, the final observation is around provider directories, and so there was consensus within the group that this hybrid approach using DNS with a sale over to LDAP solutions would provide the greatest number of implementers to effectively get to certificate discovery and management. There's a recognition that it isn't a perfect solution but it is a piece of the puzzle that we need to sort of begin building towards, and that we need to continue to work on pilots that will help us understand other issues that we haven't considered, and that as we can agree on standards with regard to provider directories and what those minimal data elements might be that, again, will, I think, inform the industry in a path forward that says, "Here's some things that we can at least begin moving towards. We don't know what the best technical infrastructure is." We need to do some work outs there but this at least, I think, begins to provide some

help for folks that want to get the ball rolling, get some real experience out there and see if we can't get things running.

There's a series of other initiatives as well. I can just very, very quickly go through these. These are included more to just give you a heads up because it's likely that I'll be coming back to this group in a couple of months with some additional observations and additional findings so stay tuned. This is just sort of—I guess this is the preview of what is yet to come. So we've got a certificate interoperability initiative, again, one of those pieces. When we think about the identification of gaps that we need to help support information exchange one of the things that we noted was that the Federal PKI policy, this sort of federal bridge, doesn't have the validation of organization in it. It's really geared toward individuals, and so it's on our radar. We're working on it and that we need to continue to sort of work within GSA, which manages sort of the federal bridge, make sure that we align all of the pieces, and then monitor some of the other things that are happening out there like a health bridge and the like, and we certainly can help inform this committee as we go forward.

Query Health, which was launched just a couple of weeks ago. We talked briefly about that this morning but this is to establish the standards and protocols for distributing queries, sending the queries to the data rather than having the data come to the query. They've got a charter call. This is being led by Rich Elmore who has reached out to I know a number of you, and they've had a series of meetings just in preparation, and so they've got three working groups. There's the clinical one that's working on user stories, a technical one that's thinking about a model for how this data might be queried or represented and what are the applicable standards, and then a group that's called business, which is really about requirements for privacy, security data use, integration, sort of those business processes that need not be neglected as we think about how this might role out. We're working very closely—I think I just need to assure you that ongoing conversations with the HIT Policy Committee and the Tiger Team around a policy sandbox is an important learning lesson that we had from the direct project and one that we are going to continue to use in this project as well to make sure that as we explore the technical issues and the clinical issues that we do that in a place that's safe and that doesn't expose information that shouldn't be exposed as we're working out those activities.

Finally, there's an activity that is coming up on data segmentation. We anticipate launching that very, very soon. I think this is like the iPhone release, right. It's coming out, just look for it. But we've had some calls for participation and so you've probably heard some information out there. This is a project that is being lead in large part by Joy Pritts as a privacy and security officer within ONC that enables us the implementation and management of disclosure within health information exchanges so that individually identifiable health information may be appropriately shared. This is about making sure we've got granular levels of sort of data segmentation, and we're working very closely with SAMHSA on this to make sure that we've got something that will kind of fit within that. So expect to have some announcements coming out that will talk a little bit more about this and hopefully be able to provide some additional work.

I guess another—I guess this isn't the last. There's more but what there's more. Electronic submission of medical documentation, we've been working with CMS to make sure that some of the work that they do about medical documentation submission is aligned with the kinds of standards that we've got here. Now, this is something that we are just beginning to sort of look at. We are trying to get some people that can help us with participation, and we're going to be reaching out to folks over the course of the next couple of weeks so that we can begin looking at this electronic submission of medical documentation and make sure that aligns with the other kinds of standards like transitions of care and the ways in which we've looked at with the NwHIN transport standards, that they all sort of work together.

As always, you have to end with a plug. This is where all of our work occurs on the siframework.org. I'll just quote from Arien Malec, "Communities are a powerful thing and the reason why the S&I framework is able to do work is because people show up. If they don't show up then we sort of shut those things down." And everything that we've described here it works because people showed up and so with that, I'm going to stop and I'll be happy to entertain questions.

John Halamka – Harvard Medical School – Chief Information Officer
Well, I'm sure there will be many questions. Extraordinary work. When I think about the work we've all done together the last ten years—I mean let's just revisit a few of the more challenging harmonization activities. So in the CCR/CCD question it was can you use the simplicity, the basic XML CCR with the richness of the RIM and the extensibility of CDA and we came up with CCD, which you are in this transfers of care activity saying is from CCR it turns out actually hasn't been extended. I mean ASTM E31 is not working on extensions. What you would be able to say is let's ensure that the XML is really simple and let's make sure that there are templates we can lift off the shelf so that the ease of implementation—if I want to create a transfer document that has a problem, a med, an allergy, a diet and activity, I just lift those off the shelf and the XML is readable by mere humans. That's really does achieve a synthesis of two kinds of things that we tried to do with that CCR/CCD activity, and the labs another one that was interesting. If you have a very simple use case, and Jamie and I know the hours we spent on this so nothing more than an EHR sending an order and a lab coming back and there's no public health reporting and there's no bio-surveillance and there's … complex use case, ELINCS was fabulous. The problem was we were given a set of constraints that said you need to do 100 different things so ELINCS wasn't sufficient. So now you'll be able to put the ELINCS community together with the community who wants more and say, in the same sort of way, here's a basic set of foundational elements, and if you need to do those more complicated things you add to the foundation as opposed to creating one giant complete standard that fits everyone's needs.

Then on the provider directory I think you've said quite wisely—I mean Dixie spent endless hours on this one—we don't know. I mean that's really the answer, is we don't know. We think because there are a couple of options out there and there's this micro data thing that's been proposed and there's this LDAP thing that doesn't quite get federated and DNS actually serves some use cases but not all implementations of DNS can deliver certificates so actually there's a whole bunch of things that we have to try. And so, in fact, you've just solved all the world's problems. You've got trackers of care that are comprehensive yet simple. You've got reportable labs that are both easy and can be rich, and you have provider directories where you've admitted there's more work to do, so I think that's very good. I look forward to your comments. Wes, I know you put up your card.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So just a couple of specific questions, as I understand Green CDA it is a simplified way to represent data but it's not a way to send data over the wire.

John Halamka – Harvard Medical School – Chief Information Officer
That is, I guess, a question.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, I'm just telling you what I understand of some recent conversations in San Diego. Is that consistent with your understanding of Green CDA is it's going to be as you describe it here?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Well, let me answer that question—I also want to acknowledge … is on the telephone as well so all the hard questions will go to him. I'll just take the easier ones with regard to Green CDA. One of the challenges with Green CDA and that people are concerned about is that Green CDA templates are a lot like V2 messages in that you've seen one simplified version of this CDA you've seen one simplified version. There aren't sort of consistent ways of creating those sorts of business friendly vocabularies and terms, and so as a result it's very difficult right now to use Green CDA over the wire because there isn't that consistent normative standard, if you will, about what a Green CDA is supposed to look like. There are ways to solve that. One is to say, "Well, we simply aren't going to do Green CDA on the wire." I think there are others that have proposed that part of the way that you can get there is if you create a standard way in which the Green CDA is represented, those templates, what those look like and once you've got that relatively standardized then it becomes possible to start talking about the Green CDA on the wire.

I know that there's a lot of discussion in the community about what's the appropriate use of the sort of simplified XML, which represents that Green CDA. I'm not sure that there has come to a convergence

about what the appropriate ways to do things are. I think any time we make things easier to implement I think that is probably a good thing, and I think we need to make sure that when that happens or if that happens that we do it in a consistent way so that people have the ability to know that when I say lab or medication list it means the same thing, and that one group has created a greening of the tags that are different than the way somebody else might have done that.

John Halamka – Harvard Medical School – Chief Information Officer
Wes just pointed out as Wes always does, there's an interesting detail that has not yet converged to consensus, and so, Wes, I get calls all the time from people on both sides of this argument, which is to say, "If you're going to simplify this that sounds great but we've got all those people out there who aren't using simplified versions so maybe what you want to do is you over at your enterprise you run the really simplified version and then you run it through a transform that makes it all complex again, and then you send that complexity over the wire so that everyone who's used to the complexity can receive and …" and that is the issues you describe of making sure that the transforms are reversible and consistent and all the rest. Others are saying, "If we're converging … let's just use simplicity." I mean forget convert this convert that and let's just use that simple readable XML from end to end. So, Wes, I think the simple answer is no one has yet converged. There are arguments on both sides and I have tended to argue I like the notion of simplicity over the wire, get it simple as you can but that's further work that we have to do.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. There were at least three words in Doug's presentation that invoked the notion that well, if we can give you a tool why do you care what goes over the wire, and it's an argument that … a lot around Green CDA, and I just want to comment that the assumption is therefore that the tool is perfect. There could be no possible bug in the tool, that the response from the other system is perfect with respect to the transformation. In fact, that people who get work done quite often look at the intermediate products of what's being sent over the wire sometimes just in order to figure out a tough thing but often in order to find usually their own bugs sometimes not. So Green CDA as it stands is a style that could be translated into, what color should I call the current CDA, … but it is not a solution to the issue of simplicity. You mention the data segmentation project, is that related to the NCRM on it's a disclosure requirement disclosed on August 2nd?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
It's not. I'm turning to my policy folks and they're shaking their heads.

M
There's no direct linkage to it. I mean Joy would know better but I don't believe there's any intent at direct linkage.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay so then it's not a—my comments on this subject for this thing. As far as ESND it is about audit recovery of data. It's also about getting data about a claim after the fact of the claim. It is not about claims attachments, which is sent contemporaneously with the claim or before the claim is paid but not contemporaneously, and yet the information requirement is virtually identical. I have said in this committee since we started that if you wanted a quick monetary fix on saving administrative costs implement claims attachments, implement HIPAA claims attachments. It may be a necessity of the bureaucratic halls in which we work but it's really a shame that this work is going on independently of and not paying attention to the work that was done on HIPPA claims attachments even though they're both varieties of the CDA, and I am particularly concerned that the work—I did the work so of course it must have been very good but the scope of the work that we did on claim attachments was to allow the same package to contain both unstructured data and structured data so that it wouldn't take another dictum to go from unstructured data to structured data. It could happen sort of one kind of claim at a time. It was possible that one provider could send structured data and the payer would just take it as unstructured. It was possible that a payer who would take structured data could accept unstructured data as well, and CMS seems to have just ignored that and gone with this E68, which doesn't permit structured data so I believe that there's a big opportunity to actually get numbers close to the kinds of numbers that Congress pays attention to if we just pay more attention to claims attachment.

John Halamka – Harvard Medical School – Chief Information Officer
So looking at the list of other folks I think Dave McCallie, then Dixie Baker, then Chris Chute, then Kevin Hutchinson, and then Stan Huff.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
First, David, thanks for the really nice summary. I can remember when the S&I framework was first presented to us a year ago or whenever it was and it was very confusing about what you were going to do. It is nice to look back and see this nice concise list of a lot of work that's been accomplished, and hats off to you and … and others who made that happen. My comments were going to be about Green CDA and Wes covered them so I'll just put my vote in for if it isn't simple on the wire it isn't worth doing because otherwise there's just yet another layer of complexity of fail, so just put that vote in otherwise I'll yield my time to whoever's next.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Having read through this I just wanted to remind everybody on this committee that when we had our discussion, another active discussion, about provider directories our solution was that a national level LDAP directory was not going to be the solution and that it should be something much more simple, and we encouraged ONC to look at the use of micro data just going to a Web page and querying a Web page, here's my yes, I support direct; yes, I support Exchange; blah, blah, blah, and that does not require the development of a complete data model to do that. In fact, I could do it tomorrow if you want me to so I'm kind of wondering why and I understand. I've heard at least two different people offer their institutions to just trial and do pilots for the micro data approach so I'm continuing to wonder what happened to that idea?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
One of the tenants that we had within the S&I framework is that if we launched an initiative and nobody showed up then we would not continue the initiative. So we launched a micro data initiative and nobody showed up and so we, at that point, tried to get the community to engage, tried to get people to come but to be consistent in the principles—I mean one of the people who didn't show up was Arien and I had a conversation with Arien saying it's one thing—the idea of the S&I framework is that people come together and we sort of convene and then people go off and sort of do the work that needs to be done to demonstrate that particular approach is useful and it works. What I found is that people came to meetings but there wasn't work that was getting accomplished and it was falling on ONC to do all the work that would help launch that initiative. That was never the intent of the S&I framework to sort of have people come in and then for us to do all the work. It was really meant to be a convening, so I'm a big fan and I would love to get a micro data project going but we wanted to maintain the integrity of the process, and basically if people show up we will support and we will convene and we will help but if we aren't able to get to that point then we have to make the decision as to whether or not if the community even though they think it's a good idea they don't see it as something as a solution moving forward.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It may be that they don't see it as a solution they can go and make money off of. It may be sometimes it's appropriate to stand back and say, "Who's my community and why are they not interested" and I know there are people, John Halamka being one of them, that we've all heard offer his institutions as a place to pilot this. I think it would be worthwhile to do that.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So I would welcome the input from this group to help us. Now, we did develop some initial pilots. We actually have paid for folks to go to skema.org, which is where sort of these kinds of things get presented. We want that community to know about the problem that we're trying to solve and to see if they can help us but there was a concern, and we can talk more about this. I don't know if I have all of the answers but there are some things for which the S&I framework is exactly the right approach to getting a problem solved. There are some kinds of problems that the S&I framework gets in the way of them being able to move quickly to innovate and things like that, and it may be that there's a need out in the community to have some sort of rapid prototyping and things, and then as things start to gel come back and say, "Here

are the issues that we're still struggling with and the like." So I think it isn't that I don't think that there's value and that might not be an approach. The question is what is the right time to pull a project like that into the S&I framework to get sort of broader consensus. Do we smoother it if we make it part of the S&I framework early on? Do we need to encourage it outside and then figure out a way to bring it back in? I present those as questions for which I think we're still working out the answers but to your point the micro data is certainly something that I think has tremendous potential. We just need to figure out what's the right way to kind of engage the community in coming up with those kinds of solutions, and to let them tell us when the right time is to sort of move that forward and to get that broader input within the S&I framework.

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This is Justin … speaking. May I just add to that Doug just one point? The one point is we do have members in the S&I Community who are interested in helping out with micro data and will be available to help out when there is an opportunity to launch any sort of work around it whether it's inside or outside the S&I framework but the issue over here partially is that micro data is still being defined as a standard and there's limited experience within the S&I Community around what would be the right steps so we have willing hands but not folks who necessarily know enough to be able to push it forward, and that's part of the reason why we just couldn't get critical mass within the S&I framework to push it forward even though there were certainly a couple of folks who volunteered right away to be participants if they could find the expertise to push these forward.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Doug, if I could say just a little bit more about that—this is David—on the micro data thing. There were several of us who tried to get the micro data thing going, and we literally just had no time left over to attend yet another set of S&I meetings so some of it was just the sheer lack of time to engage. So I think it was not a vote negative it was just an abstain because there was just no time left over. On the other hand, I think that a current approach to identify the schema and the value fields that would populate things like how do you define a provider's specialty, what's the list, is it the several thousand that's in the X12 document or is it some subset of that? How do you represent certification in medical specialties? What standard is used to do that? Resolving some of those things, which is underway in S&I, would be immediately applicable to an almost trivial micro data implementation once the schemas are set, so I don't think that the game is over. I just think it's work on the schema stuff and then the micro data can assimilate the part that matters really trivially.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I think that's an excellent point. Thank you so much.

John Halamka – Harvard Medical School – Chief Information Officer
And what I volunteered is I have about 3,000 docs in my directory that's Web exposed today and we use the American Board of Medical Specialty as an official list of those specialties that are Board certified, and we've made a bunch of decisions whether they're right or wrong, those decisions we've made and I can expose my 3,000 doctors in micro data, as you said, in a day or two. I mean just give me the schema and I'll be straightforward if you want to …

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I will add one other point though that when it comes to the point when the S&I process has settled on the schema and someone has thought through the mappings and the micro data the search engine vendors, Google, Bing, Yahoo, whoever's left in the search engine space, I think will pay much more attention to building browser support for micro data if it comes from ONC as a blessed approach. So there may be some power that comes from the S&I picking it back up at some point and saying we agree this is the right way to do this in terms of impact on the search engine vendors. Now, we can't make them do anything but that's just my bet is they'll pay more attention to it.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, Chris Chute?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you. I guess I want to begin by complimenting you, Doug, and reiterating the praise that I think is uniform around the table of the excellent work that has been done and that you continue to do. However, as with Dixie I too was very intrigued in August as I think was our organization by we didn't use the micro data word then. I think we talked about static Web pages but it's the same idea of pursuing this as a provider directory infrastructure. I guess there are really three comments around that. We as an organization have a tremendous amount of experience with LDAP. It was, after all, the original framework for common terminology services way back when we were prototyping the early 2000s and it has severe technical restrictions and performance issues as …, and clearly would not scale to the kind of functionality that I think we are anticipating for provider directory, and I think we sort of said that in August.

Two, while the S&I framework is a thing of beauty and seems to be coming up to speed in a practical way for a very long period of time it was sort of a stealth operation. You had to know who to see and where to go and what the projects were, and that brings us to the third point that we sort of did step up as an organization and say we want to work on metadata. Well, we were informed that we were too late and somewhat rebuffed, and so the whole question of how this process works— and I agree wholeheartedly with David McCallie that if whatever structures come out of this process and it's true that those structures would not be specific to micro data or LDAP or anything else, it's a generic information model that can be schematized. However, if that's schema becomes an ONC specification ultimately nobody's expecting ONC necessarily to write it but to expect that it would come from outside in some fashion, I think, is going to significantly compromise uptake and for that matter recognition throughout the industry, so I would urge that the provider directory project in particular re-examine the fairly substantial body of enthusiasm and interest and offers of assistance that I think have come forward to consider that as an alternative.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Great. I mean this is all very encouraging. I think we spent some time trying to figure out how best to do this and had some hard conversations to figure out how we can move forward but the support that's just coming around the table I think is helpful to give us some guidance about that, so thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO
I to want to echo the praise of the work that has been done in particular the structure that's been brought to the table to follow this process as you've mentioned several times if it doesn't fit inside the process by which we've established it then we don't pursue it. One question that I had related to the process is are we getting feedback from the providers or the patients because now we're actually starting to implement things and now we're not just talking about them on paper we're putting them into practice with various different organizations and EHR vendors and we're measuring the impact and the scalability from a technical level but are we gathering feedback from the providers and the patients who are on the other end of this as part of the process to really see if we're impacting the care process in the way that we hope that we are?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
That's a great comment. I think within the S&I framework we don't have a formal mechanism to get feedback from patients and providers per say. I mean it kind of comes through the pilots kind of in an indirect way. I think more broadly across ONC there is a lot of thought and attention being applied to getting that kind of feedback as well. There are groups that are charged specifically with understanding what's happening in the community. We've got our consumer engagement initiatives, which, again, will be part of engaging that community and making sure that we're meeting their needs as well. So within the S&I framework nothing specific to that but I made a note here to see—that's something that we should look for the opportunity to engage that community as well and maybe if we have standards that are directly applicable, if we have something related to PHRs or something like that, that community will become critical, I think, in helping us to tease that out. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

And Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So just, again, I appreciate the great work you've been doing. The thing that comes to mind, and it follows on a little bit from what Wes was saying, is that Green CDA in a sense is sort of a medical specific X amount. It provides a language for describing content but you then have all the variability. In fact, it's your own words, you've seen one Green CDA, you've seen one Green CDA, and even if you solve the issue of translating from Green CDA to the wire format the underlying question is the model of the data consistent and is the connection from that model to terminology as consistent? So we can have, for instance, Green CDA representing lab data and transitions of care data one way in Green CDA and the S&I framework and Floyd and the folks over in quality using a different model, and that needs to, at some point, be coordinated so that there's a consistent model behind both Green CDA and consistent with QDM. So it's just my constant whine about consistent models that will actually lead to interoperability and Green CDA is a fine language but at some point there has to be clinicians and experts who are saying for a given kind of data, let's talk about blood pressures, what is the context of that measurement? What's the patient's position? How does that interface into along just having a LOINC code that says systolic blood pressure? There's a deeper set of modeling kind of things that have to be actually behind both of those things to create a consistent world.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
And let me just say that the recommendation of the group was to use something called Consolidated CDA, which was really the extension from the consolidation work that happened over the summer as well. All the points that you make are absolutely spot on. I think we won't solve that problem necessarily within the S&I framework. I think we really have to work very closely with HL7 and the only way that Green CDA on the wire is going to be successful is if the medical XML or those terms are consistent, and that's going to require really making sure that those mappings are consistent and that the terms being used on the wire on consistent. So the recommendation from the S&I Framework activities around transitions of care is around what they call Consolidated CDA. That's the work that's being balloted right now and that's really based more on the CDA infrastructure and derives from say the C32 but additional work, I think, is going to be needed if we want to get to that simplicity and it will need to overcome some of those issues as well. The goal stage that would be tremendous would be to have a consistent green set of templates tied to the kind of robustness of the RIM and the CDA architecture behind it so that when you've seen one Green CDA you have all of the pieces that you need for that consistency but the over the wire is simple. If you've got the implementation it's easy.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I'm not saying stop doing what you're doing. It's a recognition though that even with Green CDA you have a certain population of people who are contributing there and, in fact, there's huge interest in these issues in professional organizations, the pediatricians, the surgeons, the other people who are the real content experts, which even at HL7 have always been engaged in creating, if you will, the real model that underlies these things, and at some point—so don't stop doing what you're doing but I think we want to put sort of a sticky note that says at some point in the future we probably need to rationalize that across the bigger population that includes quality measures, that includes what clinicians think is actually important to collect besides just knowing the structure of what we're collecting. All of those kinds of things that ultimately we hope we can bring into the process.

John Halamka – Harvard Medical School – Chief Information Officer
Walter Suarez and then Wes and Jamie and then we need to get to Judy and Liz because you have a big body of work to cover.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Thank you. This is Walter Suarez with Kaiser Permanente, two quick comments or a comment and a plug. First about attachments, one of my favorite topics on ESMD and Doug and I have talked about it. I just wanted to mention that in the realm of attachments and claim attachments specifically there are regulations coming up that will establish the national standard to be used to submit claim attachments. Those regulations will also name operating rules, which will guide the standard business rules to

determine when attachments are going to be needed, and so NCVHS, which has oversights on HIPAA standards will be holding a hearing November 17th on attachments. This will be a first hearing of at least two that we plan to have at NCVHS addressing attachments in general and claim attachments. We will hear from the SMD or expect to hear from the SMD, and the concern, of course, that we have in general is with respect to the SMD is that perception, and I have expressed that to the SMD literature, the perception that the SMD as a standard for their Phase I—and it's very important to understand that this is their first phase—is going to be a simple unstructured message coming from providers. A PDF of a picture of the document to support a claim transaction and the concern of course is that this could be seen as this is a new national standard to submit claim attachments because indeed submission of medical documentation for purposes of administrative transactions is very much related to claim attachments. At NCVHS at least we're going to be ensuring that we see where the direction is with respect to attachments in general for administrative transactions because it's not just claims. There are attachments for other types of transactions, referrals … and workman comp and other things. So we are going to be looking at that and ensuring that the industry hears this strong message about the direction in which the standard development process is going, the role that certainly X12 and HL7 attachments workgroups are going to have and the development of operating rules for claim attachments. In fact, with respect to that I mentioned to John that fact that NCVHS will be inviting representatives from both the Standards Committee and the Policy Committee to attend these hearings under the Affordable Care Act. The Secretary is to listen to input from NCVHS along with Policy Committee and Standard Committee on these areas so you will be receiving a letter soon to invite two or three members perhaps or four members of the Standards Committee. So that's just an important point about attachments.

The second point I wanted to mention is a plug basically, and you mentioned, Doug, about the importance of commitment and support and interest in the industry to move forward with a particular initiative and I think that is exactly probably more of that that we have in one area, probably health. The public health, I guess, community lead effort has started and it's moving forward and it has, I believe, already submitted a proposal to have the public health activities around standardization of messages be defined as one of the S&I Framework initiatives. So from that perspective I think we and this group of people in public health that are looking for that to happen are very hopeful that it will be officially identified as an S&I Framework initiative. I think through the work of the surveillance of Power Team we heard—and through the work of IHE and ISO and public health and other areas, HL7 and others we head the importance of the standardization of messages in the public health realm so I think we're very hopeful that will be something that will soon be activated as an initiative.

John Halamka – Harvard Medical School – Chief Information Officer
Wes and then last word Jamie.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, Stan, do you mind if I'm a little blunter than you were?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
No go ahead.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, there are two related issues around CDA. One is accessibility to three special populations, programmers, analysts, and subject matter experts that really need to look at examples in order to understand what the generality are that are being derived from a model. Green CDA properly extended to help there. The other is …, which doesn't have anything to do with sainthood but it has to do with out of all of the millions of ways you can combine codes to create a set of structurally correct statements what are the ones that really matters to the physicians or other clinicians? They interrelate in the sense that it's hard to talk about that without examples but they also relate to how the CDAs developed and how consolidated the CDA is developed because the modeling artifacts that are used—I'm not aware that HL7 believes they've solved the problem I'm describing. It's messy because SNOMED is messy. There are all kinds of issues around it but it's hard to get interactions with the clinicians because of the abstraction of the model.

So we have been sitting, in my opinion, on a gold mine for ten years and we're still sitting on it and we're not getting our butts up off it, and that is a body of work that has already been done with clinicians to say what are those important … that are in the public domain that are available but aren't expressed in terms of the HL7 realm? I think HL7 consolidation is a good idea. I mean I'm glad to see it happens. I think it has the potential to make things simpler because you can at least turn the specifications into a plugin, put this data field here, put this data field there, put this data field there and send that as opposed to having to understand all of the—trouble is it's here, here, and here. It's not here, here, and here that you have to describe that. There's a lot of work going on primarily by people outside of the country to try to put that gold mine into production. Start to actually pull the ore out and use it, and I think we should be watching it and considering what impact it would have on future standards. I recognize that there is almost no time in the scheduling from one release of meaningful use to the next to count on this developing full blown and therefore being ready to implement in it. Nonetheless, we could let the world pass us by very easily.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
The specific words I forgot to use were detailed clinical … and the … group, CIMI.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. So I don't pretend to have the answer or a magic ball to the issue that Stan and Wes raised but I did want to make a comment along the same lines actually about one tool that I think, Doug, could be in your toolbox going forward in terms of next steps, and it is one of those things that's used by some of the people involved in the groups that Wes just mentioned and that is the use of the Web Ontology Language or OWL in combination with certain tools can be used to test the semantic equivalence of implementation of the RIM such as the CDA templates that you're talking about as a future vision. So I mean RIM is complicated. It is possible to have different representations that are semantically equivalent and so how do you test for sematic equivalence? Well, this is one of the things that actually is being worked on or it's on the work list for the newly reconstituted Health Care Life Sciences Semantic Web Workgroup of W3C, and so I would just urge you as a friendly suggestion to put some collaboration there on your roadmap for future use because in the world that you've described of the future where there is perhaps a repository of templates, they're created by different creators at different times. There may be semantic equivalence and so there's going to be a need to test for that and this is, I think, an important tool in that toolbox.

John Halamka – Harvard Medical School – Chief Information Officer
Well, thanks very, very much and thanks, Doug, for extraordinary work, a rich discussion. Today is a big day and it feels to me like as you guys described S&I sort of stealthy at the beginning is now part of the family, so thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dave, the scope of your presentation led me to wonder what you are doing with your spare time. It's an immense amount of work, great appreciation. I particularly appreciate the very thoughtful comments. There was a lot of very constructive advice that can be taken back to S&I to move to next steps and so thank you very much for that.

M
Before we go on I think it's important though to at least have the committee help us understand are we directionally going where we should go given the summary of findings around transitions of care, laboratory interfaces, and provider directories? Are there things that we need to change? Certainly as we get guidance from this committee in terms of a letter to the Office of the National Coordinator having some semblance about where to move in some of these activities would be helpful.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I think there's some body language there. There seems to be consensus around the direction of what you've articulated then why don't we contemplate at the next meeting if there are additional areas of your scope that is already very broad is that the group—

M
Accommodating comments that have been made.

M
Inaudible

M
That's the money slide right there. Thank you so much.

Jonathan Perlin – Hospital Corporation of America – CMO & President
All right. Thank you very much for that. We have borrowed time in the past from the Implementation Workgroup but this is the closing of a cycle of the work that they've been doing, looking at not something that conceptually projects forward, but taking stock of that which has occurred with the first traunch of activity in Stage I Meaningful Use certification process and input on recommendations for Stage II. So welcome Judy Murphy, Liz Johnson, and Steve Posnack. Really look forward to a very robust set of recommendations that you bring forward.

Judy Murphy – Aurora Health Care – Vice President of Applications
I'll go ahead and get started and we'll go quickly. So there are our workgroup members again. As with many of the working groups that have been reporting this afternoon in the Power Team lots of work was done by lots of people and let's just say we met, I think it was three times in the last week, for two hours each to try to beat out what we had to get done. A special welcome to our new member that's listed there, Steve Palmer from Texas Health and Human Services.

This is a slide that we've been using in the past just to give you the context of our work, again. We did a certification survey, we closed the comments, we compiled the comments, we analyzed them and decided that we were not going to collect any more data because then we just had more work, and at the last meeting, which was our virtual meeting August 17th, we did talk about the overall certification process, recommendations that we had based on the survey and that's in the throes of being formalized into a transmittal letter. So what we're here to do today is to talk about Stage II certification criteria of standards and you've got two documents, a copy of our slides and our grid as we've been calling it, and yes we are going to go through this and still make our time. No, we're not going to go through every line but we are going to go through some of the highlighted items that we either want to explain to you for your information as this is the direction we're going. We will ask you to comment in some sections here today, and in a few sections to get us any additional thoughts that you've got in writing. Again, as we go through the grid that's basically what we're going to just go to the sections that we think are not so much controversial but were there was a fair amount of discussion within the workgroup.

We have some additional work to do and this just outlines that, completing the transmittal letter that we talked about, working on finishing this grid because we are not completely done specifically in the area of recommended certification testing. That's not part of something that falls under the rule making so we actually don't have to have that done by the end of September so we will continue our workgroup in providing some guidance related to the certification testing and any other implementation specifications more of the generic nature that don't need to fit into the rule making process, which is where we have the end of September deadline that we've all been living under. And then, just looking ahead a little bit to Stage III and thinking about—well, the words been used before by John—the glide path how are we setting the stage today for where we know we're going to be needing to go in Stage III, and spending a little bit of time in the workgroup thinking about moving to true health care transformation and how can we make sure that we're looking ahead to that.

So with that, I will turn it over to Liz to begin looking at your next handout, and you'll have to have this in front of you because we will not have it on the slides and it's the grid that starts with row one and two.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I think Steve wants to give us a little context in terms of—

Steve Posnack – ONC – Policy Analyst
Sure. This is Steve Posnack with ONC and I want to thank—I call you the ladies—Liz and Judy for taking on this task, and I like analogies so bear with me with analogies. We are running a relay and the implementation workgroup has been running around the track as fast as we can and I'm here in my capacity to catch the baton in that middle area where you usually catch the baton if you're on a good relay team that don't drop it. So I'm here to actually catch it physically, which is what is represented in the body of work that we'll be walking through and take that next step going through the rule making and using these recommendations.

And I think it's important to note, especially on the header that's accompanied on every page that we did do a ton of work, the Workgroup and Carol Bean, who is behind me and Mike Lapinski, who contributed from ONC, as well to get as far as we can with coming up with draft certification criteria, but there's more work that needs to be done and that will have to be done as part of the rule-making process. And then after that, as I think we've discussed with all the other activities, you'll get a chance to comment and everyone will get a chance to go through the public comment box.

So, just in terms of setting up the context and for folks to know what they're going to be signing off of in terms of recommendations, we recognize that it's an imperfect table, but it's the best that we could do under the time that we had to do it. So, I will turn it back over.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Great, thank you. This is Liz Johnson. I first want to orient you to the document itself. If you'll notice, and it's in your handout and I'm sure Post at this point, but what it is is it's a Word document that's set out in column format. Each row represents a meaningful use criteria or something that we need to speak to and there are 54 rows that we went through and assigned information to.

The second column actually speaks to what the Meaningful Use Workgroup assigned us to take a look at to then examine against the current certification criterion that was in existence. Then we went to the next column, which is the fourth column, which says did we need to change this or not and what is our recommendation. And then, finally, if appropriate there was a recommended standard implementation specification added to it.

What will be part of the final grid that Judy referred to earlier is actually the testing procedures and additional information in that manner. So, we have highlighted the areas that we're going to go to. This is a very intense document. As Judy said we have spent many, many hours with the Workgroup on this. So, we are encouraging you, as you have more time than we have today to look at it, to give us your comments. Please get them to us immediately. Get them to Judy Sparrow because as we submit this towards the end of this week this is the time that we have for the criteria itself to make changes. So, given that orientation I'm going to take you then to the second page of the document and to row three and this is simply to tell you that this is the part of the document that deals with electronic prescribing as is indicated in the fifth column we will take the recommendations that came from Jamie Ferguson's group this morning. They will be incorporated into this document so we will be in a direct alignment with Jamie's group and that's how we'll move forward.

When we are simply moving forward with another power group Word we are not going to stop and ask for questions, as we did discuss that this morning. So, from there then we can move to row five. And, again, these are more notes around the work itself. This is the problem list. This is where the Meaningful Use Workgroup has asked us to do a problem list.

There is no proposed change, but as we went through the document we noticed the use of the word longitudinal care, but there is no definition for longitudinal care, so we are directing this as a work to be

done. We need CMS or someone to come up with a definition because we know as we go through testing procedures that persons are asked to test against it. It's very hard to test against things that are undefined. You'll note as you go through the remaining part of this document that that definition is used on rows five, six, seven and 22, so it's very important that we actually come to a definition related to that.

So, then there are no more further highlighted areas until you get to page six and that is on row 12 having to do with clinical quality measures and I will hand that one over to Steve.

Steve Posnack – ONC – Policy Analyst
Okay, so this is a Back to the Future question, which some of our discussions today have already addressed. We included in the first rule the PQRI XML Registry specifications for quality measure reporting CMS. Since then, there have numerous discussions, alignment of quality measure programs. CMS put out a proposal for a pilot. They all point to QRDA as the reporting mechanism. Don't need to get into the levels, just need to get into what type of standard is used to report. It may depend on the program as well. There's also a philosophy that folks are going to be using their EHR technology to do reporting for multiple programs.

You may want to certify at all three levels of QRDA and then let policy determine which ones need to be used for a particular program reporting, so wanted to get general feedback on does everyone see QRDA being the direction? Obviously, it's also dependent on CMS saying that that's the direction and capacity in terms of them willing to accept the data.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Marc, you have input?

Marc Overhage – Regenstrief – Director
Yes, I think, obviously there's been some good work done trying to think QRDA and CMS has at least once before said we're not going to use it. I think there are, as you try to use at a more granular, individual level, QRDA very pragmatic problems. We talked a little bit earlier talking about exchange and the problems of scalable implementation and I think those are very real yet with QRDA and they haven't been sorted out.

So, from a technologic standpoint, it seems not ready for prime time. They're not another, obvious, alternative and so then the question becomes do you try to fix this or do we have a fall fun festival, right, Doug, is this playing the fall fun festival this year? And try to come up with another alternative that addresses some of those problems.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
First of all, I think Octoberfest sounds better than fall fest. That I can help you with. But I think the challenge with QRDA is basically what Mark had indicated. But what I did hear through the morning, including Farzad's comments, is to get something that at least has some capability out there and get it used.

I think having a decision is better from the quality measure standpoint because as we look at measures being specified in HQMF eMeasure format always thinking about so what's the report out going to be and if we're not sure we end up with requests to put things in the measure that don't belong there, but belong in the report. So, I can't say that QRDA is the right or best answer. I do need to remind the group that only level one or, is it level or? Category one, I want to get the right term; only category one was approved as a DFTU address standard. Levels two and three were not balloted. I'm not saying that to be negative; I just want to remind you of the facts. So, I'm sorry I can't give you glowing recommendations, but I think it would help to have something and, again, as Marc had said there's nothing else clear that's out there.

Marc Overhage – Regenstrief – Director
Yes, in the prospective I trust that the PQRI XML doesn't seem sufficient?

Steve Posnack – ONC – Policy Analyst
Yes, a lot of it is also dependent on CMS's capacity to receive the data and if they decide is QRDA is the direction that they're going with it. I think some indications have been already that that would be what they would require or expect to receive, probably to be more precise.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, John, you see in the column we actually posed a question.

John Halamka – Harvard Medical School – Chief Information Officer
And that may be okay or go to Carol. Let me just point out the point that Floyd made that part of the recommendation may be the comment of what belongs in the measure and what belongs in the reporting and that in and of itself is helpful. Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, I'm just reflecting on the day a little bit as well. I think it only helps to have something if it actually works and does the job. It makes it worse if it doesn't. So, I'm going to make a recommendation and I think this is a gap that we've identified for (audio out). I don't know how this all happens, but there should be a group that comes together that determines whether one of the existing standards needs to be expanded to accommodate this kind of reporting or whether QRDA needs some work or what the right approach it because I think we're going to keep coming up against this and I would hate for our default process here to be, well, we know there's something out there, it's got some serious problems, it can't really be used, but it's what we've got.

M
As we found out with Stage 1 pilot testing some of these things was absolutely key, so one would wonder that if we see the directionality from CMS is QRDA, then through the S&I framework or some other context we actually put it through its paces.

Judy Murphy – Aurora Health Care – Vice President of Applications
Because just to comment, one way to drive the development of getting it to be good enough or better is to directionally look at making it the standard so that then we put effort into it. Again, there is nothing else. So, these were the comments we were looking for, though, from the group I think.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
There is nothing else like it, but I think there is the option to expand other things to accommodate the same function and I think all of that should be under review, and not just assume that because that's there that that's the only thing. I think there are other vessels that could be used as well.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
If I could make one more comment. I understand Carol's comment and I agree. I think that what I did hear in Doug's comment was having gotten something through in HL7 valid in two ballots, since this is already and DSTU perhaps some work could go on to get it in, if it's still possible to get it approved for January's ballot to upgrade the DSTU to something that is more implementable and then pilot. Just a suggestion.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
All right. Thank you for your input. We will make all of those comments part of the grid so that they'll have the appropriate direction.

We want to now move to line 15 and, Doug, we'll be calling on you for line 15. He's looking quickly to see what it might be that we might be calling on him to do. What this is about is the laboratory results. You provided us with input on laboratory test results and so we have, again, looked at your summer work, but we didn't have it until today to include comments. So, Doug, if you want to talk about that.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability

And… should be on the phone as well. We sort of exchanged some e-mails about this even during the day. That's what I do in my spare time. I guess one of the questions was whether or not that particular standard or specification would be suitable to sort of beat this.

Within the S&I framework, and hopefully… can correct me if I misstate this, we did solicit input from hospitals. In larger part there were fewer people that participated than we would have liked, but there was representation from vendors who served that community and this was included in sort of the assessment, so the quick back and forth would suggest that this would be a standard that could be used and supported for the hospital to provider interfaces as well.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
The other thing that we were putting to you was the MPRN that just came out from… recognizing that it's brand new, but trying not to create difficulty of work for the persons who are participating in all of this, so we'd ask that also be taken into consideration as part of this process.

All right, great. So, we will now move and, again, there's nothing like being the last topic before the White House. There's no pressure here, guys, whatsoever. So, now we'll go to row 18 and row 18 is a new requirement for Meaningful Use on the use of electronic notes and there are several things we just want to point out to you.

First of all, we did provide a definition that can be examined in terms of the criteria about what electronic note is. But there are a couple of things that we need to point out to you. First of all, again, there is a new definition called for here, which is eligible hospital days. We have provided a starting definition for hospital days to CMS. It will be their responsibility to provide us one back, but this is certainly a standard definition that is used very universally.

The second thing in what we need some input from you on specifically is does this definition need to be broadened to the ED for treat and release patients? The reason we're asking the question is we know that in measuring CPOE/ED patients were a great source of discussion and occasionally controversy and some of our physicians on the group wanted to know if they would be included and if their ED patients would be included for electronic notes and would we use a per visit measurement in lieu of a hospital day? I know it's a lot to swallow. I know you probably haven't read this thoroughly, but I think the concept is pretty clear, asking should ED patients be included in the concept around electronic notes or not. Wes, your spring is not working.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Hey, I'm out of my depth here.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
The general consensus from the Workgroup is that they should be included and that we would include them on a per visit measurement. So, if we don't hear from the group otherwise then we will go forward with that recommendation as a part of this process. And I'm seeing no problems with that, so we'll move forward.

And then we also provided for you, for your reading really, just a comment back from the Meaningful Use Workgroup because we had a lot of questions about free text and scan documents and what would be accessible, so as you read this document you will see that they were really trying to allow persons to get into this business of electronic notes in a very real pragmatic way. David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Does the notion of an electronic note have a time window around it? In other words, is a dictated, transcribed note that shows up a day later considered an electronic note?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
It's considered an electronic note.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, it has to be text and searchable is really what they're after.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, and that is exactly the criteria that we got to was text and searchable. So, just good comment. Any other comments on that one? We'll go to 19 now. Number 19 is, again, a new standard and this is where we'll be able to do medication orders using electronic medication administration record. This is a very complex standard. We wrote to you and provided to you all of the rights that the Policy Committee called out, the right patient, the right medication, the right dose, right route and right time. So, that's all in there so that you could understand what will be included.

But what we recognize is because this capability has never been asked for before and there are no standards, we're going to have to get further definition. So, in order to get through testing we will have to work with testing methodologies to be able to come back and make this reasonable, but we feel very confident that we have covered the full gamut in terms of what is required to do a medication administration record appropriately.

Great, we've either worn them out; oh, we have one.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I'm sorry. I don't understand 19. Are you saying that the certified EHR has to have a bar code methodology without saying bar code methodology? I'm not sure I understand that one. I am a nurse, I've delivered medications, so I just don't know what this one means.

John Halamka – Harvard Medical School – Chief Information Officer
It's a closed loop for secure administration consistent with the electronic medication administration record. I think it's agnostic in terms of the mechanism used for the secure completion, but specifying the attributes of the five data elements that need to be completed in closing the loop.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That's right, John. If you read, in the context we were very careful and said you can use a bar coder or you can visually match, so we were very specific in assisting the persons who would be following this advice, or this criteria, frankly, that you have the choice. You are not required to use the bar code. It certainly is an option. Does that answer your question?

Tim Cromwell – VHA – Director of Standards & Interoperability
It's so hard to actually write criteria for because there are new technologies that do facial recognition of the patient who is in the bed. So, do we want to use RFID, do we want to use bar code, do we want to use biometrics, do we want to use DNA, do we want to do facial recognition? The answer is they're all fine and who knows what technology tomorrow will bring?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
And we were really trying to leave it open so that we would allow innovation. Doug, did you have something?

M
We haven't made a point to say in this, Tim, but the actual criteria from the Meaningful Use Workgroup, the measure, is in that second column and so when we were doing our definitions we were taking it right off of the direction that we got from the objective from the Meaningful Use Workgroup.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Doug?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
My question has been answered with the clarification, thanks.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

All right. We will now move to number 23 and this is a very challenging criteria. And I think what we'll do is all of us have input with that. Steve, do you want to start with this one or have Judy do it?

Judy Murphy – Aurora Health Care – Vice President of Applications
I'll start. I'll start by setting up why this was a difficult one for the Workgroup to handle. The whole concept of a patient and how they're going to interact with their personal health record information and/or their own information, let me say it that way, because a personal health record would be one way of doing that. Another way of doing that would be through a portal and that's where this view and download concept really came from.

So, there was a lot of discussion in the Workgroup as to whether or not there had to be a portal, there didn't have to be a portal, there had to be a PHR, there didn't have to be a PHR. And with that context, I'll turn it over to Steve. So, I'm just kind of setting you up there.

Steve Posnack – ONC – Policy Analyst
Thanks. So, I think what would be most helpful from the Committee and what we're probably looking for most would be some direction in terms of, I don't want to say, settling, but greater feedback in the tension that the Workgroup had relative to crafting a certification criterion for this objective. And so when you start with the Meaningful Use requirement it's that healthcare providers are responsible for making sure that a certain percentage of patients and families have the ability to view and download their health information.

And if you start with that, then the next things that we can do on the certification side to ensure that there's a requirement that allows the provider to select EHR technology that's been certified to accomplish that. And it could be implemented by EHR technology developer that offers a native portal or PRH or other type of direct interaction with a view into the EHR technology or it could be through another means, through a third party, but the question remains and I think is where the tension is is that should the third party also be required to be certified to provide view and download else we have a question as to whether or not it's actually possible for the patients to view and download that information.

Tim Cromwell – VHA – Director of Standards & Interoperability
So, I would take a stab at that, and that is in the concept of this modular certification that is I buy a complete EHR, I'll make a use case, that has the capacity of sending a patient summary via Direct to something that can receive it. But it has no portal or blue button or anything in it. Well, if you had a modular certification of HealthVault, as the recipient of that message that had the capacity to push a button and then see it, then you would have achieved what needed to be achieved through the combination of the two products.

So, you would say either or. It could have a blue button in the EHR, could have modular certification of due products; as long as you get to the end result.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So, I want to just say that I don't think either or is actually good enough. The first thing I want to say is that the view part was already in Stage 1. So, now we're just talking about downloading the data that the patient supposedly already was able to view, and presumably to view you need some secure log-in. So, it's nothing more than that.

I think one of the things that's confusing here is the terminology. When people hear portal, they think tethered PHR. And I think the advantage of view and download is that it doesn't require the patient to sign up for a service, get an account with HealthVault, find a third party to help them see their own information. It is just a secure log-in through which they can view and download their own information.

Now, they may want to store it in Word, they may want to put it in Excel. They may want to do nothing with it more than that and I think if we don't have a certification criteria that enables that at a minimum then what we are saying is that the individual has to find some service to get their own information and that may not be ideal. That is not ideal. I think if there is this secure log-in and the patient wants to use a

third party to manage it or wants a HealthVault account or wants to put it somewhere else. That's great. It's the same doorway, if you will. But I think not to have that as a function of qualified technology just makes it very hard, harder than it needs to be on the individual to get their own information, which, in fact, in Stage 1, we really should have been already down that road.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. The term portal is defined differently, even within the technical community it's defined differently, so my advice to you is to avoid the use of the term completely. And my second piece of advice is you have on rows 46 to 50, and these are security and privacy requirements, they came out of the Tiger Team, but they all have to do with patient's access to their health information and I suggest that you move all of those requirements up to this 23, because you really shouldn't have view and download separate from the security requirements around it.

Steve Posnack – ONC – Policy Analyst
So, if I could just consolidate, we'll use that word, the comments, the fundamental principle that I seem to be hearing echoed or suggested is that regardless of whether it comes with what the doc has purchased or if they select something else that needs to be able to perform view and download. They both need to be certified. Does everyone agree with that? Okay.

And then, as Dixie mentioned, the…, then if that's the case, then everything in those rows that Dixie just mentioned would apply to either scenario, whether it's built in in what they've got or the provider elects to find another way to satisfy that outcome.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And whether they call it a portal or not.

Steve Posnack – ONC – Policy Analyst
Whatever it's called, whatever EHR technology it is.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So, I would also suggest in rows 48 and 49 you just delete the term portable.

Kevin Hutchinson – Prematics, Inc. – CEO
The discussion we had, Steve, as you remember I was totally with you where you said it needs to be certified and then the phrase comes in of EHR, which is just a confusion. And so the technology that Carol has just described could be lots of things that don't include an EHR. So, the question is are we talking about certifying Microsoft HealthVault? Are we talking about certifying some other thing that could be extendable from an EHR, and I understand you've got a statutory problem here and it feels kind of tough to hold you up against that, but we've got to resolve that nomenclature problem.

Steve Posnack – ONC – Policy Analyst
I think it's a terminology issue. The definition of certified EHR technology as we've established it is a construction and it means whatever technology that you use that's certified. And so, if that requires HealthVault to get certified to be a module, then that's how it plays out. And to show that it can offer view and download if that's providers would like to use to meet Meaningful Use and it's part of their construction of "certified EHR technology." The same is true if they want to use a public health agency to do their immunization reporting. The public health agency would need to be certified today as a module.

M
So there may be a challenge that's introduced by opening the door to HealthVault becoming certified or maybe in some locality maybe the local HIE is providing a PRH, all those sorts of things, so I think we need to note that, but the alternative is for us to force fit everything into the EHR meaning what we might classically think of as EHR is really, I think, a confusion.

Steve Posnack – ONC – Policy Analyst

And we've definitely seen and experienced that, that is, there are classical definitions of EHRs that folks have hung onto and tried to relate to what we have dealt with with the statute.

Kevin Hutchinson – Prematics, Inc. – CEO
How much flexibility do we have on the wording of, I guess, what the Policy Committee has put forward on the definition? I have a concern where it says, "more than 10% of patient family's view" and then it says, "have the ability to download." If only 5% of the patients actually ever go in and view it then they're not meeting the criteria according to how it's worded. Shouldn't it be, "more than 10% have the ability to view and download?"

Judy Murphy – Aurora Health Care – Vice President of Applications
I happen to be on the Meaningful Use Workgroup, so I'll comment on that one. The intent actually is that we, as the healthcare organizations or as the payers or whoever we are, that we have an accountability to help market this and sell this and help patients see how important it is to partner in their healthcare. So the intent was that we figure out how to ensure that 10% are actually doing this.

Kevin Hutchinson – Prematics, Inc. – CEO
Yeah, good luck on that.

Steve Posnack – ONC – Policy Analyst
But just as a point of order, the Meaningful Use side is kind of off limits because that's already been dealt with and we're working with CMS on it.

John Halamka – Harvard Medical School – Chief Information Officer
I do have a question, though. If the language is inconsistent, regardless of the recommendation, there's a structural issue that we can't support with standards.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
And we'll put that back.

Martin Harris – Cleveland Clinic – Chief Information Officer
So, I'm back to this question of the 10% again. I hear you, but I just think that you need to get that information from both sides of the fence and that we need some clear understanding about what we are placing on patients. It's one thing to market. I have no issue with the marketing. We drive that all the time. But patient choice is incredibly important. So, I'd just set that aside.

I think the second, I wanted to go back to Carol's point because I'm not sure I heard the answer. So, if I just want to load it down into my Word document, does that count? It does. So, what has to be certified on that?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
The capability of downloading.

Martin Harris – Cleveland Clinic – Chief Information Officer
Only the shipping side, not the receiving side, but HealthVault would have to be certified?

Steve Posnack – ONC – Policy Analyst
If that was what a provider wanted to use and they wanted to get into that area of the market to provide this capability, to construct their definition of certified EHR technology, then they could go ahead and get certified. They would say we provide the capability to offer your patients view and download. You can use us to accomplish that Meaningful Use objective.

Judy Murphy – Aurora Health Care – Vice President of Applications
I know where you're getting confused, though, because if the patient chooses to use a certified electronic health record to download and then they take the information and put it in HealthVault that's a different

kind of use case and we're not actually addressing that. HealthVault for that purpose wouldn't actually need to get certified.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
That should be okay, too. In other words, the capability has to be innate.

Martin Harris – Cleveland Clinic – Chief Information Officer
Right. I just wanted to be clear. And so from a vendor point of view, if I were interested in that space for some reason, I'm just trying to understand the distinction. So, you're not asking Microsoft to certify Word in this process, right? And I'm just asking would you be asking a vendor who could provide that service otherwise, who is not in the EHR portal business whatsoever, it just so happens they have the ability to do it, would they have to be certified?

Steve Posnack – ONC – Policy Analyst
So, certification is voluntary. They don't have to come forward. There's no mandate or requirement. If they want to be able to market their product as being able to do view and download that providers would be able to subsequently use to offer their patients that capability, then – I'm not offering advice – it would be in their interest to go ahead and get certified. Otherwise there's no express requirement that they have to go get certified.

M
Wouldn't it be the case that the only case you'd have to worry about is if there's a vendor ABC who has the capability to reach into EHR vendor Acme and pull data out and insert it into a PHR, then EHR is not providing that out-link capability and that vendor XYZ would have to become certified. Other than that, I think what you're saying is as long as the EHR has the ability essentially to expose and publish. Publish is the wrong word.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Publish might not be the wrong word. So, I'm very appreciative of Carol's position that it needs to be easy for the patient to do it, but the mere provisioning of a secure log-in is a sufficient step to create a direct account for a patient, for example. Partners could do that with exactly the same amount of work, so you could imagine a scenario where when the patient says I want to be able to download my record and they go through the provisioning process to get a secure account they have, in fact, created a direct address at a designated PHR partnered with that provider or if the patient already has one they say use this one and it would be just as easy and automatic as if they literally downloaded it to a file on their disk and then proceeded to lose it.

So, I'm anxious to make sure we define an outcome rather than the outcome is that the patient can easily get a copy of their record. And that download might involve a transaction using a standard protocol like Direct or whatever else we choose and not to say that it has to be only a download. I mean in the long run we're better served if the patient accumulates this data in a secure and manageable place instead of having files strewn around, which is not to say we shouldn't allow them to have files strewn around if that's what they want, but I would urge us not to define it in a way that requires that it must be just a file download. So, if we can get through Direct to a place where the patient can easily manipulate it that would seem to be just as good.

Jonathan Perlin – Hospital Corporation of America – CMO & President
So, I'm going to borrow Steve's point here. On the consolidate thus far we've heard first that there are a number of use cases that become problematic, but the intent of providing both view and download is understood. Second, we've heard a comment that the security recommendation should be consolidated around both of those conditions, view and download. Third, that there is an inconsistency in the language that needs to be resolved so it can be best supported with standards, though in technical terms beyond the scope a concern that patient behavior is difficult to regulate or mandate. The point has been made about the choice in that instance.

So, I wanted to just to catalog those we may not be able to resolve, but just identify as issues that will require consideration and certification. I probably left some out. Quick, Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
So, to David's point then, because the measurement is on views, it seems we should come back and make a recommendation that a download is considered a view, because to your point if it's direct and you're bringing it down, because there is no measurement on the definition on downloads, on how many downloads. The 10% is on the viewing and the ability to download, so it seems to me that if we do have a transaction where people are downloading their information, we just need to make sure that it's considered to be a view.

Stephen Ondra – NeHC – Senior Policy Advisor
This might be a…, but it strikes me that the more different ways that we allow the patient to download their data, or we enable the patient to download their data, the harder it is to count views. Just think about if a patient chooses, prefers to have their data sent to a PHR and then view it there, how does the institution that was the source of the data get to count that? If you can list a little series of things that need to be resolved, I think the ability to count the views through third party needs to be part of it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good point as well. So, there are five issues to take back as considerations in this one.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Thank you for that input. With that we'll move to row 26 and this is about, again, enabling secure messaging. And certainly we will get the secure messaging feedback from Dixie, from your group and add that to this group. We didn't have it to add. That was our note to NIST specifically is that we need the technical capabilities that have been sussified by your power group to be included within this criterion. Anybody have an issue with that? Good.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The Tower Team really didn't address patient secure messaging. Between providers was our focus, but I'll assert this right now. Walter and I would like to request the opportunity to show all of these security recommendations to our Privacy and Security Workgroup and we'd to include this one as well.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That would be terrific. As I think Chris said, this would be an extra bonus assignment if you were willing to take it.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
And the only issue is going to be when do you need it by?

Steve Posnack – ONC – Policy Analyst
This is it. I already have clearance deadline that I need to meet in the next several weeks, so this is where the handoff is occurring. The feedback will be helpful in terms of when the MPRM comes out for comment, but we have to hit our kind of tentatively scheduled deadline of January, so we're up against a wall to do that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, I've requested a number of times that our Privacy and Security Workgroup have an opportunity to have inputs into this and I still would respectfully request that.

M
I would guess that this is almost directly analogous to the previous discussion in that you could accomplish this by built-in secure messaging Web forms part of the EHR, or you could accomplish it via Direct to a third party PHR or some other service and it's exactly analogous to the download question and, hopefully we've solved them with the same answer, meaning that if it's acceptable to use the PHR in one case it's acceptable in the other.

Steve Posnack – ONC – Policy Analyst
I think we want to be as flexible as we can to accommodate the use cases that folks have brought up, underlying this is the general principle that whatever is used needs to be certified.

M
This is allotted you to count; that is to say you know that a messaging interaction happened. Certifying it is very difficult, but counting it for Meaningful Use is pretty easy.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
All right, so chair persons.
M
So, Steve if you could just do a loop with Dixie's group on the pledge of rapid input that's helpful.

Steve Posnack – ONC – Policy Analyst
Sure. Do you have a time frame that you have in mind?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It wasn't two days, I can tell you that. By next Friday, let's say. A week from Friday.

Steve Posnack – ONC – Policy Analyst
I think if you can get it into the next Standards Committee meeting it will still.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Cool, we'll take it.

Steve Posnack – ONC – Policy Analyst
It would be helpful to have your input. I can't guarantee. We'll try to take in any suggestions, but it will already be going through.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And we'll try to get it to you as quickly as we can.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
And with a deadline of the following Standards Committee meeting, that's terrific. Thank you. I think we'll move to 27 now and what we were looking for is more of an FYI, but we were going to query this group. We were unable to identify. This is the ability to document a patient's communication medium preference and we were unable to find a standard for that and wondered if anyone was aware of such a standard. And then we certainly went on and gave other direction, but we wanted to query this group as one last sort of ditch effort to identify that for Steve and his group. And I'm thinking there are no hands going up, so there may not be one. Okay, great. Steve, we'll leave that to you then to take our other direction and figure something out for us.

We'll move now to row 29 and you'll see in the far column on 29 and you've seen this several times now where we have tried to leave open the recommended standards to be inclusive so that we would continue the same philosophy that we've used in the past. The one question that we've not discussed today and I don't know sincerely whether we have time to have this discussion, was are we moving to a single standard between CCD and CCR?

That continued to come up in our meetings. We did not attempt to answer that question. The rest of this we feel very comfortable are the right standards as appropriate. You'll notice that we have listed RCD10. That is under the supposition that we are going forward with the timelines that have been currently still intact. I do not know whether you wanted to approach the CCD/CCR.

Judy Murphy – Aurora Health Care – Vice President of Applications

Let me ask the question a different way. And I don't know if this is to Doug or who, but you, obviously, talked about the consolidation of this in the S&I framework so the question is at what point do we harmonize this work with the S&I framework?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I think even in Stage 1 Meaningful Use there were two standards that were adopted, but there was language to say that we would like to eventually see a convergence that would occur. The efforts of the transition of care was to try drive that forward and I think we've had some successes there. I think it remains kind of a decision of the Committee here to sort of provide some directional recommendations around that, but we are trying to tee up all the things that would allow us to begin to converge on a single set of standards.

M
And so I mean generally as this Committee would probably respond to that is I think we're all for the parsimonious number of standards and, boy, it sounds really great what you've done, but do we have active, deployed, templated CDA summaries in production yet?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
It's been less than 72 hours since it was approved as a draft standard for use, so I can probably say no.

M
So, maybe this is one of those timing issue is that sure, once it's out there in production, once it's out there proven successful it sounds very reasonable, but there has to be a glide path to get there.

John Halamka – Harvard Medical School – Chief Information Officer
Totally agree. Just as a quality metrics cannot strip the data model so too the certification can't outstrip the standards. But I think the glide path is pretty clear.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Then I think what we will do is as we move these certifications and criteria forward we will leave both options in place waiting for further guidance, okay? All right.

I think now we're going to move to rows 31, 32 and 33. I'm sorry, Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just a question. Would it make sense to think in terms of a transition period? It seems to me, though it's anecdote, that the reality is that very few organizations of any type are supporting CCR and if we could provide any sort of roadmap clarity about our guests within 18 months or two years or something and it could be presented just as a guess or sense of the Committee. It seems like that might useful to the industry.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That's a good point, Jim. And I think that as we move forward with further work from this Workgroup you will see those sort roadmap specificity and we will include that in that discussion.

M
That point is something that the Implementation Workgroup has brought forward in terms of helping to telegraph what the glide path does, notwithstanding the practicality of what exists at the moment.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Right. All right. We will move then to row 31. This is the attestation around immunization registries. This is only moving to core, but there was a thought that came out of the survey data that we wanted to share with the group that we recommend and that is that the ONC may want to split the two capabilities that have been described. One is the ability to record, modify and retrieve immunization data. And the second one, and you're going to see this theme repeat itself is to submit the data.

And the survey data that we took and received from across the industry was that there are modules that are sold to do these activities independently and today they cannot be certified to do such, so we are bringing this forward for your consideration. And, again, you will see this theme repeated twice more and it came out of the survey data. So, what is the preference of the Standards Committee? Is there any objection?

Judy Murphy – Aurora Health Care – Vice President of Applications
So, this is very similar to the discussions that we were having related to the view and download. Okay, so if there was functionality in a health information exchange, for example, to be able to pull that information out of an electronic health record, then would we want to allow individual certification of that ability to submit, so kind of that polar aggregator and submitter, if you will, as compared to that coming directly out of the EHR.

M
I'm just not clear. In 17302K does it literally mean retrieve from a community source? I mean record, modify and retrieve sort of looks like it's applying to individually HR as opposed to the thing that would be very valuable for vaccinations, which is to go to the state registry or whoever is available.

On the other hand, so this is certification, this is not measurements for Meaningful Use. Then just clarity is all I'm concerned about.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
For the group we're going to assume that since we are not hearing an issue with the fact that we would be able to do these two activities independently that we will move forward with that recommendation 201C for their consideration. All right.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy
Well, the word and right after record, modify, retrieve and submit is the one that might be creating the expectation that all four might have to be achieved and if you change it to or instead of and that might create the opportunity to say the system can do either of those.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Sure, Walter, that's a good point. The adopted criteria was the previous criteria, the new criteria. So, I think you're exactly right. We'll put the word or in.

Steve Posnack – ONC – Policy Analyst
It's not even an or means and in this case. The construction of a certification criterion is at the power graph level of the regulatory text, so everything under K is one criterion, so it does need to physically be separate. We need to be the next letter in the alphabet, so to speak.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Okay. So, we're very short on time. I'm sorry, did you have something?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I agree with the split, but it does seem to me to fall upon Wes's that it would be good as a follow-on to build a careful map, process map for what this looks like. The care organizations are going to need to be able to receive them at some point, and even if that isn't now, it's hard to read these verbs and map them onto what we, in fact, do.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
And actually use case, right.

Steve Posnack – ONC – Policy Analyst
I mean, we're looking at the phrase because we use that in a lot of places and how it's communicative in terms of each individual certification criterion. It is an outbound related criterion, so it isn't bi-directional.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Right, but part of communicating that might be to make that clear and part of that might be to have the whole model and say this is just this part of the model we're talking about. I think it would be easier for more people to understand what was at issue.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, from there I think what you'll find is that 32 and 33 is exactly the same premise that we've suggested to you, that we'd be able to do the same thing with portable lab result and with development surveillance. So, pending that there is not a concern with that, we will move forward with those recommendations as well. And with that we are able to close our report.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, a lot of material very quickly and appreciate that. Appreciate the opportunity, Steve, for Privacy and Security Workgroup to weigh in. And under just I think the point that a mapping of a the use case so that all the scenarios can be anticipated may reveal areas where further guidance is required understanding that you've got a regulatory cycle to honor.

So, if there are comments to provide back, certainly let's get those to Liz and Judy and then Steve, to make sure that the end of that handoff is completed. Kami?

Kamie Roberts – NIST – IT Lab Grant Program Manager
Yeah, I just want to make a quick comment. I wanted to thank the Implementation Workgroup. They worked really hard over the past week to address a lot of the comments that NIST had to make the criteria more testable. There are still some concerns that we have, but we're going to work with them and see if they go through the drafting of NPRM to try and get them resolved.

There's also continued issues with criteria that were carried forth from Meaningful Use 1 that there continues to be questions and we'll work with them and CMS as well.

M
Thank you for saying that. That's Kamie Roberts from CMS . That interface is absolutely critical to all of the different communities that intersect around Meaningful Use so appreciate your support.

Steve Posnack – ONC – Policy Analyst
When I finish my baton hand talk, just for everyone else's contact, the next step in the Workgroup is to do the testing procedures analysis and coming back with the recommendations in that and that's where we get into more of the operational issues, so Carol will be the recipient of that wisdom.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I just wanted to bring to your attention, Judy, that line 52, row 52 is not security and I suspect that you're going to get some comments about it. It's about amendments and lord knows, I don't want that on Security's back.

Steve Posnack – ONC – Policy Analyst
It's generally lumped under the category of Privacy and Security, so.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't think so. This has to do with amending a data element in a record.

Steve Posnack – ONC – Policy Analyst
Right, under the construct the Privacy Rule provides individual rights so that is why it's under Privacy and Security, for lack of a better area.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

And so if you want for us to take that one back and do the same thing, while you're working on the Privacy and Security, if you would like for us to take this one back, we had assigned Privacy and Security under our guidance. We will take it back.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yeah, I was thinking that people in this room would be interested in providing input into that because it is beyond Privacy and Security.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
No, that's a good point.

Judy Murphy – Aurora Health Care – Vice President of Applications
We hope we whet your appetite to go through the whole document in detail.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, do you have any other closing comments? Terrific work. This is where the rubber hits the road. It comes together with work with CMS and appreciate Kami's comments. It also comes together in this test strips, so I'd ask the group to be thinking about the pragmatics of that implementation, any guidance that you would foresee to make the previous work of the standards that have been identified, recommended to support the Meaningful Use policy really represented as accurately as possible by the subsequent guidance and testing implementation. So, thank you very, very much for that.

Let me go immediately to Judy Sparrow for public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Right. This is the time we invite people to make public comment. Anybody in the room that wishes to make a comment, please queue up at the microphone and if you're on the telephone, you just need to press star one. If you're on your computer, please dial 1-877-705-6006. Please state your name, your organization and there is a three minute limit. Sir?

John Valutkevich – MEDITECH – EMR
Good afternoon. One question on row 23 in terms of the recommendations, two points, please. Note to HIC, the number of downloads should be electronically counted or tracked for issues of compliance and measurement. That would be the certification requirement I would presume.

And then I'd just bring to light something for consideration the legal ramifications of that. A patient that views and/or, more importantly, downloads that information is going to take it onto the next location perhaps for some medical decision support. Where do we draw the line in the providing EHR third party portal viewer for keeping a copy of what was actually downloaded? So, something to think about there, please.

And on the other side there, in terms of the recommendation for the certification criterion, it's just curious to me that if this is for the patient to view and download, the human readable format, I, as a patient certainly understand, probably going to use it for my own information, bring it to my doctor. But then we get into that it appears that it also has to display and be codified with all the standards next to it. What you would expect in an interface exchange for a CCD or CCR for data walking and making medical decision support, but if I have a human readable format that includes all kinds of standard nomenclature in it also, I'm wondering about the usefulness of that. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, John. Carol Bickford, ANA.

Carol Bickford – ANA – Senior Policy Fellow
I wanted to say thank you to Judy Sparrow for her significant support to those of us who are consumers of the activities of this Committee. We really are sorry that she's headed out to her second life.

Judy Sparrow – Office of the National Coordinator – Executive Director
Pasture. Thank you. And we also have Mark Siegel on the line from GE Healthcare.

Mark Segal – GE Healthcare – Director Government & Industry Affairs
Yes, thanks very much. And also, many thanks to you, Judy. I'd like to thank the group for a terrific NWHIN discussion earlier. As the ongoing issue that you've identified it as, I'd really ask the Standards Committee and ONC to look carefully at the detailed comments that the EHR Association delivered earlier this week on the Power Team materials. I think they remain very relevant and I'm sure EHRA would be happy to elaborate on any of the points.

Clearly, there are issues here and there with the analysis, but I think in my view, especially with the conclusions that as finalized or as put in the document today seemed in balance on exchange relative to Direct. And I certainly agree with Dr. Mostashari on the need for a portfolio of approaches, including both push and pull. And as you all know that's really how Direct has always been positioned, as a push approach to complement other push approaches and Exchange in other pull approaches.

What the Standards Committee and ultimately ONC recommend or issue in regulations will really be critical as signals to the market. Vendors and providers have already invested in using Exchange and related HIE type capabilities, but broader uptake in investment has really been constrained by uncertain federal signals around transport. So, we need to focus on what can be done now, but also what can be done in the medium and even longer-term given the kinds of investments that are needed for HIE.

Also, I really appreciate Wes's recognition of the need to look at the Exchange siblings being used more widely and effectively locally and regionally. Although we shouldn't assume that these are one-offs or done outside of SDOs. To the contrary, many of these are really focused on using XDF, CCD and other standards and profiles.

And so, finally, I think ultimately what's defined as appropriate for the NWHIN and that gets at the implications of your work, really has broader implications for HIE infrastructure and for Meaningful Use in certification, particularly where it references things like Direct that have both local and national implications. So, I thank you very much for your time and for a terrific meeting today.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mark, for your comments. And there are not more comments on the phone, so I'll turn it back to Dr. Perlin and Dr. Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Which brings us to the end of a truly remarkable meeting, very robust discussion, a huge amount of work represented behind, meets the goals not only of transport across the network, but serving a broader improvement of health and health care. I appreciate Carol Bickford's comments. I think you spoke very eloquently the feelings of all of us.

As hard as it is to believe the amount of progress that's been today, the amount of work that lies ahead is equally difficult to believe and accept that Judy Sparrow will not be at our next meeting and so we all join in great admiration and appreciation and look forward to celebrating a terrific year or a terrific career and we certainly remember this not only as summer camp, but as a symbols of not just professional association, but friendship. So, on behalf of all of us thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What more can I say that hasn't been said, a fabulous summer camp. You all get a medal. You know, I've done this for ten years and I would say what I've said before, you are the most collegial, extraordinary

group I have ever worked with and we have made amazing change and will continue to do, to thanks very much.

John Halamka – Harvard Medical School – Chief Information Officer
I think that we stand adjourned. Thank you.

Public Comment Received During the Meeting

1. HITSC Implementation Workgroup Recommendations for Certification Criteria, Standards, and Implementation Specifications to Support HITPC Proposed MU Stage 2 Objectives and Measures. Line 18: regarding "eligible hospital days" . Comment: Payers (insurance companies) pay providers (hospitals) as per a contract. Contracts in the commercial realm are often by a "DRG Payment". That is one fee is paid to the provider (hospital), regardless of the number of days the patient is in the hospital, as long as the number of days is below the trim point. In other words, this is a “lump payment”, instead of a per-diem payment. Thank you

2. Please #HITSC change MU §170.302(u) my blog tells why http://healthcaresecprivacy.blogspot.com/2010/10/meaningful-use-encryption-passing-tests.html I recommend http://healthcaresecprivacy.blogspot.com/2011/09/document-encryption.html

3. Please see all comments made by the general public on Twitter using the hash tag #HITSC http://twitter.com/#!/search?q=%23HITSC

4. Thank you to Ms. Judy Sparrow for all of her hard work and devotion. The work and accomplishments from the HIT Policy and HIT Standards Committees could not have been done without her expertise.