

**HIT Standards Committee
Final Transcript
February 29, 2012**

Presentation

Operator

All lines are bridged, Ms. Deering.

Mary Jo Deering – ONC – Senior Policy Advisor

Thank you very much. Good morning, everyone. This is Mary Jo Deering in the Office of the National Coordinator for Health IT. This is a meeting of the Health Information Technology Standards Committee, and welcome to the 33rd meeting of this committee. I'll begin by taking roll. Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Good morning.

Mary Jo Deering – ONC – Senior Policy Advisor

John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

Dixie Baker?

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

I'm here.

Mary Jo Deering – ONC – Senior Policy Advisor

Anne Castro?

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

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Chris Chute?

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

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

Tim Cromwell?

Tim Cromwell – Department of Veterans Affairs

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Carol Diamond?

Rebekah Rockwood – Markle Foundation – Manager, Health

This is Rebekah Rockwood for Carol Diamons .

Mary Jo Deering – ONC – Senior Policy Advisor

Lorraine Doo?

Lorraine Doo – CMS – Sr. Policy Advisory Office eHealth Standards & Services

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Floyd Eisenberg?

Floyd Eisenberg – National Quality Forum

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

Jamie Ferguson?

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

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Steve Posnack?

Steve Posnack – ONC – Policy Analyst

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Kevin Hutchinson?

David Kates – Prematics, Inc. – Vice President Product Management

Dave Kates for Kevin Hutchinson.

Mary Jo Deering – ONC – Senior Policy Advisor

Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Becky Kush?

Rebecca Kush – CDISC – CEO & President

I'm on the phone.

Mary Jo Deering – ONC – Senior Policy Advisor

Arien Malec?

Arien Malec – RelayHealth – VP, Product Management

Hello.

Mary Jo Deering – ONC – Senior Policy Advisor

David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Nancy Orvis?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Present.

Mary Jo Deering – ONC – Senior Policy Advisor

Marc Overhage? I think he's here but on a phone call. Wes Rishel?

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

Here, on the phone.

Mary Jo Deering – ONC – Senior Policy Advisor

Chuck Romine?

Kamie Roberts

Kamie Roberts for Chuck Romine.

Mary Jo Deering – ONC – Senior Policy Advisor

Thank you very much. Cris Ross? I think he's here too. Walter Suarez?

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy

I'm here.

Mary Jo Deering – ONC – Senior Policy Advisor

Sharon Terry?

Sharon Terry – Genetic Alliance – President & CEO

Here.

Mary Jo Deering – ONC – Senior Policy Advisor

Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Yo.

Mary Jo Deering – ONC – Senior Policy Advisor

Thank you, everybody and over to you, Jon.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you. Good morning, everybody. It's obviously been a quiet week in the world of health information technology, and obviously a lot of people have been traveling to HIMSS and back, and of course to the NPRM and the NPRM up on the Web site creating a little light reading for all members of this group. I appreciate all the conversation that's already been launched. Of course that starts a set of activities for us, contemplating not only how to support with standards for stage 2, but we'll hear later from Paul Tang on the beginning thoughts about stage 3. I was mentioning to Doug Fridsma this morning that it's really nice, the materials that Mary Jo sent out, to be able to look at the use cases and to realize that the use cases that are being developed now are so sophisticated that they really are, for those who are clinicians in the room, if there were anybody who has pushed experienced healthcare, they're reflective of the real world activities in providing services for patients for ... services ... in supporting transitions amongst ..., as well as teamwork in the delivery of care. And that's really exciting.

I want to thank everyone for travel today. A logistical note on our meeting, we're in a big ballroom here at the Shoreham, and you may have noticed that there's another conference going on, a very active conference, there was a lot of security. And you should feel very safe, that security is both for you and apparently the best attended meeting in bioterrorism microbiology, at 715, that this particular organization has ever held. The speaker was the guy from the Netherlands who weaponized H1N5, so apparently the place has been buzzing with the conversations and so that's the other meeting going on in the building and thus the heavy security that you might have noticed, the motorcade, ... and the like.

With that, thanks, as always, for your work. It's amazing to look at the proposed rule as a culmination of a set of activities that everyone here has been so invested in, and greatly appreciative. I know it's taken your nights, your weekends, and that you have day jobs as well, and thank you in advance for the work ahead. Today in terms of our meeting we'll turn to John momentarily to talk about our assignments, to really go through the response to the NPRM and really our go forward work in terms of the glide path that threads not only through the needle of stage 2, but to stage 3 and the intent of meaningful use.

Also recognize at a very practical level that what is rain for this region is a potential heavy storms, blizzard even for the Northeast, and a disruption in tightly couple process leads to amplified disruption over time, that means that there could be a little bit of a challenge with travel logistics this afternoon, so with your agreement we'll compress lunch to about 45 minutes. There are a couple of presentations that are a little shorter than a lot of time this afternoon. Jim and his team have done great work with the clinical quality. I think Jim, five slides is actually what sits there – one slide? One slide, so I think that's even tighter and I think Doug, the S&I framework will be probably the focus of his comments later on this afternoon. So we'll try to compress, we won't set a firm time, but let's try to shave half an hour, maybe an hour, off the agenda and allow people to seek alternative travel if that's possible.

Let me turn it to John and then we'll come back and take a look at the minutes, if you will, and we'll go to that as our first official action after, John, your opening comments on the work ahead.

John Halamka – Harvard Medical School – Chief Information Officer

Certainly. When I was having breakfast this morning I was surrounded by people with ear pieces, and I just thought it was the controversial standards discussion we were going to have today, but oh well. When we laid out our 2012 work plan we broke it into quarterly activities, so remember that our January, February and March activities were highlighted by a review of the NPRM, assuming the NPRM would arrive in the first quarter, which it did, and as we'll discuss today it is poetry. There may be items that you would polish, but generally it was consistent with our recommendations from each of our workgroups. So that certainly is a great body of work for today and for our March meeting.

We also said we would review the NwHIN Exchange comments because we had a blog post, and we'll hear today from Dixie on some of the NwHIN Exchange review work. We will review value sets, vocabularies, APIs, things that will be necessary to support ... content, vocabulary and transport standards, all the vocabulary componentry that's necessary as part of Meaningful Use stage 2. We'll hear from Betsy Humphreys about that. And the quality measure standards, and I'm sure you've all read the 184 pages of the NPRM on standards and the 600 and some pages on Meaningful Use stage 2, the quality measurement comprises a very vast amount of that particular 600 page set, so I think what we'll

certainly hear today from Jim a bit is that there's going to be a lot of additional work in figuring out how we're going to do the electronic submission of quality data, recognizing that we had PQRI XML in the past, QRDA, HQMF, many options, a lot of standards and evolution, a lot of unanswered questions how that's going to be done.

Then as we'll move on to our second quarter of work, April, May, June, we will have additional discussions on the supporting components of the NwHIN and provider directories and PKI and make sure all the supporting components are well specified. Of interest as we review the NPRM you'll see there's a lot of discussion on the use of transport standards, specifically the SOAP and S/MIME SMTP standards of direct and connect, but there is a discussion of the supporting components, the PKI structure, some of the provider directory, things that we've talked about. So we want to make sure that that's as well specified for the next stage of rule making as it can be. We'll talk about query health, and we have to make sure that we are organized to address the query health discussions. Radiology standards and making sure whether it's DICOM or novel cloud-based approaches of exchanging images is going to become more relevant because we have a menu set criteria that describes that 40% of all radiology images ordered should be displayable in an EHR. And as currently written it's not precisely clear what that means in terms of standards. Does that mean that an EHR needs to support DICOM exchange, or is a JPEG okay, or is a cloud hosted URL sufficient?

So again as we start thinking through this as a committee we want to make sure that we are getting a lot of testimony from those in the industry, the experts that have worked for many, many years at DICOM and related standards, and make sure that dovetails with the Meaningful Use menu set item, and governance is also going to be important as we think of what is the future of the S&I framework. We heard, for example, that NwHIN is going to be a 501c3 sustainable structure going forward, well, what will the S&I framework be going forward? Is it going to government funded activity forever? Is it going to be privatized? How should it best articulate with the HIT Standards Committee, the SDOs? So it's a rich discussion to have. I only mention these second quarter items because, well, here we are in February and planning for the second quarter items has to occur now. So a rich agenda covering all our first quarter items today and then certainly a lot of us will be on the phone planning for second quarter items and then teeing up our upcoming meetings. So I look forward to the discussion.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, John, as always a very eloquent overview of the poetry of the language. I think it's particularly apropos, it reminds me of my accounting professor, once upon a time, who talked about the romance of accounting. This is the romance of the standards world, and I appreciate all the work here. Every word does have value, does have meaning, and when one thinks about the simple statement, "40% displayable in certified EHR," even the mechanism of "in" has an implication. "In" is different than "through," and part of our work is to remove the ambiguity. I think Wes has really challenged us over the course of time to be very clear in our language that "and" and "or" are different words and I really look forward to the work together so that we remove the ambiguity, because the romance of standards, the art of standards, and the poetry is in the parsimony and the practicability that can be implemented because when different people look at similar information they come to a shared understanding of the intent. So our work is tremendously important in terms of making those use cases real.

We have the opportunity to be here this morning, but we're not joined by Farzad at the moment. He has the opportunity to be on the Hill, which is always important, but I can tell you from past ... it can be stressful at times, so we appreciate the good work he's doing. We'll miss him in terms of opening comments, but I appreciate Judy and Doug and Steve and the rest of the ONC team and look forward to that. And if Farzad is able to be here we'll welcome his comments when he arrives.

One other logistical order of business, the HL7 and the May meeting overlapped, and I appreciate Mary Jo's looking at the calendar with the members of this committee to find a time and date that's most compatible with schedules. I appreciate your forbearance and Mary Jo and team's hard work to find it. Speaking of the hard work of ONC, when you think about the work that went on this past week and indeed over the weekend you realize how hard the staff at ONC are working, and much appreciated. By way of introduction to the minutes, we welcome your amendments and modifications to that. Hearing

none, we will declare consensus and get on with our agenda. Perhaps, John, I'll turn it to you to introduce our colleagues for their first topic.

John Halamka – Harvard Medical School – Chief Information Officer

For the first topic we have the dynamic duo of Doug Fridsma and Steve Posnack, who, as I've mentioned, have created an NPRM for standards and certification which is both creative and comprehensive, that achieves, you've already used the word "parsimony," and it assigns one standard to each domain, whether that's content vocabulary or transport, it removes optionality and ambiguity, and although I'm sure there will be comments I think in general it's an extraordinarily good foundation. So we look forward to your presentation.

Steve Posnack – ONC – Policy Analyst

Thanks for having us. I have the pleasure of not having, two things, two pleasures, Farzad not stealing my thunder and not following CMS, which happened all last week at HIMSS, so I actually get time to talk slower, for anyone that caught my presentation at HIMSS because ... did a great job but ate up quite a bit of time going through the Meaningful Use stage 2, which is very important. But for you guys, this is what you care about, and this is about what we care about, so we will spend some tender loving care talking about our proposed rule here.

I'm here today to talk about the fresh look that we took at our policies for certification, the flexibility that we are trying to introduce with respect to some of the policy that we've received a lot of feedback on over the past year and a half, and then the additional clarity that we're bringing to some of the proposals and just the regulatory process in general. And I think, to John Halamka's comment, the NPRM process is imperfect, and even when we get to a final rule we do try to polish it to be more perfect, but there are still things that just never quite get 100% right. So your help in the coming months to get us closer to perfection is what we're looking for, and I would be very interested and very hopeful for the feedback that you have over the coming months.

I have been trying to make 2012 the year of making regulations fun. Poetic is, I think, a higher bar, but I will take it as much as we can. The one thing to keep in mind as I go through this presentation and as you have subsequent discussions in the workgroups that you're part of is to keep in your mind where we're trying to go and what we want the world to look like. This rule is about 2014, not today. So that's one of the things that they have to keep in mind with the proposed extension, the meaningful use stage 1 through 2013, stage 2 starting in 2014, that that pushes out where we're looking at the world and where we want the world to be, and so we're really looking two years ahead of where we want the world to be, and that's where, as Farzad probably would have said, we've really tried to push the envelope in a lot of areas, both on transport, exchange, interoperability, picking specific standards where we can, and trying to push the industry forward with respect to certification. ... is working today.

A quick agenda: regulatory history, some of the key lingo and facts and other major highlights that I'll go through to summarize and boil down and distill the NPRM, which is quite lengthy but not as long as the CMS one. We've been pretty busy, and you all have been pretty busy vicariously through our business, this is the tenth regulatory action that we've published in two years, so counting NPRMs, final rules, and separate regulatory actions, because they do each in and of themselves take many months to finalize and get put together. This is the fourth regulation related specifically to standards and certification criteria and we've had others that have had to do with our certification programs and metadata standards, in which you all are well versed and aware of.

The first thing to keep in mind as part of the new NPRM has to do with some new lingo that we're going to be using, and that has to do with our certification criteria. Previously it was easy to just reference the one set of certification criteria that we had. They were represented in our Sections 170, 302, 304, and 306 in the Code of Federal Regulations, and they were published in our standards and certification criteria final rule in July of 2010 and applicable to certification today and when they first came out. Because this rule will be effective coming this summer and we expect that EHR technology developers will need to go forward and get certified to the new set of certification criteria that we're proposing, we'll have two sets of certification criteria in play at the same time, and we need to be able to distinguish between both of them. And so what we've done, and this ties back into the regulatory clarity that we were trying to introduce, is

to come up with two easy distinctions for the previously adopted certification criteria and the set of certification criteria that we're proposing thus far. The ones that we've already adopted we now refer to as the 2011 edition, and then the ones that we have proposed to adopt we refer to as the 2014 edition. Also, to make it easy for people to remember and as another clarification and regulatory clarity aspect that we're trying to build in, we're proposing to adopt them in a single section of the Code of Federal Regulations, 170.314, and we've purposely tied the year and the section number to make it explicitly easy for people to remember which edition of certification criteria that we're adopting. So the 14s are there parallel to each other for a reason and I would see us continuing this trend going forward as we adopt new editions of certification criteria going forward, whether it be for 2016 or 2017, will kind of mirror this. We have plenty of room in the Code of Federal Regulations to go as far as we need to, way past my regulatory lifetime, so an extensible process there.

The one thing I did, and I've always caveated this as unscientific analysis of the amount of certification criteria that we have, like you've probably seen if you've caught any of the presentations for CMS we've merged and split some of the certification criteria, so in the 2011 edition we have 41 plus an optional, in the 2014 edition we have 50 plus an optional still. I wouldn't submit that to any type of scientific journal. It has no validity in terms of anything that you could base it off of, but just to give folks a sense of it can go from 40 to 100, we're pretty much in the zone that we expected to be. There really are no surprises, so to speak, with all the certification criteria that we've adopted, and I will move forward.

I'll go through the next three slides, and I'm not going to stick on these very long, they're just for your reference, and I'm going to voice over and then continue on with our proposals. We have three categories of certification criteria, we identified this in prior rule makings, it includes new certification criteria, so previously never adopted capabilities that hadn't been specified for certification criteria, revised certification criteria, and unchanged. It's all set through new, revised and unchanged as I go forward. And each of them has a little bit of nuance to them. These are all the new certification criteria that we've adopted. They tie back to the correlated meaningful use objectives and measures that have been proposed for stage 2 that are new as well. And we, on our side, and being joined at the hip with CMS, have adopted or propose to adopt these, for certification.

The next bolus of certification criteria that we have has to do with the revised ones, and so these are certification criteria that were previously adopted in the 2011 edition that we have now added to change in some way to specify or reduce optionality with respect to certification criteria, etc., and standards therein. And so anywhere where we had something in the 2011 edition that we've carried forward into the 2014 edition where we've made changes, these wind up in the revised bucket.

The last category has to do with the unchanged certification criteria, and these are ones that carry over from the 2011 edition to the 2014 edition, where we haven't made any substantive change to the certification criterion by way of a new capability that would be expected for certification. This is important as far as the permanent certification goes because when that kicks in, which would be at the same time as the final rule for all these proposals' effective date, it would allow for what we call "gap certification." And so that would enable EHR technology developers to bring forward prior test results for all of these certification criteria and let those test results count towards the certification for the 2014 edition. That's an area where we're trying to introduce some efficiencies, we talked with you about the permanent certification program and gap certification before. As we worked through with Judy, and Liz when she was part of the Implementation Workgroup, this is something that we tried to remind folks to keep in mind about not refreshing everything where there didn't need to be, if it wasn't broke don't fix it, I think was what Judy was saying, and so we tried to keep that mantra available and, as you can see, I rounded up a little bit, I think when you do the real math it's probably about 36% that are eligible for gap certification. But it's a good showing and we have other statistics, when you get down into the ambulatory setting versus the inpatient setting that it's actually kind of higher than we expected it to gap certification.

Moving on, this is one of the bigger aspects of the rule in terms of both quantity of patients and policy discussion, and this has to do with the definition of certified EHR technology. This is, as I said in every presentation that I've given thus far, it's a proper noun, we capitalize it in our rule making to make it clear that it's a definition and it has a defined meaning to it. That's really important because it's easy to just say lower KC certified EHR technology, which may or may not be something that ultimately meets the

definition and that can be subsequently used to demonstrate meaningful use. So we've gone forward, based on a lot of the feedback that we've received, to revise the definition and propose a revision to the definition of certified EHR technology and its requirements, also while keeping in mind continued progress towards interoperability and to reduce regulatory burden consistent with Executive Order 13563. Following, especially number four, that policy directive from the administration has been very important to us and we've used that and followed that policy directive in a number of places in our regulations.

Just to give folks a quick background before I get into the nuts and bolts of the proposal that we've made, today the definition of certified EHR technology is structured around 100% of the certification criteria, so it has to do with a finite set of certification criteria. If you don't have EHR technology that's been certified to this finite set then you don't have something that meets the definition of certified EHR technology. So for those of you that have gone forward and attested and have used the Certified HIT Product List, the CHPL, to get the CMS EHR ID number that you need for attestation, you need to check off 100% of the certification criteria for the applicable setting in which you're practicing to get that CMS EHR ID number and to meet the definition of certified EHR technology. That's something that we propose to change going forward so that you don't need 100% of your EHR technology certified to all of the certification criteria, and I'll walk you through how that change could have manifested itself in our proposal.

This is one thing that we've heard feedback more than anything else and the question has been asked, why can't I just have EHR technology that I need to demonstrate my meaningful use and the path that I've chosen to meet meaningful use? And so we've listened, as Farzad would emphasize had he given his opening remarks we are always listening, and so this is an area where we felt we could take strides to increase flexibility and to reduce regulatory burden.

As a quick image of what – my animation died already thus far because 2014 wasn't supposed to be here yet – the definition of certified EHR technology looks like today, and this is by no means a reference to the Blue Button but happens to work with our color scheme, it's a solid circle, and the circle's going to play in as I go through my diagrams here. It's 100% of the certification criteria that are required to meet the definition of certified EHR technology, so what we're proposing – this is about as much fireworks as you're going to get today – is a more dynamic definition starting with the calendar year fiscal year EHR reporting period for meaningful use that relies on a couple of new concepts but is largely driven by the stage of meaningful use that an eligible, I'm going to say, provider, as the umbrella for EPs, eligible hospitals and critical access hospitals, would need to meet starting in that 2014 EHR reporting period. And it's important to remember, and I'll take a slight pause here to lay this out, the definition of certified EHR technology doesn't speak to just one audience. It's not just for EHR technology developers, because it equally is important for eligible providers since they need to use it to demonstrate meaningful use.

One of the things that I think is a lesson learned for us and why I'm here and any of the other Webinars and something that we'll be doing on the rules has been to encourage, for those listening on the Webcast, read ONC's rule as well because it has a significant relevance to the meaningful use component too. And so I think folks got caught off guard in some cases when they just read the meaningful use NPRM the first time around, didn't necessarily connect all the necessary dots, and that's on us to do as well to make clear for everyone that the definition of certified EHR technology is specified in ONC's regulations, CMS cross-references it, and that's what you need to demonstrate meaningful use. So keeping that in mind, where providers will look at it from the perspective of what EHR technology do I need to demonstrate meaningful use, and EHR technology developers will look at it from the perspective of what will my customers need to have certified in order to demonstrate meaningful use, and finding some alignment between those two. So looking at the definition from both sides is something that we kept in mind as we went through our proposals.

At the center of this bull's eye, which I'll be referring to, is what we call a base EHR. This is a definition, it's a new concept from a terminology standpoint, but it is rooted in the HITECH Act in statute. Congress gave it the definition of what they called a "qualified" EHR, and that term is a term of ... used in other programs, so we determined that it would be easier and more communicative to use a simpler term and we landed on a base EHR, which I think is better than some of the other acronyms that we've created. At the center of everyone's EHR technology is the statutorily defined base EHR, and I have a table next on

my slide, Congress indicated that there would be these fundamental capacities in everyone's EHR technology that would be necessary to meet the definition of certified EHR technology, which they also gave us a definition in the statute. We've extended the definition that was provided to us in the statute to include privacy and security capabilities, because that was not present, and that will be clear on the table that I'll show you next.

The one thing I'll stop here and mention is that the base EHR definition, which is a regulatory definition, just like the definition of certified EHR technology, is a construction. It's meant to constitute a certain set of certification criteria. It's not meant to be this new product that everyone has to go find on the shelves and label as a base EHR, it's meant to be a mile marker, an analysis point where you can say, on my way to meeting the definition of certified EHR technology do I have something that meets all the certification criteria that constitute a base EHR. And that's one of the things that we want to make clear to folks, we're not putting out there this concept that you need to buy something new. As part of most likely what everyone had thus far, or is going to have thus far as part of the 2011 edition certification criteria, there are some tweaks that I'll talk through with respect to how it jibes for the 2014 edition EHR reporting period.

The other thing that I will mention about a base EHR in terms of its construction is it doesn't need to be one solitary EHR technology. Just like we have today with combinations of EHR modules, it's really about the certification criteria that constitute the capabilities that are part of what makes it meet the definition of a base EHR. So you could have two or three EHR modules, Capital M is another term of AHRQ that we define in our regulations that span across the certification criteria that constitute a base EHR. So again it doesn't need to be one monolithic, smaller EHR technology. There are numerous ways to meet the definitions.

I'm sorry if this is going to come across small on the Webcast. As well I know from being an avid listener when I'm not here in person, the Webcast is limited by your screen size. The first five rows of this table, and this is in our regulation as well, constitute the statutorily defined capacities that Congress gave us for what was included in the qualified EHR, what we call a base EHR, and we've tried in a parsimonious way to only put in, at a minimum, the certification criteria that we believe lined up with those statutory capacities, and, as I'll discuss in more detail, didn't cause a scope of practice issue from a meaningful use perspective. So especially when we get into the EP realm we didn't want to include certain certification criteria in a base EHR that all providers would need that would then be subject to certain meaningful use exclusions, depending on a provider's scope of practice. This is really the minimum set of certification criteria that we believe everyone's EHR technology will need to have in order to start their quest towards meeting the definition of certified EHR technology. The definition in the statute didn't include capacity related to privacy and security, so in a parlay with some of the other policy changes that we made we believe that it would be best to include those certification criteria as part of everyone's base EHR because really they are fundamental.

For those of you that caught any of the Twitpics or slides or videos that were taken at HIMSS, and I don't suspect that there are iPhones and other types of cameras popping up behind my head now but it was quite interesting, we did joke around a lot about HIMSS, that there were a lot of cameras and flashes going on since we couldn't make the slides available until the rules were on public display, so we did pause and give folks some time to take pictures of our slides. This is the definition of certified EHR technology, as I noted in the bull's eye that I previously showed you, and I'll walk you through how the new proposed, revised definition of certified EHR technology is really driven by meaningful use and the stage and pathway of meaningful use as an eligible provider we'll need to meet.

And I've elaborated, on my plane ride home I thought of new messaging that I'll be using when I get asked, some of the crystal ball types of things that we can do now that we've had a rule making experience, a full cycle, is to anticipate questions, and so, and I will speak for my CMS colleagues as well, a lot of the a priori work that we did in the preamble of the regulations was to say we've written "x," what are folks going to ask us about "x" and we've tried to include those responses in the preamble to include addition of rationale. So I hope you find that as you've read through either some or most or all of the regulations that we've tried to do a better job of answering some questions up front that maybe we didn't do as good a job last time around.

In the future, if anyone asks me how do I meet the definition of certified EHR technology, my response is going to be it's as easy as 1-2-3 plus C. So starting with a base EHR every eligible provider must have EHR technology with the capability certified to meet the definition of a base EHR, and this is regardless of stage, and I'll talk a little bit more about that, regardless of whatever other types of path that they're going to choose to meet meaningful use, and everyone starts with a base EHR, so that's level one.

Where things start to diverge relates to the meaningful use core and the meaningful use menu that are available to an eligible provider based on the stage of meaningful use that they seek to achieve. For the second ring of the bull's eye an eligible provider would only need to have EHR technology with capabilities certified for the meaningful core set of objectives and measures for the stage of meaningful use they seek to achieve unless they meet an exclusion. So in a case where, as proposed for stage 2, certain of the public health reporting objectives and measures have been included in the core, and this gets, especially with respect to eligible providers in different scopes of practice, if you're a dentist and you don't get immunizations you won't need to have EHR technology that is certified to do immunization reporting. And that was something that was a pain point at our current policy, in that the eligible providers in some cases, either based on exclusions or other scope of practice reasons, had to have that EHR technology, had to possess it, even though they weren't going to use it to meet meaningful use and especially when they could qualify for, legitimately, foreign exclusion.

Further flexibility has to do with once you get in this outer ring with respect to the menu whereby it's really up to the eligible provider to make sure that they have EHR technology that's been certified for the capabilities that they need to meet the menu set objectives and measures that they seek to achieve for the stage of meaningful use that they're going to meet. So if you're in stage 1 you'll only need to have EHR technology at a minimum that's been certified for those stage 1 objectives and measures, to support those objectives and measures, and no more. "And no more" is really the big change with respect to the definition of certified EHR technology.

The last point that I'll make here with respect to my new little catch phrase, "1-2-3 plus C" is the CMS in its analysis and how it's presented meaningful use stage 2 and going forward took out clinical quality measures as an objective because it has to be done. It's part of meaningful use. And they've included that in the definition of meaningful EHR user, which is a regulatory term of ours that they have defined in their regulations. So it's no longer part of the objective and measure set, it's a correlated reporting requirement that everyone needs to do regardless of their stage of meaningful use. And that's part of our definition of certified EHR technology, it just isn't part of the dynamic aspect because everyone will need to do it.

Moving on, I know there is an insatiable ask for representing our rules in an easy to read, easy to view format, and this is something that my team is working on that we hope to make available, hopefully in a higher resolution type of graphic, but to really show folks based on the stage of meaningful use correlated to the 2014 edition certification criteria applied to the new bull's eye diagram, the certification criteria that are in play for each of those stages and the pathways and the setting in which the eligible provider will participate. That's one of the things that you can look forward to coming from us. I know other folks have been putting together tables like we have, with grids laying out the certification criteria or the standards that are associated, especially between the 2011 edition and 2014 edition, and so we'll probably flatter some of you by imitating some of the great work that you've done in making those materials available as well through our Web site. But this is one of those things that we have been working on to make available to folks.

With respect to the definition of certified EHR technology, to close this out, today an eligible provider can meet the certified EHR capital fee technology definition by either having a complete EHR, which by definition has been certified to all of the applicable certification criteria, or a combination of EHR modules that is equivalent to a complete EHR. In either case, again, we're at 100%. With the way that the new proposed, revised definition of certified EHR technology works, you could meet it with a complete EHR, which is a concept that we kept in and we felt was valuable from a consumer perspective, in this case providers being the consumers, but they don't want to look into customizing their pathway to meaningful use, they can go ahead and get a complete EHR upgrade to a 2014 edition, complete EHR. But where things divide and where there's a difference now with respect to our proposed policy would be that in the

case of the EHR modules you could combine a set of EHR modules that have been certified through the 2014 edition that just do enough to meet your stage of meaningful use, and that would be good to meet the definition of certified EHR technology. It also created the opportunity for there to be single EHR modules that are, I like to call colloquially “mega” EHR modules that do everything that’s required for certification in a base that covers a broad setting specific meaningful use core set of objectives and measures for which they’re certification criteria associated, and then some selection of menu set objectives and measures, for which there’s also certification criteria. So you could foresee there being available EHR modules that do just enough for someone and they’ll take care of business, and that will be good enough to meet the definition of certified EHR technology going forward.

This is the last one that I have put together with respect, and this maps our definitional change and proposal to the EHR reporting periods, with the proposed extension of stage 1 through fiscal year calendar year 2013. That dividing line, that vertical line used to be between 2012 and 2013, and we’ve now moved it to be between 2013 and 2014. The one thing that we’ve done to modify the current definition of certified EHR technology is to allow folks to reflect this transition and anticipate that there will be a transition throughout 2013 to EHR technology that’s been certified through the 2014 edition is to make clear and say that we highly encourage that to occur and that you won’t fail to meet the definition of certified EHR technology if ... rolled out upgrades to the 2014 edition EHR certification criteria that are equivalent to the 2011 edition that we have thus far. We have a nice table in our regulation that cross-walks all of the equivalent certification criteria between the 2011 edition and the 2014 edition to make this very clear about which ones you can roll right over and get upgrades on.

With respect to fiscal year calendar year 2014 that’s when our new proposed definition would kick in for any reporting period that begins in 2014 and so on, and carrying on after that everyone will need to be on EHR technology that’s been certified through the 2014 edition certification criteria. The one thing that I’ve noted here, which I mentioned verbally all throughout HIMSS, and I asked that those of you go back and speak to your stakeholders in your communities, it was convenient in the beginning to refer to EHR technology as being stage 1 certified, but that’s not how we’ve ever approached certification. We don’t believe that it’s necessarily a communicative and a helpful approach taken and vocabulary to use with respect to certification because we will have a single edition of certification criteria for every rule making that we have, and as you carry that out, especially looking forward to stage 3, there will be three stages of meaningful use effective at the same time for which we expect there will be one edition of certification criteria to keep our escalator on the standards and certification criteria side going upward and to keep the same level of interoperability required and standards adoption going forward throughout our trajectory for our regulatory processes.

So there is no such thing as being stage 1 certified or being stage 2 certified, the EHR technology is certified for the editions of certification criteria that we have now instantiated in our rule making with respect to the 2011 edition and 2014 edition. And that’s one thing that if folks can help us communicate that and not to perpetuate the lingo that was previously being used that was synonymous at times and wasn’t too harmful, going forward it will be challenging to folks to hear the words stage 2 certified because it’s not necessarily about the stage anymore from a certification perspective, it’s about the quantity of the EHR technology that’s certified through the 2014 edition that the provider will need to have. And that’s really where the difference is between certification and the meaningful use stages, so from our perspective everyone needs to be on the 2014 edition EHR technology, it shows the difference in the quantity of EHR technology that a provider would need to achieve the stage of meaningful use.

Standards, standards, standards, this is where we get into the meat. If this was an ‘80s movie there would be a kitschy tune going on here, Doug running around giving everyone high-fives in a slow montage of slides ticking by, so keep that visual in mind as we go through. With respect to transport, for those of you that remember the interim final rule that we published in December of 2009, we included SOAP and REST. We pulled those back as a result of public comments, due to immaturity and ambiguity and insufficient specificity, and the final rule that we promulgated in 2010 didn’t include any specific requirements for transport. This time around, and as we mentioned, keeping in mind that we’re looking at the world that we want to see in 2014, we’ve proposed to include the direct specifications as well as the NwHIN Exchange modular specifications for SOAP. Those are applied in different certification criteria,

and I won't go into any level of detail there, but we do have and we have been making efforts to reflect the great work that's been going on and to include these transport standards for public comment.

We have a new category of "standards" that we've included and we have categories of standards that we identify in our prior rule making that we set up. One of those categories has to do with functional, and it may not be the best term, but you can cast that aside, and that's where we put some of these other standards that are not necessarily transport content exchange or vocabularies or code sets. One has to do with accessibility and it has to do with the view download and transmit to a third party certification criteria, we worked with our Office on Disability and Office of Civil Rights. As we are making information more accessible to patients we believe that there needs to be some standardization with respect to the accessibility of that information. We've also included ... info button standard and then with respect to clinical quality measures the NQF quality data model for CQM data capture certification.

With respect security standards, you'll notice in our regulation, which is, for those of you that are not well versed in the regulatory text part at the end, we amend now our current set of regulations, and so there will be asterisks in the regulation text toward the end where we've added to our paragraphs that are in the Code of Federal Regulations. We haven't gotten rid of any of the standards that we previously adopted, but there are places where we have changed them and have now referenced what would be a 2014 oriented standard that's now referenced by 2014 edition certification criteria. Any of the standards that we adopt get brought to life when they're referenced in this certification criterion, so we have just standards in our regulatory text at the end just simply listed, and then we pick and choose, depending on the certification criterion and the need that the certification criterion, the capability that it needs to express the specific standards from our list of those that we propose to adopt.

With respect to audible events and audit logs we've added certain things to the 2014 edition standards, so to speak, to include more specificity. We've referenced ... as a standard for encryption and hashing, and that, I believe, is referenced by our secure messaging certification criterion, maybe a few others. We still have the hashing standard that ... in our standards already and then we've adopted a standard for synchronized clocks, which I understand is very well adopted by the industry already, which is also included in those certification criteria that expressly have time and date stamp oriented requirements.

The content exchange, and I was doing this late at night so I hope that everything is accurate here, summary records, we've moved to the consolidated PDA; ePrescribing, we've moved to NCPDP Script 10.6, electronic submission of laboratory and test results; but for everything that's public health we've moved to HL7 2.5.1, which was a suggestion of the Standards Committee; implementation guides also where they have been recommended and available. I'm going to click through these pretty quickly, Doug's probably made his way halfway around the table now at this point giving people high-fives. Content exchange continued, we have a new proposal with respect to cancer registry reporting, which has to do with supporting meaningful use stage 2, we're working directly with our folks at CDC, and they published on their Web site information related to these specifications. I don't remember the exact – do you remember, I'm looking at Doug to ask. It's a pretty easy to remember URL and we can provide it later, but I think it's cdc.gov/meaningful use, or something along those lines. And I'm sure I will be corrected because I'm not confident in that.

Where imaging is invoked we have proposed the adoption of DICOM, and that's in the view and download and transmit with third party section, not in the access imaging certification criterion. And so those are two distinctions that if you read the rule a second time you want to make sure that you keep in the back of your mind the incorporation of lab test results. For the ambulatory setting on intake and receive we've proposed the adoption of the great work from the S&I framework, the laboratory results interface.

Moving on to vocabulary and code sets, many of these have been in there before, some of them, as previously mentioned, we've gone down to one standard, so immunization, CDX, no surprise. For problems we have proposed solely the use of SNOMED to represent problems. For medications previously we had in the 2011 edition a more flexible any source vocabulary that's in RxNorm we've now moved to the world in which we want to see for 2014 solely the use of RxNorm for medication, preferred language, preliminary cause of death, ICD-10, SCM, counter-diagnosis ..., smoking status was previously

in line in the certification criterion relevant to smoking status. That was a drafting inconsistency that we had so we just put the ... codes that we had in a standard itself, to just list them as opposed to having them in line in the certification criterion, because it was the odd man out with respect to some of the other certification criteria. But that isn't the change between editions in certification criteria.

A few points about the permanent certification program, this rule not only modifies and creates a new addition of certification criteria, but we have made some corresponding changes to the permanent certification program, one of which is a name change. Going forward we will be sunsetting the temporary certification program, so we didn't see the need to have this artificial separation between temporary and permanent. Therefore, we're renaming the permanent certification program, which actually requires some regulatory text instruction to the federal register to go through the entire regulatory text and change everything from permanent certification program to the ONC HIT certification program. But no one's world will alter or fundamentally change because of that.

The one thing that we are doing in the same context of reducing regulatory burden and making it a more flexible and easier path for EHR to acknowledge eDevelopers to get certified, and then on the other side for eligible providers, in cases where they are adopting EHR modules, piece together those EHR modules, today we require, if I'm an EHR technology developer and I seek to get certified, the EHR module that I bring forward needs to also get certified for the privacy and security criteria upfront. This has been identified both as having some ambiguity in terms of what privacy and security criteria the EHR modules need to be certified to, because we include certain exemptions that EHR technology developers can qualify for when they present their EHR module for certification.

Also, on the purchaser side we've heard feedback that it's resulted in redundant capabilities, and so that was one thing where we didn't want to have folks have the capacity to adopt and customize their approach to meeting the definition of certified EHR technology and then wind up with EHR modules that all do encryption different ways, or other types of different things. And if you sort through your mind all the way back to the definition of a base EHR, that's where we have expressed a policy outcome now reflected in the base EHR where we've said everyone's base EHR, however you get there, needs to have these capabilities for privacy and security, that's where you need to start and start from the center of that bull's eye. And by doing that we felt comfortable that we had mitigated any risk with respect to EHR module certification, because we weren't losing, on the net, any of the privacy and security capabilities. We made some other tweaks to the certification process that are really devil's in the details that I won't burden you with today, other new certification criteria that have to do with reporting and EHR technology having a little more artificial intelligence to capture some of the usage with respect to meaningful use, and then one of the other new ones that we've included has to do with safety enhanced design. And we've tied that in response to the Institute of Medicine's report on health IT and patient safety to focus on and prioritize the eight medication related certification criteria.

So for these that are listed, an EHR technology developer, when they present their EHR technology for certification, will need to provide documentation that they have pursued user centered design in designing these capabilities that their EHR technology includes. That can be done in a number of different ways, and we've identified a number of different resources that have user centered designed processes, but the bottom line is that we expect for these that we feel from a priority perspective pose the greatest risk to patient safety also provide the greatest opportunity for some initial foray into this area. So that's an area where we would welcome public comment, but also a place where we felt we had some room to make some significant progress.

I'm about to conclude here. We're doing a few things to enhance your common experience, enhance the public common experience. We have a Word version of our rule available now. I know that folks have struggled with the tri-column federal register version, copy and pasting. We don't want your time spent on our rules to be any less efficient than our time spent on the rules, so please have it. The Word version is available on our HealthIT.gov Web site, if you click on the policymakers' image, box, that will get you to the new meaningful use landing page. We're also going to be making available a common template and so for those of you that standardize things we took standardize things and I can speak only from the person that has the disposition all of the hundreds, hopefully of public comments that we receive.

One of the things that sucked up a lot of our time on the back end is going through the public comments, which we do each and every one of them, and find each place in everyone's public comment where you've all talked about CPOE. So on someone's public comment it will be on page 11 and on someone else's public comment it will be on page 81, and so if we had it in a way that was logical structured expected and reliable for us, we think, the hypothesis is, and this is something that we're piloting, that we might be able to more efficiently process the public comments and turn our rule around faster. I'll let you know on the other end how that works out, but for those of you that work with the stakeholder community please let them know that this common template will be available for the workgroups that will be supporting, especially probably the Implementation Workgroup, this might be something that we hope you all would use, and I have a snapshot of that next.

There will be other grid materials like the bull's eye that's fully populated with all the certification criteria that I showed that we're going to be making available over time, some of the other tables that we just didn't include in the preamble of our rules just to save some space, three ways to public comments, snail mail, express mail, and electronic at Regulations.gov, that's our preferred method, you make sure you get a confirmation number when we make them available and you can track your public comment. That submission, in case any of you are the A+ students that want to submit your comment on day one, will be available starting after the formal publication date in the federal register, so starting after March 7th, and that's in Regulation.gov. I would encourage you to take more time if you do want to submit your public comment on day one to really go through, and then hand deliver, so if you want to see Doug in person I will give you his office number and you can hand deliver the comments to him as opposed to me.

The one thing with respect to the public comment table, this is a snapshot of what we intend to make available. This would include all of the certification criteria correlated to the meaningful use objective that they're related to, if applicable, and it will have this kind of structure, as you can see, where it will have the certification criterion proposed in the 2014 edition, the meaningful use objective, the certification criterion that we've proposed. As soon as the federal register version is out we'll actually include the page number to make it easier for folks to get to. And then the one other important thing for folks that have just joined ONC and getting the experience to the rule making process in general, I realize that this is important to mention as well, there are a lot of places in the preamble, both in ONC's rule and in CMS' rule where we need your help, and we've asked for public comment, and so there will be a point in time where we say this is our proposal, this is our rationale, and then we'll ask a question. It may be because we need to get more information to really make sure that we're taking the most appropriate approach, or we want to test to make sure that it makes sense what we're saying, or some other reason that ranges the spectrum.

So we will be noting for folks where we do ask specific questions to help us in these comment tables and the template to let folks know to keep a keen eye out for those questions. Those are really important for us, because another public service announcement that I failed to mention earlier with respect to comments generally, if you like something let us know, because what you say that you like is equally, even more so important sometimes, than what you don't like, because in a lot of cases what we do, and I think what we experienced the first time around, there's a little bit of asymmetry between the hate it, don't like it, have a lot of constructive criticism, and I support this, and I like to call this the *American Idol* paradox, where the person you think is safe gets voted off because no one votes for them. This is an area where the regulatory process, we don't just look at how many votes we got for certain things, but it's important feedback for us to know that there's a balance in the community of voices and we want to make sure that everyone's public comment is heard. So in those cases, for those that are listening on the Webcast, we'll be making public comment so please keep in mind to also include the positives as well as the constructive criticism.

I believe that wraps up my formal presentation. Oh, the one other public service announcement, I have the official CDC URL, so it would be www.cdc.gov/EHRmeaningfuluse. And yet another note, Mary Jo is regulating me, we need a first draft of the HIT Standards Committee comments by March 27th.

Mary Jo Deering – ONC – Senior Policy Advisor

... No, I'm asking you

Steve Posnack – ONC – Policy Analyst

Oh, asking me.

Mary Jo Deering – ONC – Senior Policy Advisor

... what to tell them.

Steve Posnack – ONC – Policy Analyst

There will be a number of different meetings. The public comment period should expire roughly May 7th if you do a rough calculation between 60 days. We would like to have comments in by or before that, so there will be a spring camp sprint to do this, which I think –

Mary Jo Deering – ONC – Senior Policy Advisor

Spring break.

Steve Posnack – ONC – Policy Analyst

Spring break, yes, that all of you will be going through with us and we will be helping. But like the Policy Committee, you'll probably hear from Paul Tang, they will be going through an equally sprint process to get through this. We'll get back with more official dates when we really prefer to have things, sooner obviously than later.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Steve, obviously a tour de force, you've broken ground on a variety of levels, including, I never thought I'd actually hear health IT standards and *American Idol* in the same sentence.

Steve Posnack – ONC – Policy Analyst

... regulations and fun, that also –

Jonathan Perlin – Hospital Corporation of America – CMO & President

You ... the romance of regulations and standards, just terrific, a lot of work ahead, a lot accomplished. And before we go on to a discussion, a number of cards are going up, I was remiss in introducing Rebekah Rockwood and want to acknowledge her being here for Carol Diamond, Markle Foundation; welcome, Rebekah. Thank you very, very much. And before we go on to the discussion, back from the Hill and looking in fine shape is Dr. Mostashari, so we welcome you and thank you for your early morning excursion and for being here.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Thank you. I'm glad to report that bipartisanship on health IT is still alive and doing very well, thank you. We've had a big couple of weeks as a community, with the news that the secretary announced the Friday before HIMSS about the amazing jump in adoption of electronic health records by hospitals in one year, up to now 36% from where we started. It's really been a dramatic rise nearing that, and in some ways actually exceeding the increase among outpatient providers, and I made a bold prediction that in a year's time we're going to have the majority of healthcare delivered in doctors' offices and hospitals delivered through electronic health records next year, so the trends look promising that way and it really is truly amazing to see that dream come true for so many of us and those around the table here and listening who have been working on this for so many years.

The main message that I emphasized at HIMSS was that these regulations in many ways are staying the course, and one of the things that was brought home to me touring the floor exhibit hall at HIMSS was how much time it really does take to not just incorporate the certification criteria into electronic health records in terms of the letter, but actually making meaningful use of those certification requirements and really incorporating them into workflows efficiently and effectively. And this is going to be a journey that we're going to be on with all of our stakeholders and all of our providers to really hone and polish that stone of meaningful use in the certification criteria to make them better and better and better and better over time, more usable, more friendly, and more effective, more interoperable. That takes time, and that takes predictability.

And I think one of the most important functions that our federal advisory committees have provided is that predictability, so there aren't any sharp turns, any left turns that would create a sense of uncertainty in the industry and their development process, so much of what we presented was predictable and that's one area where predictable is good, is in regulations. There were areas, though, where we, as a matter of policy, pushed harder than the Health IT Policy or Standards Committee had recommended in distinct ways. And I think the main message that, if you look at where we did that it was around interoperability in exchange, and I commented to the Standards Committee when we last met around the NwHIN Power Team recommendations, that we can't wait five years for interoperability in exchange and we have to move ahead with good enough and not waiting for perfect. We tried to instantiate that in our regulations, but really looking at the full scope, as we'll see, of what's in the regulations, it's amazing how much has been accomplished in how short a time, where we really have all the different pieces, all the different building blocks of interoperability falling into place now, and it didn't just happen. The ability to make that was around prioritization, around focus, and then around the targeted work and really community participation in the Standards & Interoperability framework.

We're really very grateful to be in this position where we can propose a single standard for medications and problem list clinical diagnoses, a single standard for patient care summary, and a single standard for laboratory results, and the ubiquitous availability of protocols for transport. So we were able to push because the framework and the work and the groundwork had been done, and not only in terms of those building blocks for exchange between providers, but also with the patient and including, importantly, even more of an emphasis on patient centeredness and patient engagement in those rules. We are really at a great moment where we can imagine now not only the hockey stick curve around adoption that we have seen come to life but imagine what the shape and contours of that curve might be for exchange and interoperability as well over the coming year or two. So we're very optimistic, we're very grateful, and we're proud to serve. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific comments. ... optimism and hope are different. Optimism is hope based on data, and I think their common experience really supports a lot of data. With that in mind the go forward work as well as responses to Dr. Mostashari and our work, our timeline, and Mary Jo reminded us it's really this coming month, let me turn to John Halamka for some opening comments to lead this segment of the discussion.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, there are many cards up, though, Wes did put his card up electronically first so he gets first dibs. As I mentioned in my preamble to the meeting, just based on the input that I've had from many people via e-mail, and certainly I think you'll hear some discussions from Dixie on the incorporation of TLS for patients to be able to access data, especially because that's not specifically called out as a transport standard, but it is certainly a mechanism of accessing data, it's how the blue button in effect works, so we want to make sure that's not precluded.

On the content side, you did choose to not accept the Standards Committee's recommendation on the use of HL7 as a means of discharge medication communication, but the way that it is qualified between the two NPRMs may be okay because it basically says use NCPDP when you're going between organizations and therefore what you do inside your own house, such as Kaiser having inpatient units which, oh, by the way there's a pharmacy in the building that it owns or is related to HL7 may be okay for that. So that may be something we just want to make sure, since you didn't take the recommendation, it's qualified appropriately. I think we all just need to recognize that quality reporting submission via XML formats is very much a work in progress and that's going to take a lot of effort on all of our parts to get to specificity so that can become a reality. Then I think clarity is needed on the imaging aspects. We mentioned the word "DICOM" and we've talked about view versus transmit versus access, we've talked about in the EHR or through the EHR, and I think the industry is probably going to ask us for more specificity as to that requirement.

Okay, Wes, you were first. Go ahead.

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

Steve, I just have to echo what everyone has said about the coherence of not only the presentation but the work that underlies the presentation. This is terrific. I have a few questions about certification, or at least topics that came up during your certification section of your talk. Probably the biggest one is I'm trying to put myself in the position of an eligible physician of a hospital that needs to know is it legal, that is, with all of the things they've bought, do they have all of the certifications they need. And just from your presentation it appears that somewhere someone has to build a spreadsheet that includes what meaningful use criteria this particular physician is relying on and what various modules they have are certified for and fill in the "x's" and make sure there's no blank spots in the line, and I'm wondering if I should quit my job and set up an H&R Block Meaningful Use certification filling out agency.

Steve Posnack – ONC – Policy Analyst

Thanks, Wes. I think that's an important comment to make in an area where we can probably play a role to make some resources available to consumers, or I should say providers in this case, and the certified HIT products list has some intelligence integrated into it as well that we anticipate building out too, to help folks identify when they've got their requisite amount of certification, EHR ... certified too, for example, the base EHR certification criteria. To your point, though, they will need to do a little bit of analysis to make sure that they've got the EHR technology that's been certified for the objectives and measures that they seek to meet. That's not necessarily a new concept that we've had to confront thus far, but I think, as you're suggesting, there may be easy ways in forms or check lists that we can build to help folks.

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

By meeting the request to bulk down the total certified EHR requirement you are trading this obligation, and I do think that standard ways having vendors report what they certified for in a standard way that's comparable could be very helpful in that regard. I know that there's an NPRM out for HIPAA that implies the ability to collate audit logs from multiple clinical systems, that's very challenging for industry right now. It was not clear from your presentation in the area of audit logs, are you going so far as to specify a standard format for the audit log? Portions of the ATNA specification are about format, for example, and I'm just really asking where this stands.

Steve Posnack – ONC – Policy Analyst

Two points, what the vendors report, the certification criteria to which they've been certified, in the case of any EHR module that gets submitted to ONC from any of the certification bodies, they need to report on each and every certification criterion that the EHR module has been certified to. So that's an area where we try to already provide some of that transparency with respect to the certification criterion that EHR technology has met. On the audit log requirements, we specify the data that needs to be captured and I believe we may have referenced the ATNA standard as a best practice or something to look to but not necessarily require for certification at this point.

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

Wes, in terms of encouraging, or maybe I shouldn't enable you to quit your job and start the H&R Block, but we are aware that maybe one way that we can have not only tools on our Web site that help with the selection but also create other tools, maybe through making openly available a download of the data that's in the CHPL, so that's also something that in the upcoming year we're going to be looking at.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, certainly as I did self-verification of systems at Beth Israel Deaconess I found that the shopping cart approach of saying what do you do and how do you do it was quite useful. And of course the one frustrating aspect, which you've fixed, is that I had to develop technology I never planned to use. And so as you've done it to date, just what is needed in a shopping cart makes great sense. Well, let us go ahead and go counterclockwise. Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

I have five questions, or something.

John Halamka – Harvard Medical School – Chief Information Officer

Oh no.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

The first two are usability related. It can't be easy enough to use, this whole regime that we're creating. I think it would be useful if you did an analysis that said what would be the problem with saying you either have to be using a 2011 certified EHR or 2014 certified EHR, no cross-walk, just one or the other, how much would be lost by somebody somehow not being certified for something between those two? It would make it a lot easier for the user community.

The second is that our customers, our audience, have already told us the usability answer. It's this is MU1 certified, this is MU2 certified, this is MU3 certified, it makes sense to people, and if this were an internal process at Geisinger I would say to the team anything we try to do to teach people that no, red means green and blue means yellow, and you just have to learn that, would be useless. People would still be saying MU1 certified, MU2 certified, because it makes sense to the user. Our principle is we take the hit on the back end to make it easy for the user on the front end. And if there's any way at all for us to do that without destroying the meaning has to be very useful because they're still going to be talking that way five years from now.

Another question, probably just out of ignorance, but it seems to me it would be wise to keep ICD-10 out of certification criteria if we can do it. Organizations are going to have to be brilliant at SNOMED for all of the quality and internal process and many reporting needs, and ICD-10 is not as well behaved, is not as well carried, it doesn't have a well managed transition from this version to the next version, anything that's ICD-10 then is going to be part of the ICD-11 firestorm, whenever that happens, and so if there is a reasonable option, and it seems to me particularly in counter-diagnoses if we're going to have problem lists in terms of SNOMED, clinical quality measures in terms of SNOMED, having counter-diagnoses in terms of ICD-10, it seems to me to need a lot of justification.

The modularity and the just enough is great. By the way, this whole thing is great, brilliant work, thank you. One of the tricks is going to be that all organizations are going to find it tricky to negotiate the path from MU1 to MU2 to MU3 to really meaningful use, which will be thousands of quality measures, thousands of efficiency measures, most of which we've managed internally, not reported to anybody for reimbursement, so anything we can do to make it clear to people what the costs and benefits and risks are. Would it only cost 10% more for many organizations to say I'm going to get a full EHR, I'm just going to always have full 2014 EHR, full 2016 EHR, because the benefits I would gain by having just enough maybe make sense to John Halamka, who's smart enough and has a smart enough team to negotiate all that, but maybe everybody else pays 10% more and saves 25% fuss. So anything we can do, or somebody can do, to try to help organizations think through that cost benefit I think would be really useful. It's like do I want to get next year's Nissan or whatever's top rated, or do I want to customize something. Customization is almost always incredibly expensive.

Then finally, as we create certification criteria more going forward have we asked people like KLAS and American EHR Partners and the American Family practitioners who spent a great deal of time with customers, with users, but people are actually trying to make use of this stuff, have we asked them what are criteria that in your experience distinguish really useful EHR and other technology from not a lemon but not really going to help you get very far down the road technology? Thanks.

Steve Posnack – ONC – Policy Analyst

Okay. I've got them all down, I think. The first question, I think that's a great one to raise as part of public comment. The second one with respect to clinical meaningful use certified versus something else, I think we look at it from the perspective of there's only one thing you need to know as a provider, that your EHR technology is 2014 edition certified, regardless of the stage that you're at. It wasn't quite a problem before because we only had one stage and one edition of certification criteria, and I think we may be looking at it from the other side, and I recognize your point. I hope we can find a balance in the communication aspect. On ICD-10 conveniently we're in the throes of finalizing everything, so we do request public comment on its appropriateness given the recent announcements and where we are in the

rule making and the timeline that we're looking at for the rule making being 2014, ..., great points. And then I think both as part of our work to develop a plan going forward for health IT safety as well as the committees and the committee purview, you could have those folks come in and testify to give you some ideas.

John Halamka – Harvard Medical School – Chief Information Officer

Cris Ross?

Cris Ross – SureScripts – CIO

Thank you. Steve, I was feeling the fun and the romance too, which I think says more about my dull life, but that's beside the point. I have three comments; I'm not as smart as Jim. First is, as you know, the Implementation Workgroup has been working hard prior to the issuing of the rule to try to come up with recommendations around test cases, both to improve the observability and automation of tests based on the ... as well as adoption ..., and I think all the things that you've done to put together some simplified grids and graphics and so on, Mary Jo and Carol have been helping the workgroup with that, it feels to me as though we should take this off line, but find a better way for us to really make sure that your presentation and our work matches really seamlessly. So if we could have a chance to have that process dialogue I would really appreciate that. I know Liz would too.

More substantive, the two other comments that I would make is one of the issues that I know we saw early in adoption around Meaningful Use 1 was this idea of complete versus modules, and I think some of this was real and some of it was perceived, that may have been resolved but there was this issue that someone would have vendor XYZ's version of certified technology and they would have vendor ABC's version of certified technology, and they wanted to use both of them in their practice setting and they would use them in different ways, but the two were not certified together and so on and so forth. It feels like the 1-2-3 plus C approach is highly amenable to that. I'm not sure if you believe that that is still an issue in the community or not. It would be useful to just hear your comments about whether that combination of two vendor product issue has been resolved and how you view that.

The second comment is, I think that what's been included around transport with respect to direct and exchange and the commentary about emergence of potential standards in the RESTful space is precisely right, and I just can't applaud it strongly enough. I think that ONC is totally exactly the right line, but I had observed that the language there around emergence of RESTful transport is intentional, but a little bit vague. So I'm hoping that in the context maybe of the NwHIN Power Team we can have some dialogue about how to sharpen that a little bit, because I would be concerned with just one commentary window. People might not know how to comment on what your intent is around how to make that happen. So if we can sharpen that and dialogue in the NwHIN Power Team, that would be great.

Steve Posnack – ONC – Policy Analyst

Great, thanks. I'm happy to work with you on the Implementation Workgroup stuff. I have a mantra of good process makes good policy that I got from someone, so that's very important. Then on the modules being certified together, that's I think a topic that always keeps coming up that we've heard from a variety of different stakeholders. Today in our proposal we don't address having two separate modules from two different vendors. Being part of our certification, anyone can offer that as an additional service, so that's not necessarily something that we require for certification, although we have talked about other things, and Doug can chime in, or Farzad, if you want to say something, other options that we could pursue in the future looking at open APIs or other ways to make them work better together. And then on the RESTful aspect of things, we wanted to put that in as an acknowledgement that there is work underway and that we do have regulatory mechanisms to, if a RESTful approach was available and recommended, to get that in and to make it available for certification as soon as possible in an off cycle regulation that would then make it available for folks to get certified to and then useful for meaningful use.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Let me just follow up. In response to the NwHIN ... recommendations that happened over the summer, in fact the federal health architecture and many of the federal partners there have already begun to investigate RESTful interfaces with regard to that. So we are in the process of exploring that space,

seeing what that looks like, and so stay tuned. We've been listening and we're trying to operationalize that in a way that will be responsive.

John Halamka – Harvard Medical School – Chief Information Officer

Certainly in the Nirvana of interoperable futures we'll see the SHARP Grant funds and things like the SMART platform, which gives you an API that allows a true app store like approach to modularity, but it will be a journey to get there. Walter?

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy

Thank you. Great work, amazing work to see all this coming together. I really have now two, so we're down from five to two comments, very quick ones. The first one is maybe emphasizing a little bit what Jim said, on slide 14 specifically if you can maybe go to that slide for just a second, because I think that's what creates a little bit of the confusion about this edition affect. In the column on the left where it says "Or equivalent 2014 edition EHR" so if I'm standing today on 2012 and maybe even during 2013 and I'm going to try to get a certified EHR technology to begin to do Meaningful Use Stage 2, this reads as if I'm going to have to not only look at what's in place today in the regulations for certifying meaningful use products, or EHR products, which is stage 1, but I'm going to have to somehow look at what are the equivalent 2014 criteria for certification and somehow bring those back into stage 1 and try to comply with those.

That's what is perhaps creating the confusion. I understand that we're improving these and expressing this, you're probably looking at if I'm in 2016 and I'm looking back, there's people on maybe Meaningful Use Stage 1 and they have to now comply with both the criteria for that and the edition 2014. But looking at it today and next year when people are certifying for still what is today the criteria, this equivalent 2014 edition EHR becomes a little confusing and makes people wonder, so I have to now look at what's the next version and try to apply it this time and in this cycle. So I don't know if you can clarify the meaning of that or equivalent 2014 a little more, and particularly in light of the fact that in your slides about standards and certification certainly there's new certification in 2014 edition, there's going to be multi-certification criteria from 2011 to 2014 edition, and then there's unchanged, and so thinking of the ones that are new or have been modified, how do I read this equivalent 2014 if I'm doing today and next year the certification?

Steve Posnack – ONC – Policy Analyst

One quick point that's easy to make, for anyone that has EHR technology that's been certified through the 2011 edition certification criteria, they're good to go through 2013. So what this provision includes that we've proposed would allow folks to get upgrades, so let's say the problem is certification criterion, today the 2011 edition says ICD-9 or SNOMED, and what we said is that through 2013, which we expect to be the real transition year, you can get EHR technology that includes the 2014 edition certification for just doing SNOMED, and that's where we have a cross-walk between the problem list certification criterion for 2011 and then the Section 314 certification criterion for problem lists, and you say if you get an upgrade for this certification criterion you're good to go. And that's I think going to be an area where we can help from a communication perspective, where the EHR technology developers that will be meeting with our customers will have to work that out as well. But the primary purpose of allowing for the equivalency is to allow for the transition to occur and to permit that to occur without any regulatory interference.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Just to make it even more clear, the policy driver of that is what we don't want to happen is every practice and hospital in the country needing to upgrade on the stroke of midnight December 31st. We want to be able to spread out the time when people can upgrade to the next version, the 2014 edition of the software, and make that be backward compatible so they can continue to meet the 2011 edition requirements in Stage 1.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy

I think that would be very helpful to clarify it. The second question I have is really about products of the S&I framework. I noticed in your slides you included already some of the linkages in terms of the 2014 edition proposed standards to some of the ... and I ... developing and producing, and there's maybe a few

of them. Do you expect to see some more between now and the time by which the final regulations are produced, some more adoption of some of those products that are expected to come out of the S&I framework initiatives in the next few months or in the next several weeks? Is that something that you see, or is this basically in terms of the adoption into certification criterion standards of the products from the S&I framework initiatives?

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

All the standards that were proposed within the 2014 edition have made it through the entire cycle in the sense that, one, they were based on existing standards oftentimes with merging and consolidation, so consolidated CDA was based on existing standards that we clarified some of the ways in which it could be implemented and brought together a lot of different approaches. The same would be true of the HL7 2.5.1 and the implementation guides around that. So much of the work that came out of there was based on existing standards that were already in play and have been brought together and harmonized.

The second thing is that all of those that have gone into the proposed rule also have gone through the balloting cycle through HL7, and we resolved close to 2,000 negative ballots over the course of the last nine months, and so all of them are in the stage of draft standard for testing and use. So one would expect, as these standards argue, that there would be fixes and repairs and other things like that that may be made to them, but we have gone through that full cycle of review on those that have been proposed in the rule.

Walter Suarez – Kaiser Permanente – Director, Health IT Strategy

Some of the testing of that, after the end of the full cycle of reviews and adjustments, or I guess negative ... being addressed, has that been achieved in terms of demonstrating the final product after having completed a full ballot, is executable and it's functional?

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

It has gone through the entire ballot cycle. We have resolved all of the nearly 2,000 negative ballots associated with that. That's led to some refinements and some clarifications in the standards. But the reason I preface it is these are based on existing standards that have been out there and that have been used. It isn't as if these are de novo brand new, in fact, we've tried to leverage all the good work that's gone on before as we move forward. So it's based on existing work. We have some sense that the existing work prior to this was useful and that people were using it. This I think will result in a step forward in terms of the clarity and the interoperability that we'd like to see, and it has gone through the ballot cycles that we have within HL7 resolving the negative ballots and both transitions of care, consolidated CDA, as well as the HL7 laboratory results interface, both of those have gone through that cycle.

Steve Posnack – ONC – Policy Analyst

It's not without precedent for us to include in the final rule standards that are brought to our attention that have sufficient maturity and use that we can include for certification, but what we've got in the rule is really what we thought was best available to include in the proposed rule and we have other regulatory processes like the RESTful example type of thing that we could go through a smaller off cycle regulatory process to adopt something that if the Standards Committee so recommended a year from now that we could adopt and include as an optional certification component that allows people to voluntarily go through that and that expedites our regulatory processes because we can go through an ... rule at that point.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks. John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer

Yes, two comments and two questions. First, I just wanted to compliment Farzad on his dynamic leadership at HIMSS. I thought he and the staff did a great job of energizing everybody on this. Secondly, to thank you for in the paragraph on the proposed rule, V, you included healthcare providers other than the ones that are eligible, and since I represent long term post-acute care, that was very important to us to put a little bit more in perspective Golden Living, whom I work for. We have over

60,000 patients under our care at any one point in time, so it's very important to us to be part of this whole thing.

Two questions, the IOM report that was referenced in there, do you know when that's going to be put out? The second question is, can you give me a little bit more feelings about the third party A little fear I have is that patients will say, or doctors or hospitals will say, transmit the third party to that skilled nursing facility or to that home care, and I don't know really if you have any more thoughts behind who third party is, and is that really part of what we're doing with long term and post-acute care and skilled nursing, assisted living, home care, hospice, etc.

Steve Posnack – ONC – Policy Analyst

Thanks. On the IOM report, the report itself is out and publicly available, if that's what you were asking. I think you can go to the National Academy Web site to get to it. On the third party aspect, that is related to the view, download, and transmit to a third party. That's one of the patient engagement objectives and measures certification criteria . The third party in the context that we're referencing has to do with the third party that the patient determines, so it could be another PHR or some other type of health record bank or something else that would be a third party in that case. But it would be a transmission capability from the provider's EHR technology to that third party.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

A patient who's in the hospital just having surgery could say then we want that transmitted to a nursing home.

Steve Posnack – ONC – Policy Analyst

I suppose it could be –

John Derr – Golden Living LLC – Chief Technology Strategic Officer

If they're going to have rehab that's probably what they would do. So then we have to really accept those things, and that's what I wanted to point out.

John Halamka – Harvard Medical School – Chief Information Officer

Floyd Eisenberg?

Floyd Eisenberg – National Quality Forum

First of all, I want to thank you for what I see in the certification rule. It's a very balanced approach and you've clearly listened to all the comments you've heard over the last few years, and it's a lot of work and congratulations. There are a couple of comments I did want to make, and tying on to Jim Walker's comment about the encounter diagnoses, to have the diagnoses in different formats may be somewhat problematic. I also noticed on procedures that SNOMED was not included, especially on your slide. I have to go back to the rule to see if it was a slide mishap or not in the rule. The concern there was in considering procedures at least around measurement and CQI that would occur in a hospital there are procedures that are not billable and they need to be addressed to be able to identify they've occurred. Some are available, some are not, and so using only a billing terminology could be problematic to evaluate.

Another issue that I notice in the rule, it wasn't so much in your slides, about providence of data, providence of data was left to the CDA, which is providence of everything within it. I know where it came from, but the individual elements within it have specific value that is identified only if we know where it came from. This is not just for quality measurement, but if I know that there's an ejection fraction in there, that might be a bad example, I need to know what diagnostic test it came from to know how I trust it as a clinician, and that's also important for a quality measure. So if we're using that CDA content to be able to evaluate detail data and not just view, it's important to deal with the data providence.

The third issue I'd bring up, and I expect that there's going to be some discussion about query health later today, and I very much look forward to working with groups like query health to see how we can take, in the quality measure side, the query for a phenotype or a type of patient. Those phenotypes could be

represented as a denominator or a numerator and a measure, but they'd also be used for research and to make the output of that request more usable within EHRs the experience we've had in AQF addressing the referenced information patterns to indicate what you want to query for has raised a couple of issues. One is, it's hard to say what you want to say in a simple manner. It's hard to apply if things need to be mathematical operators, it's hard to apply them, and no one's really taking that to create queries directly out of it, and even with simplification it may be difficult. So I might suggest looking at simpler things like Java Script or others.

M

I just have one comment on the second point about procedures. My recollection is that in the prior rule, our current effective 2011 edition we just had ICD-9 and the HITPC CPT so ... hadn't been on the radar for procedures in general, so that's an area where a comment in the committee's ... would be helpful.

M

Just a comment, that was in the transmittal letter that came from this committee that SNOMED be included there.

John Halamka – Harvard Medical School – Chief Information Officer

Dixie Baker?

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

First, I want to thank you for changing the certification approach for certifying privacy and security in EHR modules. You guys will remember that the Privacy and Security Workgroup recommended that change because we felt that it was antithetical to the objectives that privacy and security had to have every module separately meet all the privacy and security requirements, so we really appreciate your change there. Also, I want to thank you for adding the Network Time Protocol, the NTP protocol, and it's used for clock synchronization, for those of you who may not know. It seems like a trivial standard but in fact it's a very, very important standard for patient quality of care, patient safety, as well as security, so we really appreciate both of those changes. You did a great job on this.

I also support, as John mentioned, I support the specification of Direct and Exchange for EHR exchange, and also I like including the third reserve category. Hopefully that will accommodate a RESTful third transport. But I am concerned about the omission of the Transport Layer Security, TLS as an acceptable secure transport for appropriate purposes. I did notice that on page 44 of the preamble you mentioned Transport Layer Security, TLS, as an acceptable transport but in the body of the regulation itself it's omitted, and it's especially needed for consumer communications such as the Blue Button uses TLS. It's also needed for if we ever wanted to use the micro data approach to accessing provider directory type information because you'd want to authenticate the server, you'd want to secure the exchange, so it's needed for a couple of purposes, and as David McCallie frequently brings up, just to facilitate that and to encourage innovation in the use of new web technologies, I think it's really important for TLS to be included. So my question is, is that an oversight or was there a conscious decision to leave out TLS?

Steve Posnack – ONC – Policy Analyst

Good question. Certification isn't a feeling, so the question is do we need to require a burden as part of EHR technology development to include additional functionality for certification that could otherwise be used as part of use of the EHR technology. So the question I guess I would pose back would be if the committee at large feels like it must be part of certification then that would, I think, be the dialogue that would be helpful to have. In a lot of cases, as Dixie would know and I've been part of the workgroup, a honorary member, I guess of her team, we talked through where we could identify best practices for how you would implement and apply and further use the EHR technology once it's been certified, so if we've misconnected on any of those issues and the committee at large feels like we should require, for certification, TLS, that would be a standards policy suggestion that I would recommend that you all consider.

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

Okay, then let me plug it right in to where it belongs. When in the consumer communications section, the only security requirement that you'd call out specifically for consumer interactions is an auditing requirement, the implication being that all the rest of the EHR security requirements automatically apply to consumer. I would also, in the consumer section, call out TLS as acceptable for consumer communications.

Steve Posnack – ONC – Policy Analyst

Just, and this will get way into the ..., the question of acceptable versus required for certification is something I just would like you to consider.

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

Okay.

John Halamka – Harvard Medical School – Chief Information Officer

Very good.

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

Thank you.

Steve Posnack – ONC – Policy Analyst

Thanks, I appreciate it.

John Halamka – Harvard Medical School – Chief Information Officer

Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President

First of all, I'd echo the rest of the committee and the amazing work that you've done, and I'm very encouraged by the descriptions of the modular approach for two operational and future reasons. One is that healthcare institutions purchase and acquire more facilities. The real world needs to put together modules that come with those acquisitions, and being able to mesh that easily for certification and attestation I think is a real need. And more clarity around those modules and how that can be used given that I think is important. And then additionally for the future need with Meaningful Use 3 and beyond we're looking at a lot of Greenfield requirements, care coordination and patient engagement are largely not in functionality within EMR, so being clear about how these modules can be added and interacting I think will be a very important part of the work in Meaningful Use 2 requirements and beyond.

John Halamka – Harvard Medical School – Chief Information Officer

Arien?

Arien Malec – RelayHealth – VP, Product Management

Unfortunately I'm breaking the trend of going down in number of questions, so I've got a number of them. One is, allergy terminology or adverse drug event terminology is not specified, and I'm wondering whether that was intentional, in which case the standard is text, whether it was an oversight, or whether the medication terminology was also intended to apply for medication allergies and adverse drug experiences, in which case it wasn't clear on the read that that was what was intended. Do you want me to ask the questions and then you respond?

Steve Posnack – ONC – Policy Analyst

Yes, I can do ..., if that's easier. ..., so where we're explicit we're explicit; where we're not, we're not. And we didn't have terminology for allergies previously and we didn't feel, and I don't know if Doug wants to add in anything else, there wasn't any additional discussion I think at the committee level here either.

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

I think there was, at least to my recollection there was, I think we looked at RxNorm and NDF-RT, RxNorm for medications and ingredients and NDF-RT for classes, and interoperability of allergies and adverse drug experiences is probably one of the most critical patient safety issues. So I'd just request that you look at that item.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

This is Jim. I thought we did have recommendations in the transmittal letter.

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

That's right.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

But I can't remember what it was.

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

They were RxNorm and NDF-RT for the meds, and to describe the kind of allergy, SNOMED.

Arien Malec – RelayHealth – VP, Product Management

The second, and this could just be a comment, is that there are, in some cases, and I think it's a really good thing, in some cases vocabulary standards are specified on transport or on the interoperability specification, and in other cases, which I think is generally a good thing, it permits flexibility of the actual EHR technology that requires mapping to a well-defined external standard. There are a couple of cases, and I'd point out the problem list, where there are vocabularies that are explicitly listed in the functional requirement, so for example, maintaining a problem list, and I worry that that creates, I know many EHR developers have really clinician friendly terminology that they expose to clinicians that they may map to SNOMED on the back end. There's this language of "in accordance with," and it's not clear to me what "in accordance with" means in that context. I don't know if you want to comment.

Steve Posnack – ONC – Policy Analyst

The functionality for certification that needs to be demonstrated would be at the end of the day it's recorded in SNOMED. How it gets there, there are a variety of different innovative ways that I can see taking place, but in order to pass certification the problem would need to be coded in SNOMED at the endpoint.

Arien Malec – RelayHealth – VP, Product Management

By the way, I didn't start the comments off the way I wanted to, which is to repeat my comments on for regulation this is poetry and this is extraordinarily well written and it's very clear –

Steve Posnack – ONC – Policy Analyst

But –

Arien Malec – RelayHealth – VP, Product Management

Most everything was right on, so I just want to make that the preface to all of my comments.

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

Arien, on your prior point, are you proposing or suggesting that it be only an interoperability requirement, or that it's important for it to be recorded so that it can be used for decision support of registry functions quality measurement within the system?

Arien Malec – RelayHealth – VP, Product Management

My preference would be that it be mapped to and be able to be used in quality measures, be able to be used in transport, but that there are cases where physician friendly terminology for problem lists may be the user interface level and that it be mapped to SNOMED on the back end in those cases. The same

thing, that's really common for medications, where you've got a proprietary medication database that's been with proprietary coding that's been mapped to RxNorm on the back end.

The one piece where I think I verbally understand the intent and understand the intent in the comment language but not in the actual regulatory language and the reference to the two direct specifications and then the optionality of SOAP, so just one comment. First of all, there's a name oops in terms of the actual reference in the regulation text to the XDR and XDM for directed messaging, where XDR is spelled out but it's spelled out wrong, it's spelled as external data representation as opposed to cross-enterprise reliable document something.

Steve Posnack – ONC – Policy Analyst

I think we might have pulled that from the actual specification.

M

That would be my typo.

M

We can figure it out. We'll get to the root cause of that one.

Arien Malec – RelayHealth – VP, Product Management

It's probably me. I will admit to being confused by these two specifications are required but SOAP is optional. When we wrote the XDR, XDM effectively interchange what we were intending was to give a clear path for people who used XDR, including people who use the NwHIN Exchange specifications, a clear path to interoperate with direct, where, for example, an EHR might support XDR in its native format and then work with an exchange party at HITSP to do the translate back and forth. And to do that full specification you actually have to speak XDR, and it's a little confusing to me that you've got that but then SOAP is optional. I was confused by that section, and that's an area that I shouldn't be confused by. So that's a comment, I would just look at that.

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

In terms of what you would have expected to see would have been what, that the XDR, XDM has been optional also?

Arien Malec – RelayHealth – VP, Product Management

I would have expected to see either that the SMTP, S/MIME specification is required, and the XDR, XDM specification is optional, or to see that both are required, including SOAP as a required transport. I think both of those would be logical and consistent. The way it's written creates a set of inconsistencies.

M

Probably as a friendly amendment?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David McCallie. Just the notion of what the format is on the wire, there are places where I think there's borrowing of an XDM structure ready for transport for which the reference document shows how to map that to SMTP on the wire, versus actual XDR on the wire. And it's just a little confused. It seems the intent is that the XDR is optional, but it's not completely clear. And some of that I think is the reference documentation may not be totally clear.

Arien Malec – RelayHealth – VP, Product Management

That would be my fault, and I'd be happy to take that one. Then the last comment is just a policy question or a policy statement. I am incredibly enthused by the level of focus on patient engagement that's both in this proposed rule as well as in the CMS proposed rule. I am, at the same time, concerned that the natural EHR vendor response is for everybody to run a patient portal and I'm concerned by two things. First of all, doing that well, being mindful of privacy and security is hard, and then doing that with good usability for patients is hard, and so we may end up creating inadvertently a world where if I've got my primary care provider, my hospital, my endocrinologist, and my cardiologist I've got four different log-ons I

need to manage and that doesn't lead to a world that I think we want to. So we need to square that policy circle somehow and maybe work with Liz and Chris in the Implementation Workgroup and we can come up with approaches to that. But overall it's just tremendous work, so take my picking of nits in stride.

John Halamka – Harvard Medical School – Chief Information Officer

We have David McCallie, Judy Murphy, Nancy, and then Wes gets the last word.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

David McCallie here. One point was just the same point Arien made about clarification around XDR and SOAP and exactly what the intent is, and I won't repeat that one.

The second point is really with respect to the CMS side, the inclusion/exclusion criteria of knowing whether you're sending to a vendor's similar product or not in terms of whether you get your 10% count. At the moment there's no good way to do that to know what the processing technology on the other end of an asynchronous message is. So I think we can debate, and I assume there will be debate about the logic behind that exclusion criteria in the first place, but the technical constraint would require something new for us to keep track of all that, and I think that would be a burden, and I'm sure that will all get reflected in our comments.

Then the third thing is just a fear or concern around this ICD-10 SNOMED problem list confusion. I fear we're going to end up with a world where the physician burden is now doubled and that they have to go through the ICD-10 or whatever takes its place if we don't do ICD-10 process because they're just being expected to produce a billable result and then in addition to that go through a SNOMED process to manage the problem list. And we could have, again, a consequence that nobody wants to use the problem list because it's so burdensome, above and beyond what they've had to do for counter billing, as Jim pointed out. So I don't have a proposed solution. I just think that we're on these two ... tracks and they intersect at the physician's experience in a busy setting and it could be a mess.

John Halamka – Harvard Medical School – Chief Information Officer

Judy Murphy?

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

Steve, just a thought that you can maybe make a few comments related to the clinical quality measures certification.

Steve Posnack – ONC – Policy Analyst

Sure. We broke up our certification criteria into three buckets to focus on the life cycle essentially of clinical quality measures, the first one being capture; the second being calculate; and the third being reporting. And so for capture, that's really where we took a good bit of real estate in our preamble to discuss the readiness of EHR technology today to capture all of the data, what challenges may exist relative to and juxtaposed with the quality data model and how measures are currently specified and have been retooled and try to lay out for the community of stakeholders our perspective and what we've seen. I've gotten a lot of feedback from Floyd and others over the course of time about where things are, and working with CMS we had also looked at, for calculation changing and what we did require in our proposal to focus on certification of each and every clinical quality measure that the EHR technology includes.

And so on the eligible hospital side and the inpatient side for certification, that was already part of how things played out since hospitals have to report on 15 CQMs today, and those are the only ones that are available. But going forward for both sets of eligible providers, the eligible professionals and eligible hospitals, one of the things that we wanted to make clear was that we expected that testing for each of the clinical quality measures to be done individually and that the certification, from a transparency perspective, would reflect each of the clinical quality measures that the EHR ... is capable of calculating. And then reporting, as Dr. Halamka had mentioned, we still have some room to maneuver and make some changes, but that's an area where we're soliciting some public comment, in addition to working with CMS. Is that everything that you wanted me to touch on?

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

No, I wanted you to also talk about the export part of that, just to draw people's attention to it, because I think we're looking for comment.

Steve Posnack – ONC – Policy Analyst

As part of the capture and calculate pieces of those two certification criteria not only is this part of capture, it's two fold. We expect the EHR to acknowledge and be able to capture all the data elements specified in the QDM, as well as export that information so that it can be consumed by another type of EHR technology. Then on the calculate side this would be on the intake, so we propose that the EHR technology, whether it be we have a special exemption for something that does everything, but if it's two separate EHR modules and one gets certified for doing calculations, so if you take ... health, as an example, if that were to come forward to get certified through the 2014 edition it would need to be able to intake all those data elements that could be exported by something else and then subsequently do the calculation. ...?

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

Yes, that was great. It's a big change I think from where it has been at before, so I just wanted to draw everybody's attention to look at that when you're reading through and thinking about your comments.

Steve Posnack – ONC – Policy Analyst

Floyd, did you have a friendly amendment to that?

Floyd Eisenberg – National Quality Forum

Yes, and actually I think that a lot of that focus of splitting them up is very valuable. I'm just a little concerned about requiring certification by measure, because I thought the entire vision was certification that can capture the data that are needed to handle any measure, and that means myEHR is enabled for meaningfulness, and then if you're going to calculate, sure, you can base it on the ones that you have, but I'm not sure capturing the data and exporting it should be specific measure driven. Otherwise, you're going to limit CQI and other processes. That's just a comment.

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

Another good area for comment.

John Halamka – Harvard Medical School – Chief Information Officer

Nancy Orvis?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Good morning. I had a couple of comments relating to either the overlook of the drug allergy adverse events reporting. I think it should be fairly easy to put something back in that articulates that clearly. DoD and VA for six years have been exchanging medication allergies at RxNorm with the NDF-RT and SNOMED for the conditions, and I think it's really important to say allergies are really good for computability so that you can do the drug-drug interaction in your own system, and I think you're looking for that articulation because if that's the first criteria for decision support that there's drug-drug allergy interactions, you need to state clearly that medication allergy is a computable set of attributes. So if there's anything more that you need on that, we would be happy to talk to you about that. It helps you transport between proprietary information models, and that's the only way you can do it.

Second, I'm glad that Arien mentioned this issue of a plethora of patient portals. That is a scary thought to think about. So if there are some other projects that could help either by ACO area or accountable organizations that might want to prototype something like that, say here's your one stop portal for everybody in your ACO or your health insurance or where that individual gets care, that would really be important. It is particularly care for loved ones. If you are trying to access records for a loved one you has seven different doctors and there's all different ways to get it, that would be a really, it's already a problem. I know that as an organization, as DoD with a TRICARE benefit we're facing that same issue, how can we reduce the number of portals because it's one benefit, one healthcare plan for that individual, and maybe there are some ways we can think better about that. It is each taxpayer's healthcare. It is

maybe to their benefit to have one or several small ways, one single way that they can access their healthcare information. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

And Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President

Just to add to that, I think there's great potential for the Direct project to be more engaged with patients and the ability, as I've heard Doug say, of ... that allows the patient to identify their preferences of communication and have the physician or provider carbon copy the patient, and the patient able to also carbon copy their other associated caregivers. So I think there is great potential to expand on our existing standards of ...direct and make sure that we address this concern which is real if we do have multiple portals at the patient side or multiple ways to communicate that does not allow for cc'ing important electronic medical record sources and/or recipients as well as patients and their families. We then simply automate ... and so it would be great to avoid that. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Wes Rishel, the last word.

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

Thank you, John. I want to just comment briefly on the plethora of patient portals. I agree with everything that everybody said here except that I am concerned that it's leading in the direction of linking enterprises that we've yet to always show an economic ability to link. And so I would say that I think we should move in the direction of solutions but we shouldn't concern about a plethora of patient portals as being a rationale for having no patient portals. So let's regard this as an improvement in the future rather than a replacement for what we're doing now. My main comment, however, is my favorite soap box, which is to be illustrated by the work that ONC and HL7 has done in the consolidated CDA. There has been, through a number of projects, a huge understanding of primarily ambiguities but some other issues associated with the CDA specifications, or the CCD specifications, and let's assume that all of those that were identified got reflected in changes that went into consolidated CDA. Furthermore, systematic things were improved in the consolidated CDA that make it easier to work with. I don't know what the number is now, some young whippersnapper like Arien can probably say, but in the old days for every 8 bugs you fixed in program code you introduced a bug. And there's some corresponding constant alpha for changes in standards as well, so we should expect that some issues arise out of the fixes we've done.

More important, there are more issues to be unearthed between now and 2014 in the consolidated CDA. And I'm concerned that there be a process for identifying and resolving those issues that is available freely to the community and has a faster turnaround than a full HL7 ballot cycle. So I'm hoping that ONC can find a way to work with HL7 and others to come up with a testing sandbox that goes beyond what's necessary to achieve certification, a forum for identifying issues and resolving issues that has the participation, if not the full process weighted HL7, in the sense that if the advice is do it this way, 90% of the time that advice is going to hold up through the HL7 downstream process just because the people are knowledgeable that are answering the questions. I think if we don't do that somehow, if we don't somewhere between government and industry find a forum for this, these issues will come out, they'll come out during the time when people are trying to do the interoperability in order to achieve meaningful use certification under the 2014 edition. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you very much, Wes. Excellent comments from everybody and I am sure, Steve, that as we get additional comments from the community you'll rely on this brain trust to try to help consolidate them. I think two gold star ideas to highlight is the cc:Me idea of trying to get to more consolidated patient portals, and leveraging direct for patients is very interesting and the idea that an EHR might export its data for the use and consumption by a quality reporting service, a calculation service, because lest we have a thousand patient portals we'll also have a thousand quality calculation engines and might it be actually better for EHRs to simply leverage a smaller number of consolidated services.

Thanks again to Doug and Steve, and now we have Betsy Humphreys, who's always extraordinarily succinct and time efficient. So it's Betsy Humphreys' vocabulary and then lunch.

Betsy Humphreys – National Library of Medicine – Deputy Director

I think you all have memorized the certification criteria so I don't need to tell you that that's about the list of those that are specified. I am going to today focus primarily on issues related to SNOMED CT and how it does or doesn't connect with ICD-10-CM or ICD-9-CM, since I think that certainly a specification and certification criteria that will catch everyone, or has already caught everyone's attention is the fact that SNOMED CT is proposed as the sole candidate for the problem list. And I'll do a little bit with LOINC and RxNorm as well, and then key up some questions where advice would be good from the committee about what you think we should be doing that we're not doing to help people in terms of the migration to these and broader use of these terminologies.

My slides are slightly out of order so I've gone to four and then I'll come back to three. Essentially there are a number of assets related to SNOMED CT designed to help people who want to implement them. I've listed them here, it's on slide four, not three, and a couple that I'll be talking a little bit more about are the U.S. extension to SNOMED CT and also upcoming enhancements to API access to SNOMED CT via the UMLS enhanced API system that will be available in March 2012 and I think will help us provide improved API access to SNOMED CT for people.

But now I'm going to highlight a few issues that we've been working on, NLM has been working on in conjunction with the IHTSDO over the past few years. One of course is what some people have perceived as the slow rate or speed of new content additions to SNOMED CT and if you're faced with the fact that you must use SNOMED CT for your problem list this might have greater concern for you. The IHTSDO is well aware of this problem. They've been working on infrastructure to support it, both in the tooling but also in the expansion of high level consultant terminologists so that there are more people who are trained and equipped and empowered to resolve some of the policy issues that prevent rapid update in certain parts of the terminology. Last year they established this consultant terminology program and it pointed the first five people to it, one of them is Jim Case at NLM, and they're right now accepting applications for the next group of five, probably about five again. You can get your application by Friday and become one of these if you'd like to, or have somebody in your shop become one, and so this is increasing the capacity for making high level decisions and moving ahead.

The other is moving to what we've all been desirous of, which is true distributed editing, and as we get more consultant terminologists and editors more people can directly edit the international release and go through the final validation. And I'm happy to report that as of earlier this month the consultant terminologists are now able to edit directly into the international release of SNOMED, and Jim Case is off doing this as we speak, and there intends to be a gradual expansion of that. I think we've gotten some of the infrastructure in place and I think we will see a more rapid addition of new content to the international release.

And on NLM's end, we have created the U.S. extension. The next release of that will come out in March, and that is a way to more quickly get SNOMED CT modeled content for things that are of particular interest to the U.S., and the next release does have a fair number of additional problems. That's obviously our highest priority. We have neglected to bring this up before, but one of the things that we may provide comments on and think about is whether in specifying the use of SNOMED CT for the problem list we should say the international release and augmented by the U.S. extension and that will give us a faster way to get stuff in that is needed. We may want to go there. Then there is now a U.S. content request system, a new version of that was released recently. When I took this slide thing, I think it said that there had been seven thousand things put in and this is the any user version of this request system, so you can actually see what has been requested by other people. There's a lot of interest potentially in having this thing, which was developed by my colleagues at the National Library of Medicine to serve as essentially the basis for an international request system that may resemble this one.

The other issue of course is, you can imagine, perhaps, that some people reading this stage 2 proposal might say, okay, well I've been using ICD-9-CM for problems but maybe I should go from ICD-9-CM to SNOMED, and the issue is what's available to help people do that, other than obviously a number of

excellent vendor services and vocabulary services that might help people do this. But available from the IHTSDO is the conceptual mapping from SNOMED CT to ICD-9-CM, which is going in the opposite direction. From NLM you have the synonymous mappings between ICD-9-CM and SNOMED, and they're available within the UMLS metathesaurus, and coming soon we're working on a trial map for evaluation to see how useful this is to people, which is going from heavily used ICD-9-CM codes based on CMS' data, and we're going to set that up as a map from those to SNOMED CT.

Now, you all know enough about the granularity of the two systems to know that there's a percent, we estimate about 40%, that will not be one-to-one mappings. That is, if you're looking at this ICD-9-CM code you will need additional information beyond that entry in the problem list to determine which of potentially several or many SNOMED CT entries would be appropriate. However, we do feel that since we also have frequency data on the problem side that we've assembled that we may be able to set this up in a way where, yes, there are more than one but in fact we can show you what the relative frequency is, or at least say it's more likely to be this one because this is more frequency. So this is something that might help people. It obviously would need intervention. And of course this is going to be available for anybody who wants to make use of it, which might be providers, but might well be vendors who are providing services to providers.

The other issue, of course, the one that we had been focusing on in terms of 10-CM is the issue of, okay, if I'm using SNOMED CT in my problem list I don't want to do what I think it was David was talking about, which is do everything twice. So can we get from SNOMED CT to generate encounter diagnoses or other diagnostic information that is required for billing and statistics, so again, the IHTSDO. And then of course the issue is, yes, I want to do this for 10-CM in the future when I'm supposed to do that, but right now everybody's saying well, if I'm going to move to SNOMED CT well, I still am using ICD-9-CM for at least a few years here now, so how do I do that? Available from the IHTSDO, and it has been available for a long time, is a conceptual mapping from SNOMED CT to ICD-9-CM, which is somewhat helpful.

Again, we have the synonymous mappings in the UMLS from SNOMED CT to either 9-CM or 10-CM, sort of helpful, more so in the case of 9-CM than 10-CM, we have an old, I think it was 2008 we put this out, rule-based map from a subset of SNOMED CT to ICD-9-CM, and a question for you is whether it's now going to become a priority given the change in potential time frame for 10-CM for us to do something more with this, update it, make it more robust. But absolutely new, I think released today, we have the first tranche, or the first section, of a map from a subset of SNOMED CT, heavily seen problems, to ICD-10-CM with a demonstration tool that shows you how it would work or could work inside a system. And what is available today maps from 7,277 SNOMED CT concepts to ICD-10-CM, and in June of 2012 we will have the complete version of what we see as the initial map we're going to produce, and that will be from about 15,000 or more SNOMED CT concepts.

I just want to say right here that this is when international cooperation and collaboration with other groups in the United States really pays off, because we definitely leveraged, in producing this map in a relatively short period of time, procedures, data, and tools from the IHTSDO, from the U.K.'s National Health Service Terminology Center, which of course is the U.K. member of the IHTSDO, and also data from Kaiser Permanente CT donations where they had produced basic mappings from SNOMED CT to ICD-10-CM, so we're very grateful to all of them. This tool is really cool. We always allow anyone to name anything whatever they want at the National Library of Medicine, have you noticed that, and IMAGIC is the name of this, which is kind of cool. But I have given you the URL for this thing. It is very cool to look at it. It's live. It's running against a version of the same data that you can download from us, and it doesn't include everything in SNOMED CT because, as I told you, the map only has the 7,000 plus, but for those it does a pretty neat job. And then as you see, it keys you up for these refinements. In some cases we'll say it's mandatory and sometimes it says it's optional in terms of what you're allowed to report, and then if you click on that it will tell you what additional information you need in order to decide to further refine the code, the ICD-10-CM encoding.

On the RxNorm side, the RxNorm is based on responding to recommendations from this group and others. I think it is very capable of representing both medications and allergies to medications or ingredients in medications. So we're not talking about the adverse events these caused, but in fact the substance that somebody may be allergic to. As I reported to this group before, there was a

recommendation from the Vocabulary Taskforce and the Clinical Quality Working Group that it would be great if we could get inert ingredients represented within RxNorm, they weren't previously, just as free floating things so that you would be able to find in RxNorm those inert ingredients that may have to appear on a medication allergy list because a person is allergic to that, not to an active ingredient.

We have a very robust API to RxNav, RxTerms, other types of drug data, RxNorm now, and it's heavily used. Again, this is the general question, what else do you think, and we'll come back to this general question at the end, we ought to do to support meaningful use? In the meantime, I'm just giving you the top part of what's in the RxNorm API reference list on our site, and there are more specific API calls specified, and we have added a number recently, and more are being added as people come in and say, gee, this is what I want to do, can you give me a specific thing for that, so this is a heavily used resource already.

Then on the LOINC side, as mentioned before, again, based on input from this group and others we have two subsets that are designed to help people move forward in terms of mapping internal things or implementing LOINC, and this is the top 2,000 plus lab observations and a mapper's guide for that. Then a much smaller, I think it's 200 to 300, common lab orders value set, a lot of community engagement involved with both Regenstrief Institute and ... in producing these. The other issue is whether there are any other high priority convenient subsets we should be thinking about. Then there's not yet API access to LOINC, and we know one other obvious API use case, which is if I get a LOINC code and I don't know what it stands for can I send it to an API and is there a good way for me to go and pull back the information by what it means. That seems like a very obvious API requirement for a code or something from any of these vocabularies that we're using. But beyond that the issue is what are the ones that will be particularly useful, and so that leaves us with where we are on the discussion.

Let me just skip first to the future topic. I know that there is vast interest among all of us and all of you, I'm sure, on the issue of value set creations validation maintenance and dissemination with the clinical quality measures vocabulary value sets being an immediate case that we're all fascinated with, and of course there are many more, and I decided that we would have more to present on that the next time around, perhaps in conjunction with ONC and others, and I didn't think we could cover that in addition to this. So the discussion issues that I'm laying out here is what else should we be doing to help support meaningful use of these vocabularies in the pursuit of meaningful use of electronic health records and of course we'd be glad to take any questions or input. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Comments? Of course Jamie's group early on described the notion of one stop shopping with all of the necessary vocabularies to support the various stages of meaningful use in one place with the necessary supporting tools to implement them, and so, for example, I still am spending \$5,000 to \$10,000 on every lab interface that I create because of the custom compendia that has to be created for every non-standard subset of LOINC that is used by every lab and EHR vendor, and so I think Clem has been working for a while on getting the canonical 98% of all lab ordered tests in a single download compendia for ordering.

Betsy Humphreys – National Library of Medicine – Deputy Director

I think that there are those things now. I think that they probably could use, I'm sure they could use use and validation input about what else needs to be done to make them more useful.

John Halamka – Harvard Medical School – Chief Information Officer

Comments from others, we'll go to the other direction, so David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

The mapping from SNOMED to ICD-10, that's great, I'm glad I could chew you up with my previous question and I'm glad we coordinated that. That looks very interesting and I haven't had a chance to study it at all. This is the first I've heard of it. I assume the data behind your demo is available as part of the data set, there's no hidden knowledge in the application itself? In other words, could you wrap this knowledge into an existing –

Betsy Humphreys – National Library of Medicine – Deputy Director

That's the whole idea.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay.

Betsy Humphreys – National Library of Medicine – Deputy Director

And I will have to find out. The basic mapping and the rules are there in the map, so essentially as you can imagine, those of you who know more about ICD-10-CM than I do, you're dealing with things and then okay you're supposed to, if you're reporting this you have to report two codes, you have to report one for this and one for that. And then maybe for one or the other of these codes you have to specify a trimester, or you have to specify laterality, or you have to specify something else, so obviously within the map what can be done is specify rules that are required to refine the code. You have to refine it by laterality or whatever. But then obviously in any given application you have to know where to go get that data if you're going to help somebody do it automatically, or you're going to have to ask them in your application, you're going to have to say, give me this additional piece of information and then I'll be able to give you the right code. Or, here's the one for this, here's the one for that, select it. There are various ways obviously you can implement this mapping and given the application we expect people to do what they think makes the most sense.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

My experience, and again probably not as deep a knowledge as I should have, but there are numerous cases where a single ICD-10 code would require a post coordinated SNOMED code in today's world to represent it. The most problem with tools that capture SNOMED don't capture post coordinated SNOMED simply because it's so hard to –

Betsy Humphreys – National Library of Medicine – Deputy Director

I think that this particular map as delivered here is not using post coordination on the SNOMED side of it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That was one of my questions. And then if the knowledge that drives the rules, let's just call them the rules, is available, then it would be feasible for people to incorporate those rules into systems that, for example, parse the text of the node looking for laterality so as not to have to make the doctor pick from a pick list, because the extra overhead of managing all these pick lists is burdensome. You wouldn't necessarily think it would be, but it is at speed, so I'll have to look a lot more closely at it. But I think that's a great step.

Betsy Humphreys – National Library of Medicine – Deputy Director

And of course the thing is that this is the first subset and it is the first version of this, so there is a serious request there for input about what is good, bad, or indifferent or whatever about this map. So we would really like to get input. One of the things that happened when we did a rule-based mapping earlier, as I said, in 2008, between SNOMED CT and 9-CM is that we got about zero serious feedback on it because I think no one was there yet, they didn't want to deal with it. They'd already solved their problem of how to report out ICD-9-CM codes and they weren't using SNOMED yet, so we couldn't get any real feedback, so we'd really like some on this, because we would like to be useful, obviously.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I predict you'll get it.

John Halamka – Harvard Medical School – Chief Information Officer

Arien?

Arien Malec – RelayHealth – VP, Product Management

Thank you, and thanks for the presentation. This is all really helpful, and I want to second or third the call for convening subsets, in particular to think through in the certification testing the role that subsets have to

play in the context of transitions in care and in the context of pushing information to patients, having a common subset that everybody knows, even though there may be terms that mutually people don't know on either side, so that's a comment. The question I want to ask is, again, back to allergies and adverse drug reactions, and in particular in many cases the rules for class based interactions are a bit of a mess right now because drug classes, compounds or physical substances are a little easier to get there, brands are regulated so it's a little easier to get there, and classes in most drug databases are a weird mix of common mechanism of action, but common therapeutic indication and it's often very, very hard to get real interoperability to reactions to classes of medications. And I didn't see that listed here as a major area of focus.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, it clearly should be, yes.

Arien Malec – RelayHealth – VP, Product Management

Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

Nancy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

It was a very good presentation summary. Betsy, my question is, has there been any discussion under LOINC, and particularly since the CDA standard is out there for some clinical documents, to organize a clinical document taxonomy? Because there's over 2,000 LOINC codes right now in there and it's a mess in terms of categories of documents, so that Suzy Clerk from Dr. A, Dr. B to somebody else can go in and figure out what codes I assign to different tags within the clinical document, for example.

Betsy Humphreys – National Library of Medicine – Deputy Director

Stan, do you want to answer whether there's any effort to do something about organizing those within LOINC?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes, there's work going on. It comes up frequently, everybody that exchanges wants to know from my local document name how do I put it into a class that's meaningful to people and in another organization. So we'll bring it up again with Dan and the team that does the real work. But there's great interest in it and actually there's interest in using the same mechanism to do other kinds of classifications that allow you to do roll up for other purposes, including decision support. We have great interest in that.

John Halamka – Harvard Medical School – Chief Information Officer

Cris?

Cris Ross –SureScripts– CIO

Thank you. Betsy, remarkable work as always. I never cease to be impressed by the ingenuity of your team. I want to echo Arien's comment and extend it slightly, because, as you know, one of my hobby horses in RxNorm has been the linkage to drug class information. And working with Olivier I guess we've discovered that it's really the VA NDF drug classes that are the only ones present right now on the RxNav application, that many of the other NDF-RT classes are not present at this time. Furthermore, as you know, we've discovered fairly serious issues with drug classes where, say, for example, a topical corticosteroid will in one instance be a topical agent and the exact same formulation with a different brand will be a corticosteroid. So the ability to be able to capture both or specifically more than one drug class per agent is going to be a crucial level of functionality as RxNorm evolves and matures. I know many of the people in your team are aware of that, but I wanted to take advantage of this opportunity to reinforce its importance since you asked for what additional work might be done.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes, thank you. It's definitely on the list.

M

Cris, much more eloquently voiced my question about the classification of drugs, as did Arien. I have another question related to what you asked Stan, I thought in our Vocabulary Taskforce we talked about artifacts of the record, for instance, documents would be using SNOMED and now I'm hearing LOINC. And I don't have a preference, I just want to know which ones we should be addressing.

Betsy Humphreys – National Library of Medicine – Deputy Director

I thought that we had specified LOINC, but I would have to go back and look.

M

I just wanted to clarify so we know where to go.

M

I thought we had specified LOINC, and in fact there's not a very strong document naming the content in SNOMED.

Betsy Humphreys – National Library of Medicine – Deputy Director

No, and this of course goes back to way back in history when the original work was being done on the claims attachment HIPAA standard.

M

You had to bring that up.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you. Jamie?

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

Thank you very much, Betsy. I just wanted to note that I think it was last month the IHTSDO approved a pilot program for implementation consultants similar or analogous to the consulting terminologist program but for more broadly dissemination SNOMED implementation expertise. So I would hope that we could have perhaps a U.S. version of that program rather than just the international version.

Betsy Humphreys – National Library of Medicine – Deputy Director

I think that we are very interested in having an official set of vetted U.S. editors and people who have had certain types of training. I neglected to mention that, as Jamie's just alluded, the IHTSDO seriously probably will go ahead with setting up a ... mapping service with trained mappers who are available for particular jobs. And obviously if this had existed we no doubt would have enlisted this purchased assistance for mapping from that group. So I think that will be a useful resource going forward.

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

I'm sorry, just to clarify my comment, it was not about editors in the U.S. but rather implementation consultants for the implementation consulting program that IHTSDO is just starting up.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes.

John Halamka – Harvard Medical School – Chief Information Officer

Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President

Thank you for the presentation. I think I would also like to offer a comment for future work and that is as we start to define more patient engagement principles, building upon the work that Kaiser has done with you, NLM, I think would be good as a precursor to a future environment that will include much more consumer friendly terms, much more patient involvement and integration into the Health Information Technology ecosystem, just as a future thought.

Betsy Humphreys – National Library of Medicine – Deputy Director

Those are obviously very important issues, and ones that the National Library of Medicine is concerned about also in terms of our providing access to our consumer health information. As you point out, Kaiser's donation includes patient friendly terms for some that have been determined to be useful in the Kaiser context and those are things that we can link in. There, as we also know, sometimes the issue is not a consumer friendly term, it's just helping them spell that drug correctly so that they can find the information about what they're taking.

Leslie Kelly Hall – Healthwise – Senior Vice President

Yes, thank you, Betsy.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. Well, and a remarkable morning. I'm turning it back to you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

John, that's absolutely right, just a tour de force, a lot of acknowledgement of the great work that the ONC team and broader community, and Betsy, just stellar work. I appreciate the framing in terms of the support for meaningful use. I appreciate Leslie's last comment about the extension go forward, is that meaningful use defines a set of capabilities that are required and necessary. That doesn't necessarily define the boundaries of what we might hope for, really improved health, improved value ... health system. As I think of medications, one example, and I know we're thinking in very practical terms, because I really look forward to the day where we look not only at allergy but code more systematically what medications worked, or what weren't problematic but offered no benefit. And as we enter the era of cardionics and genomics and the ability for those data of really the clinical response phenotype really to be able to be mapped to all of this information, which simultaneous to our work is really about to explode, the opportunity for some ... in terms of making sense of that and providing better care and better health is really exciting. And for that I applaud you and ... work. I hope everyone here, as we go to lunch, feels a sense of possibility, an appropriate sense of accomplishment, and certainly recognizes a lot of work ahead.

Betsy Humphreys – National Library of Medicine – Deputy Director

I'd just say one more thing, I have to read an awful lot of draft regulations generated by various government agencies, and I agree with all of you who commented that this regulation was a great job.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, I would Thank you, Betsy. Now, it's also a hallmark of this group to eat quickly. We're going to come back at 1:00 sharp, Dixie will start, but we have to break at 1:30 because Paul Tang can be with us for that half hour and making sure that we're aligned is critically important, so see you at 1:00 sharp.

(Lunch break taken for 39 minutes)

Mary Jo Deering – ONC – Senior Policy Advisor

Jon, are you ready? Shall we open?

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm

Mary Jo Deering – ONC – Senior Policy Advisor

Operator, would you open the lines, please?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Welcome back, everybody and thank you for sticking to such a tight schedule today. It's much appreciated. One of the members of the committee brought to my attention that I may not have been entirely clear. May 18th is the date of conflict with HIMSS, and so the meeting scheduled for March and April absolutely as it was. May 18th we're going to have to find a compatible day that works for us

members of the committee. So I appreciate Mary Jo and the team checking some dates, and certainly we'll get that as soon as possible.

M

It was the 16th.

Jonathan Perlin – Hospital Corporation of America – CMO & President

It was the 16th, okay, whether it was May 16th or 18th, the May meeting conflicts with HIMSS. I appreciate that.

M

You're saying HIMSS but you mean HL7, right?

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm sorry.

M

We don't want to have to go through that again.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm going to turn to John now to –

M

The May 16th meeting conflicts with HL7 and it will be rescheduled, hopefully in person, but if no one can make it because we approach Memorial Day it might need to be virtual, but Mary Jo will figure it out.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, let me turn, without further delay then, to Dixie Baker, and I appreciate both the work of the workgroup and Power Team activities. You've got a number of things to present.

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

The agenda for today, we have recently reconstituted the Power Team, we've started up again with a new charter and a few changes in membership, so I'll introduce that new Power Team membership to you. You'll recall that in September when I reported the results of the NwHIN Power Team to you there was a question that arose about whether the public comment that we had received was representative of both the federal government and the private sector, so subsequent to that we published a blog on the ONC blog that solicited inputs about experiences with using the exchange specifications and I'm going to report back to you today the results of that solicitation for input. And then finally I'll discuss the Power Team's new charter.

The reconstituted NwHIN Power Team is the same as the previous, except instead of John Feikema, who now is working with ONC; we have added David Groves, who is Executive Director of the HealthBridge Regional Extension Center; and we also, at his request we've replaced Kevin Hutchinson with David Kates from NaviNet; and the third change is that Arien Malec is now representing Relay Health on our team. We also have added an additional support person from the ONC, Alan Lingerman.

First, I will give you the feedback on the exchange specifications. As I mentioned, we published, Jon, on the ONC blog a set of questions, there were about 12 or 13 questions that we asked, that really were attempting to solicit very explicit input about experience implementing the exchange specifications, so I'll describe the solicitation itself, provide a list of responders, and summarize the feedback that we received.

In our transmittal letter in September of last year we did request that ONC perform additional investigation on the use of the exchange specifications, specifically in the area of complexity, adoption, and deployment, implementation challenges that they may have had in implementing these specifications, and alternatives that may have been used for exchanging health information across enterprises. ONC posted this set of questions on the FACA blog and established a deadline for response of December of last year.

We received 20 responses, 5 of which were from vendors, 11 from health information exchange organizations, there were 2 from individuals, and 1 from the EHRA, and 1 from the exchange coordinating committee chair. The 2 individual responders actually used it as a forum to express their opinions about other things and didn't really answer these questions, the questions that we posed, so they aren't included in the information we're reporting back to you today.

I know this is really hard to see, hopefully you can see it better in your handout today, but this is the list of the relevant responders. As you can see, they really represent a broad sample of organizations. Some are federal organizations, like the CDC and CMS, and some are health information exchanges like the Utah Health Information Network, and some are individual providers like Kaiser Permanente. The summary is that the implementation of the core exchange specifications, and we identified these as core in September to you, the messaging specification, the authorization framework, patient discovery, query for document retrieval of the document, are currently operational within a limited production context and are demonstrating value to participants, including federal agency benefits, exchanges with federal agencies, the expedited benefit payment to the disabled, particularly through the Social Security Administration improved benefits.

There was little evidence that the implementations deviated significantly from how they were specified. You'll recall that in September it was brought up that perhaps some of these implementations of the exchange specifications were not exactly implementations that exchanged specifications, so we did ask that explicitly and they said no, we implemented it just as they are specifying. As of September 2011 there are 20 organizations that are exchanging data in limited production, and I have there what these represent. The exchange coordinated committee is developing a business and transitional plan to guide the exchange to a sustainable model. The core exchange specification can serve as a basis for HIE innovation in critical elements and our critical element is a nationwide health information infrastructure. Several of the individuals who responded described ways in which these exchange specifications are being used within an HIE set of organizations, so they described how they're being, I would say as a summary, the responses that we got primarily they implemented the exchange specifications for exchanges with federal government agencies, but in other cases they implemented them for within HIE organizations to exchange among organizations within an HIE.

Some of the responses seemed to be, in some cases it was really difficult to ascertain whether the person was really making a statement and expressing judgments about the use of the HIE profiles versus the exchange specifications that leverage those profiles. Literally all of the implementations of the exchange specifications were for exchanges with federal agencies and one large organization, Kaiser Permanente. All of the current implementations of exchange are in limited production mode and have not been used for large scale production. None of them are really used for large scale production. The only one that's really in what is considered production are the exchanges with the Social Security Administration where because they have deployed exchange for the disability determination profile, so people are using them for that purpose.

The complexities around exchange seem to be more related to the specifications themselves than to the exchange architecture. You'll recall that we had considerable discussion about this at our September meeting, and what makes the specifications themselves complex are the optionality and the layers of indirection or references that reflect to an HIE profile which will reflect to another specification, and these layers of indirection is what really makes up the complexity and not the fact that they use SOAP, or REST, or whatever the method of transport. In fact, nobody said, well, they're way too complex because they use SOAP. That was just not something that was said. This optionality does increase ambiguity and as one of our NwHIN Power Team members emphasized what's especially problematic is the optionality with respect to CDA exchanges. Another significant problem is the lack of scalability of identity management which limits the use cases that the patient discovery specification can be used, and this is a particularly difficult challenge for the Vila program, which includes a lot of information exchanges as well as organizations and the lack of scalability of identity management is a huge challenge for the Vila program.

The core exchange specifications, which I identified earlier, do have the robustness that is required to meet the needs of a comprehensive health information exchange, but the inputs that we received from

this solicitation agreed with what ... back in September, there is a need for substantial efforts to reduce the optionality and indirection, to reduce the ambiguity, to improve the scalability, and to reduce the cost of the implementation. The suggestions that we received included the simplification of the specifications by reducing this optionality and indirection, and you recall that was one of the primary recommendations of the Power Team, consolidating the core specifications into a single document or perhaps a repository of documents, sort of a one stop shop, if you will, where you could go to get the specifications for these core capabilities and to improve the testability of the specs. In the appendix I think there are three pages of the appendix that identify exactly which of the exchange specifications each of the respondents implemented, so I'll leave those with you.

Now, moving ahead, the ONC has recently reconvened the NwHIN Power Team with a different charter. Our charter no longer is focused exclusively on the Nationwide Health Information Network or even on exchange, but rather it really builds on the criteria that we recommended and we used during phase 1 of the Power Team. You recall that we developed a number of criteria that we used to assess the readiness of a specification to become a national standard, and the ONC has asked us to use those criteria as a starting point to develop a set of criteria that are to the extent practiceable, quantitative, so that any specification, whether it be for transport, for vocabulary, for content, for any purpose that we could use these criteria to gauge whether the specification is ready for primetime, ready to become a nationwide specification. The ONC has suggested to us a categorization or classification of three levels of readiness, which we also will be addressing, whether it's ready for national adoption, whether it's emerging and moving toward national adoption, but not quite there yet, or whether the ONC is aware of it, but it's really a pilot or domain specific and we don't consider it really moving toward emerging, that it really needs further development or a combination with other pilots or domain specific specifications in order to even be considered emerging. These are the three classifications that have been suggested to us.

The criteria that we are starting with are those that we defined by this summer camp effort last year and those five criteria are: the need for the specification, the maturity of the specification, the maturity of the underlying technology, deployment and operational complexity, and market adoption. And again, these are what we're starting with. We're going to try to quantify them. We may be adding to them. We may be splitting some of them. That's our challenge that's in front of us. The time frame is, again, very aggressive, as it was in the summer. We plan to present a draft by the April meeting. As I mentioned earlier, the exclusions are that these criteria should be applicable to any healthcare specification for national adoption, whether it be vocabulary, content, transport, whatever.

Okay, with that are there – I would add that I personally am really pleased with this new charter. I think that this work will add real value to our industry because it will provide us a means of truly standing back and objectively evaluating whether specifications are actually ready for national adoption. And as Doug has pointed out, it also will provide a metric for us to use to determine when an existing standard is ready to be retired as well. Doug, would you like to add anything more?

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

I think you've covered it. I share your enthusiasm towards this project. I think having explicit criteria also helps inform us from the ONC and from the industry to know where we need to put our investments, depending on where on that scale something needs to have additional work. So if it's something that lacks consensus, we know where to put some resources. If it's something that requires more pilot and real world work, we can then make the appropriate investment. So I think it is a way of us really, as we think about the NwHIN and our portfolio it really helps us to understand how best to manage that portfolio.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Dixie, as always a terrific job summarizing the input regarding exchange. The framework can be very helpful not only in that discussion but as you look at it more broadly. I note that Paul Tang has dialed in, so if he has any comments in this portion of the agenda, we certainly welcome him. We'll move to his presentation after discussion, but we have John Halamka for a comment.

John Halamka – Harvard Medical School – Chief Information Officer

Just a quick comment, I, at my hospital, Beth Israel Deaconess, have not implemented the NwHIN exchange specification, but I have done something called a poor man's version of it, and that is a point-to-point SOAP-based query exchange that actually works really well because I don't have to build a patient's discovery mechanism. As you highlighted, that turns out to be a real scalability issue, and what we've done, again, it's a nasty approach which is we asked the patient who is your primary care doctor, and can, based on their knowing their primary care doctor, infer where their records might be and then do a point-to-point SOAP-based query that returns a result about 90% of the time. So it's in effect good enough. Here's the problem: I now affiliate with Needham Hospital, Milton Hospital, and Lawrence General Hospital, and what worked great as a point-to-point query mechanism has now become a, you have 17 different buttons you can choose. I hope you choose the right one. And oh, if you ask them the primary care doc and they don't recall, or that doctor has multiple offices, it doesn't scale either. So I think that if we were going to get to something that's robust we can agree, sure, lack of patient discovery may get you short term satisfaction, but it's ultimately going to be needed for long term scalability.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, John. Let's start with Dr. Mostashari, Farzad.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

That was a fascinating comment, John. I wonder if we can do something incremental. A lot of the use cases, for example, around Vila are point-to-point, a lot of the large systems, I was in Cleveland visiting Metro Health, and they know that a lot of their traffic is across town to another large integrated delivery network. So I wonder if we could look at a subset, Dixie, of the stack there that by simplifying out some of the pieces like the patient discovery or the location discovery of the patient matching, to enable what one might call the clothed and conscious and well memorized ED use case as a beginning step, and then as John points out, that may not be scalable when you get to N x M places to look for information. But again, our mantra of bold incrementalism may serve here. Any thoughts, Dixie, whether that simplifying takes care of a lot of the scalability issues with the current stack?

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

Well, I think it's something that we should consider in our criteria. There could be particular problems, patient identity being one of them, that could be subsetted out. Doug, that may be another category of specification that we evaluate and we say this is not a complete nationwide scalable solution, but for a subset of the nationwide population this could be used to solve the problem locally. I think that's a really good point.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

And I think your point about modularizing and assembling these portfolios may play in well with this subsetting approach.

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

Just a comment to Farzad and to John's point, these kinds of use cases and experience are what we need to be able to drive towards the criteria, because I think being able to have, well, we tried this but it was really hard and it only worked in this limited range or it doesn't scale, even though it's very good in a local way, is the kinds of things that we want to have in these criteria to evaluate it. I think our experience with the NwHIN Power Team over the summer and really the complexity of trying to figure out opinion versus fact and different interpretations of the same thing, I think has led to this additional work, which is to say let's try to create a set of criterion where we're trying to bring on board to support Dixie and her team, folks that have some experience and expertise in measurement and get us measurable reproducible criteria that will give us an appropriate spread across the different specifications that we have. I just think it's important for us because otherwise we don't have evidence based criteria for the kinds of recommendations that we make, and in medicine we make a lot of decisions anecdotally, and we want to get to the point where we're not necessarily making recommendations around standards anecdotally, but in fact have a here the best kind of criteria that we can apply and that we can systematize it a bit better.

Jonathan Perlin – Hospital Corporation of America – CMO & President

We've got about 6 minutes and about 8 cards up. Wes is also flagged on line, so let's come around fairly quickly and very directed to the charter and needs toward bold incrementalism. Wes, why don't we start with you?

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

Thank you, Jon. I just want to comment as I understand this line of questions we started talking about standards for exchanging information and we quickly got to patient discovery, and from there I believe to issues of policy and governance. The thing about maintaining policy and maintaining governance is it costs money. At this point an interesting question to ask is, is there a difference between what we're asking or what John was asking for and what we've thought of traditionally as an HIE or a RHIO. If there is, if there's a chance to somehow sharpen the pencil, then maybe we can do standards to support it. But I think that we're really up against the same issues that, in my opinion, contributed to the complexity of the exchange specifications, which are the kind of role-based access controls and policy initiatives and things like that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Wes. Does anybody want to comment on that? It is interesting to note that there is a level at which one defines a problem in terms of looking at the set of solutions. Let's go around, Leslie Kelly Hall?

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

I would just like to add that the first step that this new team is going to do is to define a set of use cases. And I think that that will be an important step to constrain the kinds of specifications that we'll even be looking at, because we certainly can't solve all problems that are out there.

Leslie Kelly Hall – Healthwise – Senior Vice President

I have two comments on this, on the criteria. One is, have we accounted for any sort of innovative or leap frog criteria? These seem to look at things that are already well known or easily adopted when new innovation should also be an opportunity for a back door to drive new change. So I'd offer that up. Then also, the idea that this could also be used to enable direct communication facilitation with patients, consumers, and the like, can also help drive new use cases and drive adoption of the Nationwide Health Information Network, just as any sort of large scale connectivity to consumers has driven market and driven new opportunities. So I'd like not to table completely how patients are identified because that will be a cornerstone of how patients enter.

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

With respect to leap frog I don't think we're excluding leap frog technologies if where the frog lands grows very rapidly, because there are technologies that leap frog developments in our industry and very rapidly get traction, and those kinds certainly will fall into the domains we're looking for. But unless they get traction and wide adoption I don't think that they would become national standards.

Leslie Kelly Hall – Healthwise – Senior Vice President

I'd just caution us to not be too backward thinking.

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

Absolutely, good comment.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Nancy ...

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Just to build a little bit on what Wes said, and for Dixie and this committee, of which I've got some representation on, we're going to have to really narrow these use cases because I think it's going to come up very quickly and we should continue to point out where there are policy issues. Patient identification is super critical, and I'm finding in my own internal use cases that once you're not sure whether you've got

the right John C. Smith you're reluctant to do anything more, and you won't go and do medication reconciliation, you won't go to the next step, you won't exchange anything, because you're not really sure. And that's going to be a stumbling block. Chronic disease patients, I said we have a lot of people where we're going to need to be pointing out quickly that this will not work for people with multiple doctors, multiple diseases, if there's any issue of reconciliation among six different identifications. So I think that as we go forward there I think we'll have some successes, but I'm going to be guessing they're going to be pretty constrained in terms of the use cases.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific. I'm glad Paul Tang was on the line to hear that comment. That is a challenging area, as this group knows. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Repeating something that Dixie's heard me say numbers of times on the committee, but just to bring it out to everyone, I think that evaluating tools and building blocks is a good effort and you have to start there, but you also have to keep in mind what someone intends to do in terms of the architectural thing that you plan to build with those tools and building blocks. We have a good example today of things where the building blocks themselves may be fine but the architecture that gets assembled doesn't work or doesn't scale, so I think a challenge of the workgroup will be to decide how to evaluate the architectural output of the building blocks in the portfolio, to which architectures seem to work and which ones don't. We may discover that it scales fine on a small scale basis, as John described, but it doesn't scale when you try to hook it all up. And maybe the use cases can make sure we address some of those questions.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Judy?

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

Dixie, your charter clearly outlines that you're going to be focusing on the criteria for the three buckets, the framework, but we're quickly jumping into talking about use cases and talking about the actual standards themselves. Are you seeing the charter of the workgroup to also work on looking at the existing standards and putting them in one of those three buckets as well?

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

My understanding is that that's not part of our charter. However, if we really want to test out the criteria we may want to look at existing standards to see if they apply. And if we can't take an existing standard, use the criteria, and voila have one of the buckets, then that's an indicator our criteria won't work.

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

I think that's the perfect response, and I think we also have to think about it, and maybe the team can think about who will do that then, because sometimes it's not totally obvious, the criteria themselves will have probably some subjectivity to it. So, yes, thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks. Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Just a quick methodology note, and great work, Dixie, as always. Thank you. On the criteria, I don't know if they can be quantifiable but I think they could be operational. One of the problems with low, medium, high is that it's opaque, often to the people rating, but certainly to the people reading the ratings what exactly that means, and you can imagine something like scalability, you can see it's ready for national, it can be used with a small number of participants, it's really only usable locally, so I think if the criteria could be rated in those kinds of operational terms then we and others would understand what we meant by that and be able to make better use out of them.

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

Yes, and we did change the charter's wording so that it said quantifiable to the extent practiceable, because sometimes, at least in my experience, and I suspect in yours, you see where people force quantification on something that really is best measured in a non-quantifiable way.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Yes, I think quantification here would be false. But operational definitions are very different than low, medium, and high, in that you can look at them and get a reasonable sense, at least what the range of things that are meant are.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Cris Ross?

Cris Ross – SureScripts – CIO

Just briefly, and Dixie's heard me say this not so long ago, but to get to the thing that John can do at Beth Israel and to get the kind of innovation that Leslie's talking about, that's not amenable to a certification approach today for an EHR vendor. So we're clearly going to have to run into a case of where a vendor must do direct, then optionally SOAP, but may do some other things to accomplish some means, it seems to me, and I'm believing that the way that this charter leads us creates a really safe harbor for that kind of innovation, so that we're not going off the rails of undermining direct, but still providing an opportunity to do that. I think we're going to have to think about, for example, if CPOE is one of the measures that we want to worry about, if CPOE's going to go across a method other than direct exchange to meet John's goal, or patient exchange. We're going to have to figure out how to allow that within an attestation environment separate from certification. I just think it's really important, we're not going to get innovation if we wait for someone to do it on the side in addition to what they're doing to meet meaningful use, maybe John or a couple of other places like that can do it, and then we can backwards integrate and it seems we're going to have to include it in the work that many organizations can do.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Cris, I think that's a terrific bookend to the conversation. I heard a number of terrific points, and I'm learning from the current use guys the importance of the current exchanges and ... in terms of the level of the problem. I think the ... issue that Nancy identified, the identification of the patient, the scalability is an important area, and Leslie's terrific point not to be constrained by what's on the table and being certain that we encompass potential leap frog technologies, and, Jim, the point about the methods of evaluation operational definition as opposed to a quantification really disambiguates that, and I think Cris just a perfect bookend there, policy that is permissive to allow development but must for certain things and in fact doesn't inadvertently penalize the early adopters of solution sets, including not undermining some of the successful work, but the sort of bold incrementalism that Farzad challenged us to.

All right, Jamie, the next 30 seconds you have the last word.

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

Just very briefly, I just wanted to note that this is not the first time ONC has set a number of standard selection criteria, it took me a while to find it, which is why my comment is late, but I've just found the ONC publication from May 12, 2006 for standards readiness criteria, which I think covers everything Dixie has talked about and then some, so I would urge you to look at that previous work and see if any of that can be applied here.

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

Great, thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Sure. Dixie, we certainly thank you very, very much. And to all members of the new group and all of the work ahead, many, many thanks in advance. Well, let us move directly, I know Paul Tang is under some time pressures, but obviously, Paul, I wish you could have been here to feel the enthusiasm about all of the activity from last week. You've been very much at the heart of this, I know as well, you're looking both

at the proposed rules in terms of not only the work that needs to be done in terms of responding and completing the development of that cycle, but also a glide path for all in terms of stage 3. So we welcome you and look forward to your thoughts.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, Jon. Can you hear me?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Absolutely.

(Speaker was hard to understand.)

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, thank you. And of course all of the credit for the advisory work goes to the team, but all the heavy lifting certainly occurred at ONC and CMS, so thank you to those folks who've produced a wonderful NPRM. Thank you for the opportunity for presenting some high level thoughts on our work plan for 2012. If we can go to the next slide, please, you'll all recall this mile post, and the world doesn't revolve around meaningful use, but certainly meaningful use stages provide important milestones for our work. Stage 1 is really all about getting these systems on line and getting data as much structured as possible into them, stage 2, which is what the NPRM is about, is really focusing on getting it spread around with folks who have a need to know and can advance the care of an individual patient and the community. So it does focus a lot on health information exchange and care coordination. We're driving towards stage 3, which is where outcomes are more readily measured and then because we have access to the measurements and assessments we'll be able to improve them, both at the individual and the community levels.

Next slide, please. That gives us a construct or a framework for this set of policies that we work on along with ONC and CMS. It starts out, before meaningful use, at some of the HITECH required policy changes such as the enhancement of some of the privacy provisions of HIPAA, so that came in the early phases, and now in phase 1, although they're not identical with stage 1 in meaningful use, they're related. So a lot of the policies have to deal with how do you motivate and guide the adoption of EHRs, how do you help people achieve meaningful use of this technology, not only EHRs but HIT more broadly, which would include, for example, personal health records and patient portals, and at the same time making sure that we are protecting them as they are contained in these systems, primarily in individual organizations, at least in phase 1. You all know that the IOM published a report given to ONC ... on the safe use of HIT, and there were a number of recommendations that were given back to HHS and they're already working on those. We'll probably be weighing in later on this year to help advise ONC and CMS and HHS about that.

ONC has a consumer eHealth initiative, and part of this phase 1 and stage 1 is to make sure that we can get information into the hands of consumers. We focused a lot in stage 1 of meaningful use on the access and download, view and access kind of functionality. Finally you know that the country needs a robust HIT workforce in order to not only install these systems but to meaningfully use them. That's a lot in the early phases of the first five years of HITECH.

The second phase focus is related to stage 2 of meaningful use, which deals a lot with information exchange and care coordination. Once we have this information in these electronic health records then we need to make sure that they can be distributed amongst the people who are on this individual healthcare team. So we're focusing a lot on the information that's needed for those activities, particularly care coordination, and so the notion of what it takes to be interoperable but also the policies that are involved in governing that exchange of information are probably still emerging. We're all obviously waiting for the NPRM for governance of this Nationwide Health Information Network, but there's a lot of issues, there's a lot of health issues having to do with making sure that people trust each other and get the information securely and confidentially to all the parties that participate in an individual's care.

Likewise, that really steps up the need for privacy and security policies once you start exchanging information more broadly. That goes to where the patient goes to, but no more places, and that's the

trick. So there's always the challenge of making sure that we get the information wherever the patient needs the information to go and no other place, and the policies are still in an emerging area to cover that kind of data sharing and we're going to be working more in that area.

Care coordination is a comfortable clinical concept, but the definitions of what's a shared care plan and what's needed to share this information with the healthcare team and the individual are all concepts that doesn't have a strict or rigorous definition, so we're going to start working on those areas. This is starting to be broached in the NPRM for stage 2, but we want to tighten that up as we move further and further towards the care coordination and make sure the information goes to where the patient needs it to go.

Similarly, one of the folks, the beneficiaries of Health Information Exchange, is the consumer or the patients themselves. So in addition to them getting access to the information, we want to look at what it takes for them to be able to apply tools to that information and particularly to support the decisions they need to make, and it could be everything from deciding what providers to go to, to what kinds of self-management behaviors they can do, and what kinds of health behaviors they can change.

Moving on to stage 3, getting closer into the 2015 area, and we've already begun working toward the goal of having next generation quality measures, so we all know the origins of the current quality measures and they mainly deal with administrative and claims data, and we're trying to move over time to where they can on clinical measures from an EHR, but even more so to think that ... to outcomes that are of interest to consumers and patients, such as functional status, such as after joint replacement well, are they walking again or has their pain decreased. A lot of these things you couldn't measure them or capture that information on paper, and now that we're providing both providers and patients with electronic tools, in theory we should be able to access this information.

Now, it's one thing to capture some of this information from patients, but where do we put them? We want the patient to be comfortable in submitting their honest appraisal of the functional status and the provider would like to have an aggregate assessment of how they're doing and yet we also want patients to have the individual benefit of if their pain is or is not improving we need to be able to ... to possibly improve that. These are things that weren't possible in the past, and so we're pushing both the development of the actual software program and the policies that would cover that kind of sharing of outcomes information.

Clinical decision support is almost the Holy Grail of the use of this electronic technology. We had to take steps, bold steps, to get from where the country was, which is virtually no one using these records, to where the majority do use them. And as we go there we want to make sure that we apply clinical decision support, one of the most potent tools in the system, to make sure that we shape the decisions made by both providers and patients ... improve their health continuously. Then of course everybody is focusing on managing populations, so we want these systems to be able to produce the data in a near real time way, not in an 18 months retrospective way, give providers at the point of meeting every patient ... continuously improve the management of all people like That's an overview of the policy areas that we'll be working on in the next five years. It will change monthly. Next slide, please.

In the first quarter we've already been working on stage 3, recognizing the lead time, and I should have mentioned the ... measures there's a lead time as well almost matching the development of ..., and that's why we've been working on these so-called next generation quality measures even yesterday so that we can try to have them ready for stage 3. Generally, we've been working on stage 3 recommendations so that we can provide as much lead time as possible yet have enough time to gather ... the evolving experience we have with stage 1. So we've worked on principles we want to follow in developing stage 3 recommendations and narrowed into some areas that we can talk about later if you choose.

We're taking a break now because the NPRMs are out for stage 2 and we'll be spending the next couple of months working on those, working on a response to those. The governance advanced NPRM is expected sometime this quarter and so we will spend some time where we activate our own NwHIN Governance workgroup and look at their ANPRM. I already mentioned that quality measure development is underway ... contract that CMS has in developing some measures and we're also looking at other concepts that may not be in the development pipeline yet.

For quarter two we have a number of hearings planned. One deals with what we might call a quality measure life cycle. If we just look at what we have we probably aren't measuring enough of the things that matter to consumers and patients. We need to move upstream not only to the endorser but also the measure developers and ideally even up to the clinical trials that would produce the result that says what is effective, and then on the downstream side then we'd like to, through quality measures measure the effectiveness of the intervention ... clinical trial. So we're trying to bring together in this hearing to focus along that entire development cycle, the supply chain, the life cycle of a quality measure and see if we can't align them better so that it's the same data in our case ... from clinical trial all the way through quality measures. That's one area we're investigating.

Another is, as I alluded to you, we want to get closer and closer to the outcomes that matter to patients and consumers, so clearly we know that that's part of the patient themselves. How can we get better information, more continuous information from patients? Sometimes there's physiologic signals, blood pressure, glucose, and sometimes there's functional status that only a patient can measure, how can we incorporate that information back in, probably through the patient portal and PHR, back into the EHR so that it can be used by the provider in making decisions to make more tailored the treatment plans for an individual. Health information exchange is so important to stage 2 that we're planning to reactivate our Information Exchange Workgroup that I know works ... with yours, to see where the barriers are, how can we best knock down some of those barriers and reduce the activation

As I mentioned in response to the IOM EHR safety report, we plan to look at some of the policies and ways that we can help advise HHS about making sure that the systems that we're promoting and incenting are staged, not only are they staged in terms of the products that are developed but they're staged in terms of the way they're configured and used. So it's a pretty complex issue but we have to tackle that

The next click please, so in quarter three we'll get that after having responded to the stage 2 NPRM we'll continue our work and between the Meaningful Use Workgroup and the full HIT Policy Committee work on the draft recommendations for stage 3 ... with them. Certification adoption, one of the things that has certainly come up through hearings and through public comments is the fact that a lot of the post acute care, the long term care, is missing from meaningful use and are there ways to help get them the data in an operable way so that they too can benefit from the whole program of digitizing this health information. That's on the docket Certification Adoption Workgroup. Then what we're expecting if the ANPRM comes up sometime in Q1 that six months later that an NPRM may be coming out so we would be responding to that in the government area. Next, click please.

Finally, in quarter four we'll be reconciling the final rule for stage 2 with our draft recommendations ... for stage 3. Once we get the preliminary recommendations in the form that's reconciled and I've gotten a lot of feedback from a lot of people on the ... committee and the ... workgroup that we would like to present that sort of preliminary recommendation back to the Standards Committee for your feedback. That's the time when we think we've gotten a lot of the things vetted and we're asking for your feedback, both from a standards point of view and a feasibility point of view. As you know, ONC has its consumer eHealth initiative going and we are anticipating that there will be some policy issues that arise that they may ... into. And the strategic plan undergoes continuous revision, and they published it about a quarter ago and would seek further input from us about revisions to that plan. Next slide, please.

I thought I'd give you a little bit more high level view into the development of stage 3 recommendations. We're going to spend the next few months developing a response to the NPRM for stage 2, and then after that we'll reconvene our work on developing recommendations for stage 3. I pointed out how we're going to reconcile that with the final rule and feedback from the Policy Committee and present that to your committee for feedback.

In January, so after the holidays, we're expecting that we'd issue a request for comment as we have done in past stages. That's a chance for the public to give us feedback even before we put out our recommendations to ONC and CMS. That would come back in February, we'd have a summary produced, and we would then try to incorporate the comments we get from the HIT Standards Committee

and the public into a new, revised draft of our stage 3 recommendations, bring that back to the full Policy Committee with the target of getting ... a transmittal letter to HHS with the recommendations for stage 3.

Next slide, please.

I think that concludes my formal remarks and so I'm very open to any comments or questions from the group. Thank you for the opportunity.

Jonathan Perlin – Hospital Corporation of America – CMO & President

First, Paul, many thanks to you for the very helpful discussion of the life cycle stage 2 governance ... stage 3. I appreciate making very explicit the interactivity between the two committees in terms of necessary inputs. After we take comments ...one of the things that, John, I need to work with you on is develop our own process for formalizing response to roles, and we have a bit of work planned for that one, and we'll come back to that, but we'll move to some discussion. Arien Malec has his card up so we'll start.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

May I add, there's just one more thing that I forgot, which is you have I think in your possession now the formal, or I presented to you last time some of our feedback from the field about the clinical quality measures, and I think you have a formal letter with some of the problems that came up and some of our proposed solutions and this is all for your feedback.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Before I move to the discussion then, I was going to introduce that letter in the introduction of Jim, but everybody has their materials, and a dated copy of this letters, and here preliminarily it will be formally transmitted to Jim Walker in the Clinical Quality Measures Workgroup for consideration. But it's also I think an instantiation of the interactivity that's part of the cycle and, Jim, you may have more comments either now or later with your presentation. Did you want to say something?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Yes, just very quickly. The deadline for the response is March 9th, so we'll do the best we can.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Actually I guess the letter it took a while to get developed and transmitted. That was recommendation number 1 that had to do with how to deal with certification. The problem is you must produce the clinical quality measures to a certified EHR and some people take data out of a certified EHR to a reporting system and this inadvertently brings them back to the EHR where we have some issues with hard wiring of the measures. So because it applies to something that could impact stage 2, then we were trying to get it in time so that we could have your response and incorporate that into our response That's the reason for that deadline..

Jonathan Perlin – Hospital Corporation of America – CMO & President

Great, well we'll certainly place a priority on the response, the timeliness of certain aspects of the response. Arien?

Arien Malec – RelayHealth – VP, Product Management

Thank you, Paul. I really want to thank you for this timeline. I think it's incredibly helpful to have everything laid out this way. I've got a couple of questions for you. One is, I really appreciate the way that you've linked the policy to the standard, and one of my reflections is that in the work that we did for transition of care, consolidated CDA, and the lab results interface, we got it in just in time to make a difference, and so if there are lead time activities where there's a capability that's necessary for policy that isn't well established or doesn't have a well established standard today, the earlier in the life cycle we know about it, even if it's not ready for final transmittal, the more lead time, for example, Doug has, or the Standards and Interoperability framework or the various SGOs have to start working on those issues. And one area that I think might be interesting, just for your consideration, is some unfinished work in care coordination, in particular CMS and ONC pushed a little further than you'd recommended in terms of the

plan of care, but I think there were areas where we could push a little bit further, for example, in post discharge cases where specific follow up tests or procedures or visits are indicated expressing those follow up items in a structured format and things of that nature would potentially be interesting areas where there needs to be more standards alignment to policy goals.

Then the last question I have for you is I think the Privacy and Security Tiger Team has been doing really amazing work and I don't see a timeline for that, and I think there's a ton of policy clarity that the Tiger Team can bring related to data sharing within an ACO, data sharing across ACOs, getting more detail around this really helpful concept of meaningful consent, there's just a whole host of amazing work that Paul and Deven have already done with the Tiger Team. And just a plug for using them and scheduling that work out through the year, because I think there's a lot of good that can be done in terms of harmonizing and standardizing across states and regions in terms of policy considerations, so thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I appreciate that. I'll get that to them.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Hi. The thing that worries me, and this is more of a comment than a question, I guess, is I see the impact of Intermountain Healthcare and I think similar things are going on in other places, is that the incentive money at best has a temporary increase in the number of resources that we have at Intermountain to implement all of our information systems, and so we're chasing the incentive money at the expense of other things that we would do within our organization. And as we see increasing number of measures that are good, there's no question that those are good, the question is whether in fact they're better than the other things that we could be doing with the limited resources that we have within our organization. So we're increasingly challenged to try and determine whether something that's good and required as a measure for meaningful use is in fact the best thing for our organization. So we're trading off, for instance, doing interfaces that would integrate an oncology management system with the rest of our electronic healthcare system. It comes out of the same pool to implement these measures, and so I can't argue against the goodness of the measures. What I see is just it didn't really hugely increase, if at all, the pool of resources we have to do information systems stuff, and I worry whether being a good measure is sufficient reason to in fact require it as opposed to having more flexibility in the things that should be implemented within the institution. I don't know that there's an answer to that. I'm just commenting.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'm not sure, was that for me, or for It might be an opportunity to put in a plug for one of our recommendations on CQM, on Clinical Quality Measures, and that is something we've heard loud and clear about the burden of doing that and in particular the way it's currently implemented in a lot of these systems, which is what we call it's hard wired. It's not only hard wired in terms of the calculation, but it's hard wired in terms of the data fields that it draws upon, and that has tremendous implications for the workflow. So one of the areas that we were trying to suggest, and this is where we really would appreciate your committee's feedback, is on the notion of having a flexible, I use the word "platform" and some people react to that word, but it's a flexible system to be able to incorporate standardized quality measure definitions, whether it's part of meaningful use or your quality improvement activities internally. It seems like that's something that would advance some of your needs ... and that's why we were trying to work that into meaningful use as a very useful function in EHRs, so the availability of standards and the implications on architecture is something we'd really appreciate your feedback on.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Farzard wants to comment.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Stan, you bring up a great important policy question for meaningful use as a whole, and I did want to give you my thoughts on that. I think you're right that we have to avoid what Tony Trenkle used to call the "Christmas ornaments approach" to meaningful use, every one is pretty so let's hang them all up. I think in stage 2 we actually struck, again, pretty parsimonious in terms of adding any new measures and the total number of measures is a little complicated because there are some things that are consolidated, some things that moved, but didn't dramatically increase. There certainly wasn't the, okay, we had 20 in stage 1 and let's add another 15 in stage 2. So I think you're right that we have to be very conscious about not just adding things, and I think we've done that for the most part. But meaningful use is a floor, it's the absolute floor for what we should have as aspirations, and folks at Intermountain, for example, have been doing things far above and beyond meaningful use and will continue to do so.

Now, doing, taking an example, CPOE earlier rather than later, it was on the road map anyway, and it's not so much not doing it as changing potentially the staging of when it's done. But it really does enable a lot more that can be done. When you move away from the large benchmark institutions who have a lot of leverage over the vendors and maybe even build their own systems, the advantage of ... meaningful use breaks, of adding that to the floor set, is that it gets every provider to have an expectation that they can fulfill on their vendor side, and it gets every vendor, not to be responding to what 200 different organizations set as their priorities for what they want to work on next. So one of the positive network effects that comes as a result of meaningful use, of adding good things to meaningful use, is that everybody can take a step up together. And there are net positive network effects that come from everybody having a basic assumption that every vendors going to be able to do certain things, particularly around interoperability and exchange. And there are also ways in which it can really reduce a little bit of the chaos in terms of every person is working on what's good for them, and it's good for them but vendors have a very difficult time responding to every group, what's good for them and what they want to work on. So I accept your point, I agree with your point, we have to be parsimonious, but we can't stand still either and we have to keep raising that floor in a very thoughtful, eyes open way. There is a balance there, but I think we've struck the right balance so far.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I don't think we're disagreeing. The other issues that come to mind are, again, this may be just my perception and it comes back to something that Paul already mentioned, which is to use the No Child Left Behind as an analogy, we see people essentially teaching to the test, not fundamentally building an infrastructure that allows them continuous quality improvement within their system, but more or less hard coding exactly the requirements of meaningful use into the system, not in a sustainable way, but in a one-off kind of way, and I don't know how we change the incentive so that people are actually, maybe it's just Darwinian sort of stuff, where the people who do a one-off eventually will die because the people who do it in a more complete manner will survive in the marketplace. But there's that issue of can we do the incentives in a way that people are actually incentivized to build the basic capabilities of their system to do this, as opposed to one-off.

And the related thing that we're discussing internally you see, to really, if you will, meet the intent of meaningful use it's one thing to be able to measure these, which is what the tendency is to do is to focus on measuring these things, what we're realizing, and have realized for some time, is that the measurement should be coupled actually to behaviors in the system that improve quality so that you don't just measure how many diabetics but you start creating alerts that remind people what you're supposed to do for diabetics and incentivizing that. And again if you're not careful you just focus on measuring that and assumed magically measuring it will cause an increase in quality when in fact it may not. And you want to spend just as many resources creating the infrastructure that will allow you to change workflow and influence alerts and reminders so that higher quality is provided, not just measured. I think everybody here is familiar with those same issues, and I'm probably not saying anything other people haven't thought or aren't struggling with in their own institution.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Stan, just a personal observation, it's nothing ... personal observation, is your point's well taken. I hope we're getting smarter over the period of time since this all began, a lot, as we discussed earlier, to

celebrate, but I think that's a fair question both at a policy and standards level, are we building durable, changes, durable improvements and building a sustaining infrastructure. And I think, Dixie, about the terrific framework you offered and one of the unspoken is the assumption that the standards also offer some sort of durability ... capacity for the higher performance that we expect. I think that's a good charge to us to keep that in mind. Nancy, the final word, before we come to work plan.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Just two comments, Dr. Tang, I wanted to commend you on the presentation slides for the Policy Committee and also address to you and to Dr. Mostashari whether the first two slides you have were, the arrows going from 2011 to 2015, whether this is your new verbiage, because this arrow is very well known within my organization because we've used that as the simple way to communicate, well, what are you talking about, the goal is going towards this. I just wanted to get feedback whether we've updated HIE and care coordination for stage 2, it used to say decision support, so if these are the new 2012 versions of this it would be great to have some kind of a blessing, like you put these on the health IT site as the revised way forward, because they're slightly different than what you had before.

The second thing was following on to Stan, he made an excellent point about the equivalent of teaching to the test and No Child Left Behind. I am wondering, we can require more structured documentations in EHRs, but as I talk to some of my colleagues, if the clinical schools, the nursing schools, the allied health schools aren't training their personnel to use structured vocabulary and terminology, because it's not reimbursable for anybody other than physicians we will always have this problem. I, in my institution, cannot require that ICS is used by everybody unless I say it's part of your clinical practice pattern and I have clinicians willing to say in occupational health that you're going to do this and it makes sense to do it. I think the issue of is this a commitment by all of the clinical professional groups and the schools, not just the ONC health IT certification programs in AMIA, that they are going to make a commitment to teaching their nursing students or allied health students to use structured documentation. That is where you get the change. If you get students able to come out and say I am ready and able to do this, it's not a technology issue, it's the way they're used to doing the work.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think both of those comments are very relevant. The first one, I don't know if you agree that this represents ... stage 2 being HIE and care coordination, that seems to reflect the sentiments, so that is a slight change in the wording. And the second is the importance of when we talk about the workforce, it's not only the implementation of the HIE workforce, it's the professional workforce has to go ... otherwise your systems are not going to be used effectively. That's also, as you know, an important program of ONC, is to educate the workforce, including the professional workforce. We're trying, at least through our recommendations of meaningful use, to move in the direction of helping the practitioner understand the value that one of the single most important acts that a provider can do is to choose what goes on the problem list. If you design both the system and the ... system well, it will drive so many good things to happen for ... provider automatically. So that's a bit of our vision in terms of how do we leverage these high value pieces of information and cause the systems to be designed in such a way that it just continuously pays you back.

As an example, the ... the problem, the med allergies is so central and so fundamental, as we speak of stage 3 one of the things that you want to do is to find and actually ... making sure these data elements are accurate. There are ways to say, is diabetes appropriate to put on the problem list, or is it ..., similar to a lot of other common diagnoses you could take advantage of all the other information ... EHR. Those kinds of things are tools we can build into the system that make it easier and at the same time we ... the practitioner why is this valuable and why is it valuable to discretely describe this to the system so that it can help pay you back.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

Talk about teaching to the test and learning, and to come back to some of the comments I made in the earlier part of the session, how people are learning how to use meaningful use. And just to give you a couple of simple concrete examples, walking the floor you see smoking status, we've now set a standard for how smoking status is to be collected so that everyone can collect it the same way, it can be used in

quality measurement, in decision support and so forth, and yet walking the floor at HIMSS many vendors choose to implement the standard way of asking smoking status as a separate form to fill out to get your meaningful use check, while they still carry over their oftentimes clinically non-optimal or nonsensical way of collecting smoking status in a whole variety of different ways. That's not making meaningful use of the meaningful use capabilities and standards. We're learning to do that. I think on the provider side we heard about problem lists and how on the inpatient side there have been some pretty sophisticated hospitals who still have a great deal of difficulty meaningfully implementing problem lists, and others who have found ways of using it for patient hand-offs between residents and other actual uses of that field, to ... obviously therefore have higher quality useful problem lists. These are two examples of data collection, it's data collection and yet to make effective use of that takes time and learning and sharing.

We're all learning how to make this not be "teach to the test." We can put it out there and we can make the connection, so you said it's not about quality measurement as accounting, it's about quality measurement as a tool for improvement, and we can put in, as the Policy Committee has recommended, decision support tied to quality measurement, as if we could make it more obvious that the point of quality measurement improvement is they implement ... decision support linked to specific quality measures. We can do that in meaningful use, but ultimately it's going to have to be the providers and the vendors who use meaningful use to get to other goals. And the incentives can't be meaningful use incentives. The incentives have got to be not .01% of the revenue of the hospitals, it's got to be 30% of the revenue of the hospital tied to value-based purchasing, accountable care, patients that are ... at home and the whole gamut of payment reform and delivery reform and improvement reform. So all we can do is serve. We can try to be the best servants we can be to the cause of quality improvement and put it there, but ultimately people have to pick up that tool and use it, and the tool in this case is actually meaningful use, is the tool here, so we can do what we can to make clear but that only goes so far. People actually have to pick it up and use it that way.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

If I can just interject on this, it's a really important point, and I'll even use Farzad's smoking example, as you consider the first two recommendations that we handed you about CQM, it has to do with this flexibility in the system to be able to use this tool effectively. In smoking cessation some of us put smoking right in the problem list so it's in your face and you can deal with it, and if a vendor hard wires the calculation of either the objective or the CQM so that it has to go five levels deep into that place where you don't go, that's what caused people to not only have to change their workflow but it actually took away the value of having it in your face. That's why we made those two recommendations that said, hey, let's make sure that you can not disturb the local thought process, the local workflow of making sure clinicians use this valuable information each and every time they contact the patient. That just happens to be a good example that illustrates both points.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Paul and Farzad, those are perfect points for transition, both in terms of channeling the passion as well as the specific ... – I'm sorry, Floyd, do you have ...

Floyd Eisenberg – National Quality Forum

If I can just say one comment about that, I fully support everything I just heard Farzad and Paul say. I think what has happened is the CQM's have forced, or have allowed, it's not the CQMs it's when you ask an EHR to do something meaningful use can only push it so far and they can implement it in ways that don't get to meaningfulness, unless you're actually deep inside EHR with your regulation. And so it's not that the smoking status is the wrong regulation or the CQM is wrong, it's how it's implemented, and we have to pay attention to that, although there are some CQMs that ask for data that aren't reasonable, I get that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific points, and great discussion. Paul, I tremendously appreciate your comments and ... committed in terms of time, you're welcome to the stay for the next point. But the opportunity to transition this passion and this discussion into the next stage of activity really occurs through the work that this group is obligated to, and that's the response to the NPRM. John and Farzad and I and Mary Jo put our heads

together to try to make this as manageable as possible, and Jim, sharing with you a recognition of tight turnaround on this, and let me ask John to comment on thoughts on distribution of some of the efforts coordinating it so that the collective work is as usable as possible to ONC in terms of their timelines.

John Halamka – Harvard Medical School – Chief Information Officer

So a straw man, thinking that it would be best for us to coordinate and correlate our responses rather than having a free-for-all of all of you sending things to Mary Jo, I look at our current organization and we have a series of workgroups. We have the Clinical Operations Workgroup that Jamie chairs, we have Clinical Quality that Jim chairs, we have Privacy and Security that Dixie chairs, we have the Implementation Workgroup with Liz Johnson and Cris Ross, we have the Vocabulary Taskforce, so Jamie gets counted twice, but it would seem reasonable that if we use those workgroups as organizing principles to have calls led by chairs that would then gather input from the group and then we would arrange a co-chairs call with Jon and I to gather all that input, we roll it all up and then we present it as a collective body of work to Mary Jo, of course if individual organizations want to respond, if Kaiser wanted to respond, go ahead, but in terms of this committee I would think such a process might get us an expeditious rolled up list of requirements and comments. Any thoughts?

Leslie Kelly Hall – Healthwise – Senior Vice President

I'm new to the group so I don't know all of the subcommittees, but it seems that a focus on patient engagement and consumers, there is a group of us on the committee and would it be worthwhile to have a small group formed around patient engagement in response to this? I'd volunteer.

John Halamka – Harvard Medical School – Chief Information Officer

We'll call that the Patient Engagement Affinity Group, and Leslie has just volunteered to chair. What do you think? I've never seen a more rapid consensus vote, Leslie.

Leslie Kelly Hall – Healthwise – Senior Vice President

Was that because I just stepped in it, or was that because it's good work?

John Halamka – Harvard Medical School – Chief Information Officer

It's great work. It's usually important work.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I saw Arien was doing a thumbs up, so you've got at least one additional committee member.

Leslie Kelly Hall – Healthwise – Senior Vice President

Arien?

John Halamka – Harvard Medical School – Chief Information Officer

Mary Jo, if that seems reasonable to the group, then it's just a question of getting those calls organized in a timely fashion to get us to the deadline that ONC has wanted for comments. Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Real quick, John, I think that's a great friendly amendment. There will be some that we've already brought up today that don't fit in those buckets, so I think we probably want to have a parallel thing where we can just send stuff to maybe you guys to make sure that we don't miss those cross-cutting or whatever.

John Halamka – Harvard Medical School – Chief Information Officer

Right, and I've been taking notes the whole meeting to try not to miss anything.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific. We'll take that work plan, and consensus on this approach I think will be very helpful. And just a commentary ..., this committee, as we talked about is obviously a federal advisory committee and is chartered as such to be very open, this process, and the regulatory cycle is also meant to encourage

feedback. So we have the double opportunity to do so collectively and all, particularly our community participants who are here as well, it really is an important time to make your voice heard. So thanks, Paul, thank you very much for the leadership and really all of the accomplishments. I think all of us also feel that we had important discussions down. When one looks back is the world a better place? Yes. Would it be better still if everyone made the most of it? Absolutely. And how can we create the facilitating conditions for the very best outcome? That's why the work of the next phase, the workgroup's response is so critically important, so thank you in advance for that.

With that as a segue then let us go to Jim Walker, who has a short presentation, shorter than was even billed, and again you should have at your place the letter that will be officially transmitted.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Great. Brevity is still the soul of wit. The committee is doing great. I think all of the members are really gratified and energized by ONC's new focus on this and the re-chartering and all. The first meeting we got about probably halfway through reviewing the new charter and validating that. We are adding some new members that represent new skill sets, and it turns out gratifyingly that practically no one was interested in leaving the workgroup, so we'll have a larger workgroup, but that's not a problem, I don't think, at all. We're planning to break into two Tiger Teams. We've invited people to tell us which one they want to be on. We're sort of repeating a theme, lots of people want to be on both, but we're finalizing that, we'll be finishing the review of the charter and doing a very rapid look. It obviously won't be a meeting if policy needs it back by March the 8th, but we'll use a rapid e-mail approach to getting recommendation one addressed and work on the rest of them a little more thoughtfully. I think that's really everything that's important to say now.

John Halamka – Harvard Medical School – Chief Information Officer

Comments? Doug Fridsma?

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

I just want to thank Jim for his leadership in this very important task. I think one thing that we need to highlight, and I think it echoes some of the conversation that Paul had in the comments that he made in his presentation, is that this is an opportunity really for the HIT Policy Committee and the Standards Committee to work very, very closely together, and I know that there was, on the list, the opportunity to have some public hearings around quality measures. That may also be an opportunity for us to have a joint session that includes both policy and standards to be able to let those move together. These are so inter-meshed that this is, I think, as we continue to work on the harder challenges it's going to be increasingly important for the Policy and the Standards Committee to work together and so Jim is going to be our test case to make sure we can work through that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Great. Thank you, Doug, for the prompt. Actually the two Tiger Teams, one is working on measures and the other is really to focus carefully on how we align our work with policy to make sure that we're really working effectively and efficiently. Any other? Jim, I want to thank you for that. Paul's probably signed off but I appreciate the convergence, not only among our two workgroups but with all the other elements in the measure community. I think the group has heard very clearly that ... important measures may be less important than hard wiring capacity to ask important questions. I appreciate that as we go forward.

Let me turn to John Halamka to introduce our very last session on S&I.

John Halamka – Harvard Medical School – Chief Information Officer

Before Jason left the S&I framework leadership position I had a conversation with him, and engaged Doug too, and the question of course is how does S&I going forward best serve the community, integrate with the HIT Standards Committee, integrate with SDOs, what are the things it's been uniquely good at? What are the things that it's challenged to do? We look at some projects like the Direct Project and it actually was so big and so bold and required such a large consensus group that it was done in effect with a very large Tiger Team. But things like the consolidated CDA, this worked extraordinarily well in the context of the S&I framework. So given that we will be talking over the next quarter about governance

and the future of all this activity I thought it very important to hear from Doug on S&I framework, where are we, where are we going?

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

Thank you. In the interest of time I'm going to skip through the slides fairly quickly because I am more interested in setting the stage and having a discussion than to go through the presentation in a formal way. What I'd like to also preface is that I think this is the beginning of a conversation. I don't expect there to be any sort of conclusions to this, but I know over the course of the next two months you guys are going to be working very hard on reviewing the proposed rule, giving us some feedback and comments. I wanted to get this in so that in the back of your head you guys can start thinking about beyond this what it is that we need to do, and we may then I think follow up in a couple of months with some additional discussion and comments as we think things through.

I always start every presentation with a slide to talk about the kinds of things that we think are really important to getting to an interoperable healthcare system. There's this notion of enabling stakeholders to come up with a simple shared solution, curating a portfolio of standards that accelerate information exchange, and then enforcing compliance. The enabling stakeholder is really, at least within the Office of Standards and Interoperability, is represented by the S&I framework activities, curating that portfolio is the NwHIN, and enforcing compliance is about certification. But the three of them all work together and I think as we go forward and we think about new criteria for certification we have to think about how all of those pieces play together.

When we talk about the building blocks, and I'm going to talk about building blocks in two different ways, but the first set is a set of standards and interoperability initiatives that each one of those initiatives generated a particular kind of building block. And when we typically talk about five different kinds of building blocks that all answer a very specific question, so when it comes to vocabularies and code sets the question we're trying to ask is how should values be coded so that they are universally understood? This is about standardizing meaning, so that when I say congestive heart failure and you hear congestive heart failure, we mean the same thing.

The second part is content structure. And what question we answer here is how should the message be formatted so that it is computable, and this is about standardizing structure. This is so that a computer can parse it and pull it apart so that it's able to then use it and its elemental parts.

The third part is transport, how does the message move from A to B? We've talked a lot about that with regard to the NwHIN Direct Project, and the NwHIN Exchange Web services approach. Then finally there are a series of other things that are needed. Security is something that's present for all the kinds of exchanges that we do, and that answers the question how do we ensure the messages are secure and private, and so things like TLS, that we've had some discussion about, as well as certificates, are part of that portfolio that would fit into that security.

Finally, services, how do health information exchange participants find each other, so directories and certificates, that's the last question that we have to answer. Within this portfolio of things that we've got within the NwHIN we want to talk about standardizing meaning, standardizing structure, standardizing transport, standardizing security, and making sure that we have standardized services that people can access and allow information to exchange. So when we think about the initiatives within the S&I framework and we think about the things that need to move into a certification criteria, as we think about interoperability those are the five questions that we have to answer to get to that period of interoperability.

I'm going to skip over the patient scenario, but suffice it to say that a year ago it was difficult for us to say we had all those pieces, but I think now we do. I don't think that we have the full suite of all the tools in our toolbox yet, but I think we have the beginning set that will help us get things moving. So, for example, if we were to have a physician order an outpatient lab test on a patient the lab then sends that information to your office and the patient is there to discuss the results. We have things like LOINC to standardize meaning, we have things like HL7 2.5.1 to help us standardize the structure, Direct is a way that we can transport things in a standardized way, and then we need certificates and security to help us make sure that we are able to secure and find the information.

That's what our portfolio is right now of the different elements that enable us to have interoperability. But there's another way that we can look at this as well, and so if we want to think strategically about the things that we want to develop within the Standards and Interoperability framework or the things that we need as part of our portfolio, we can think about things in terms of strategic drivers, so health outcomes and policy priorities that we get from the HIT Policy Committee are really important. Those will drive tactical decisions about focus areas and meaningful use alignment, figuring out the right things to work on, standards challenges that we need to address in an expedient way can be then solved and things like the Standards and Interoperability framework, and then there are other pieces that help accelerate. One part is driving value and making sure that we've got that, but the other is lowering the cost so that that cost value equation is more favorable. And that includes things like having use cases out there that people can share, developing standards and data models and shared vocabularies, and then creating tools and infrastructure that helps us do our job more efficiently as well.

So when we think about managing this portfolio we can think about this, and again I've omitted some of the layers here, but we can talk about things like care coordination for providers and patients that would be supported by S&I initiatives such as transitions of care or the longitudinal care coordination of care activities, all of this is supported then by the standards, such as the CDA and the consolidated CDA work, and then finally, work on data models, or data dictionaries can help support that whole value chain that we've got. Back in January we were at a one year anniversary of the Standards and Interoperability framework, and I think we have had some successes in accelerating the change. Farzad gave me a very clear directive, he said, "We've got to write a rule. We need to get some standards, and we don't have what we need. Your job is to make sure that we get, in an expedited way, the things that we're going to need for the next stage of meaningful use." I think with this participation of the community, and really the amount of volunteers that have supported this effort has been tremendous, guided by ONC, enabled by this open community I think we have been able to engage in solving some real world problems and accelerating that process.

So things that we've done that I think have been good, I think we've tried to attack real world problems, we've attacked it in a way that has been narrowly focused and trying to drive all the way from the top to the bottom. I feel like we've been able to leverage the work of ONC and the passion and expertise of the community, and I think the community really has come together to really support these activities. But I think it's always important, even in the face of having some successes in driving things forward, to be very, very thoughtful about what are the things that we need to continue to do, what are the things that we need to do more of, what are the things that we need to have others do for us.

And so, let me see, I want to go to this slide next, so we've been thinking about the S&I framework as really our initial set of initiatives, and perhaps over a beer sometimes I can tell you about the beginnings of the fall of 2009 as we were trying to start up all of these projects and things like that. But the reality is that the Direct Project was started in parallel with a lot of the contracts that support the development of standards, and at that time it wasn't Farzad but it was David who said, "We don't know what standards you need. We don't know exactly what the priorities are going to be. But you've got some contracts that you need to write so that you can support all those things that we have yet to tell you." From that came the contracts that we needed to do to support the Standards and Interoperability framework. And at the same time we had the experience of the Direct Project. Under the leadership of Arien they really focused on this singular challenge and I think demonstrated a path forward for how best practice around standards development might be. We then tried to take contracts that were already in flight to modify them in a way that would allow us to leverage the best that we've learned from the Direct Project and to incorporate that into the contracts that we have to support these activities.

So we've changed around some of the work that we've got. We are now going from initiatives to this portfolio that we have and we really have to think about is there a way that we can get to reusable artifacts and tools, are there processes and infrastructure that we need to streamline and make better so that as we go into this next phase we can learn from what we've had in the last year and drive that forward in a way that helps us create, not so much sustainability of the S&I framework, but sustainability of the work that is being done within the S&I framework so that we can support the goals of meaningful use and the needs of the country.

When we take a look at some of the things that we've gone on, and I've had an opportunity to talk with a number of you, I've sent out folks to interview and to talk with you and people have been tremendously generous in their thoughts about the S&I framework. I still would like to get more, because I think the more I can get the better, but one of the things is that if you've got something that is innovative, that is outside the box, micro-data, for example, or something like that, that is not something that is currently in even people's peripheral vision. It may be that the S&I framework is not the right place to have that happen. However, if you're trying to make incremental progress in the standards that you currently have, that may be a sweet spot for the kinds of things that we can do to accelerate change. If there is the availability of empirically validated standards, so there are some initial substrates to work on, that becomes another high value activity where we can focus our energies. And if you take a look at what we did in the Standards and the Interoperability framework, consolidated CDA was based on CCR and CCD. LRI was based on two different implementation guides that we needed to achieve consensus on, and we tried to, whenever possible, build on existing stuff, and that seems to be a sweet spot for what we've been able to progress with, at least given our current processes and our current infrastructure.

The other is when the degree of consensus is relatively low we've been able to use the convening power of the S&I framework to bring people together, to have people not argue that my baby is prettier than your baby, but to actually go out and implement and develop it, because that's the way in which, at least the initiatives that have been most successful are when we have clinicians and people committed to using it that come back and say this doesn't work for me, and that carries a great deal of weight. So when we think about the ways in which we can approach standards, there are some things we probably should be working on and there are other areas that we probably shouldn't be spending a lot of time on because it's not the right time in the process, or in the process of innovation, the process of standards development, or in where we fit in consensus, there are probably other axes that we could include on here as well, but this is just as a way of example to realize that there are things that we should focus on and areas that probably others should do.

Here's another way to take a look at that, and that is to say if we have an incredibly high degree to which an incremental approach will solve the problem and a lot of consensus, maybe we don't need an S&I framework at all. This particular committee in the working group can just identify those standards that we need to go forward with. It may be that there's a little bit of work that needs to be done and we need a power team to work out the edges of that. There may be some things in which there is either a moderate degree of consensus or a moderate degree of incremental approach that will solve that, and that may be the kinds of things that an S&I framework approach might help with.

Then there are some other things that we may want to encourage at the SDOs and agencies and coalitions and others to really move the ball forward, get things prepared, and then bring it into a process that would allow it to move together. And you can imagine that the work that Dixie is doing around trying to identify what are the criteria for a good specification and how a specification might move from one area to another helps guide where we want to focus our energies around advancing those standards within these frameworks. So here are some examples of some of the things that might fall into this. Laboratory orders distributed query transitions of care were all things that we did within the S&I framework and that really fit to where we wanted to work. I think we're sometimes having challenges among federated provider directories. We do have an S&I initiative around that, but it is a challenge and I think that's an area that we probably need to do some more pilots and work out there as well. So we've just gone through these things to try to get a sense for let's focus on what we do well, let's make sure that we coordinate with those groups that are doing other things that are part of this portfolio, and then let's make sure we have criteria that will allow us to move from one place to the other in a way that is thoughtful and public in terms of consensus based.

The other thing that we've been thinking about is that we have poured a lot of money into some of the activities. I told Farzad that in many cases we bought time with money, because if it had taken me an extra six months to do it, I would have missed all of the targets that were set up. And you know the mythical man month, it's far more expensive to do things in parallel all at the same time than it is to stage things out. And those of you that have been involved in the HL7 process have a sense for what it takes to resolve 2,000 negative ballots across 3 different ballot cycles within HL7, and that takes resources and that takes dedication and it takes time to be able to do that. Now, we could have taken much longer to do

that and had the volunteers work on it, it would have been cheaper, but we would have missed Meaningful Use Stage 2. And so we've really been focused on that.

We also have to recognize, and I've used the phrase it's not "one size fits all" in so many different places that people are going to get sick of me when I keep saying that, but when it comes to supporting the S&I framework initiatives there's not one size fits all. There are some things that are so strategically important and that are so critical to our ability to advance interoperability that that has behind it the full weight and support of ONC. Maybe this is something that the vendor community and the industry isn't going to do, because we need to be there to help support our patients, the consumers, the providers, others people wouldn't necessarily create an initiative for. So there are some things that I think we acquire the full weight and the full support. Some things might be strategic support. Full support would be things like transitions of care that really required a tremendous amount of ballot resolutions and a lot of work to bring that together.

Strategic support is hybrid resources in which there are targeted investments on specific components. For example, the work that the California Healthcare Foundation is doing around laboratory order interface may be an opportunity for us to strategically partner with them and say there are parts you guys can do, there are parts that we can do, but we can make sure that whatever comes out of this has advanced the national agenda in addition to solving that regional need that you have. There's areas of limited support, where we say, listen, we're going to provide you a facilitator, we'll provide meeting space like that, it's certainly something that's important but we have time, or maybe we have some other things that would allow us to say we want to keep track of this and we want to support that. Then there are other aspects that as we standardize the ways in which we have the building blocks, we have Wikis, we have best practices, we have all those pieces, it could be that we say you guys can go off and do that yourself, but if you follow these practices, if you come out with a standard that looks like this, if you follow the kind of consensus based approach it will be easy for us to give you a glide path into the standards framework that we have as well.

What I wanted to do, and I know I did that in a rapid fire fashion because I want to make sure that we get an opportunity for public comment, or at least some comments around the table, is that this is a conversation that we're having at ONC and that we're engaging members of the community, people in the S&I framework, and we're really trying to get good feedback about how best to go forward with the work that we've done. We've done this in a way that I think we have to continually try to improve, we have to continually try to be thoughtful about where we're putting our resources, and so we may not have time at this particular meeting to finish all of our conversations here. But I wanted to have people start to think about this as you're looking at the Meaningful Use Stage 2 rule, you're thinking about where are the missing pieces and what do we need to fill in, and as we think about what Paul Tang has talked about with regard to Meaningful Use Stage 3, what do we need to do to be able to support the mission that we have around meaningful use, the goals that we have with interoperability and the needs that we have to support patients and providers in this kind of exchange. So with that, I'll move to discussion.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, well we have three commenters, David McCallie, Wes Rishel is on the phone with his card up, and we have Cris Ross and Jamie Ferguson. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

First, thank you for these slides. This is really very thoughtful and helpful. I need to read through them and think about them more deeply, but I really like the way you've graded out the different roles that the S&I framework could play. One question, and it probably is one that's too complicated for an answer on the spot, but I'm curious to know that as you might envision on your graph of more innovative to more incremental that if there are emerging innovative approaches that aren't going through the S&I framework perhaps, what does it take to get far enough to be considered for inclusion in a future regulatory piece of work? So, for example, what does it take to be a standard, enough of a standard to be used, or is that even a consideration at all? I'm thinking of things that are emerging in the Internet world where they're de facto standards, numbers of vendors have gotten together and agreed to do something and they maybe

even caught on and had millions of users, but it's not a standard in an IETC or a W3C or a typical SDO. Maybe that's an off line answer but that's just a question for the future.

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

I think that's an excellent question, and in fact even if we take a look at some of the things that we're moving forward with REST and RESTful approaches –

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's exactly what I'm thinking about obviously.

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

But that is not a standard per se.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Right.

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

So we will struggle with that early on, with trying to determine what that is, but I think if you take this presentation and you pair it with the stuff that Dixie was talking about with regard to what makes a good standard and where are the axes along this, combine that with where these buckets would sit and it begins to help us figure out how to manage our portfolio. And to answer that question, if there is a well adopted Internet-based standard that's not specific to healthcare but could be fundamental in terms of doing discovery of certificates, directories, where we're using micro-data or whatever, if what we have is criteria that says we can take a look at this and say it solves the problem, it does it expeditiously, it is secure, it meets the criteria that Dixie and her team have come up with, that's certainly something that then we can have a conversation and think about what's the next phase. It could be that it just leap frogs over and says listen, let's talk about it in the HIT Standards Committee. Maybe this is something that we just need to do. I don't see them as necessarily a progression from one to the other, because innovation can sometimes be disruptive, and that means it follows a different process.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Wes Rishel?

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

Thanks. Doug, this is the most clarifying presentation on the S&I framework I've ever heard. Thank you so much. I want to just make one statement for the record. The work that the California Healthcare Foundation is doing is not in any way regional, despite the name of the organization and its location. It's nationally represented, nationally supported, and the work they're doing to actually test their specifications is not in any way limited to California. Back to the bigger issues of the S&I framework, I think that it has become clear that standardization that can be certified, that can be expected to scale out rapidly to inter-operation among a lot of entities that haven't gone through an implementation process with one another, they represent just a mind-numbing amount of detailed work done in root canal meetings. It's just always been that way. Some groups are better able to reduce the size of those meetings and get by, but it still has to happen.

The ability of the government to establish a priority in a consensus organization like HL7 by, as you said, throwing money at it, is significant and I think that certainly the lab specifications are an example of that being done very well. And I'm not meaning to imply anything less on the others, I'm not just as familiar with the others. I think that the areas that you probably either fit into your other boxes on your presentation or represent a different dimension, are those areas where there is no other consensus body? So for example, the direct created a consensus body and a consensus process and so forth, that requires a different kind of facilitation and it might have been done more directly in the S&I framework as

long as the body of documents that is produced by the framework are not all targeted at the regulation, it's not clear that everything that has been done around the S&I framework went into the regulation.

Finally, I think that the S&I framework has suffered from a sense of redundancy among a lot of participants. We go to HL7 meetings to discuss these, we go to IHE meetings to discuss these, and now we need to go to S&I framework meetings to discuss these, and a sense among a lot of people is that the S&I framework was largely done by professional standards meeting goer people. I believe that what should happen as a result of the stage 2 NPRM is that people should look at the output of the S&I framework and newly evaluate whether it's worth spending their time in it. And I hope that you can see a little bit of a broader industry participation as a result. Thanks.

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

Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Jamie's last.

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

Thank you, also, Doug, for a great presentation. I know it's important for ONC to have a basis, particularly on the information modeling space, to integrate and relate models across a broader spectrum of activities, and that's one of the things that NIEM is good for, so I expected, frankly, NIEM to be somewhere in this and I didn't see it there, so I wanted to ask where's NIEM?

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

That probably requires a longer discussion than we have right here. I will say this, is that to Wes's point about having no other consensus body, one of the challenges that I think the federal government and ... agencies have had is that there has been no standards development body specifically devoted to figuring out how IRS talks with trade and how trade talks with state, and all the various agencies. NIEM, as a process within the federal government, established a standards-like process among state, local, and tribal organizations that would help them provide some standards. That has produced a lot of value within the federal government and I think there is a desire to reduce costs and not have redundancy across the federal government using NIEM frameworks. Even within Health and Human Services there is a human services domain in Health and Human Services, and there is now a health domain. As we look forward to accountable care organizations and coordination outside of what would be traditional healthcare into other services that would be out there, it's going to become increasingly important for us to understand how to interact with that.

Do I have the answer for exactly how all of this fits together? No. But I think we are actively engaged within the NIEM community. We think we can teach them some things about interacting with, say, other SDOs, and I think that there are things that we can learn from them in terms of how they've been able to formulate. And so in some sense we would rather be engaged with them and try to figure out a way that the federal government as well as private sector can work together and how we make that all work. And so NIEM doesn't show up on there because I learned in this group that if you put a controversial name in a box, then that is what we all talk about. I didn't do that, and if you'll notice in one of the slides I have the data model and it was blank. That was on purpose.

But you're absolutely right that we do have to figure out how those things fit together. And we've done some work with model driven health tools, we've done some work with some other formalisms around that, and we've actually provided some analysis looking at HL7 and NIEM and looking at the federal health architecture and the federal health information modeling effort within HL7 and NIEM, so we've done some analysis, we know where the challenges might be, and we're just trying to figure out how we can chart a path that allows us the flexibility to work with external SDOs, as well as the ability internally within the federal government to work across the agencies as we're being asked to do.

Jonathan Perlin – Hospital Corporation of America – CMO & President

The last comment, Cris Ross?

Cris Ross –SureScripts– CIO

Very briefly, this is great. Thank you. Government sometimes intervenes when there's a market failure and it occurred to me reading this that that wasn't something that you put in here. And it feels to me as though maybe this clicks for your group or not, but it feels to me as though there's a Goldilocks test, that if the market failure is low and the standards are being adopted widely, to David's example, pay no attention to them, simply anoint them, and if the market failure is profound there's probably something that's beyond the work of S&I. I wonder if you think about it that way, because if you do that certainly makes sense to me that that's what you're up to.

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

And that's just an oversight. I think market failure is another reason why the government should help intervene. In some sense that was the comment around consumer engagement and other things like that. There may not be advocates who would come to an SDO to try to create a standard that would be of benefit to consumers, for example. That may be a place where it's imperative that the government step in and produce the kinds of things that would empower that group.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Judy, a very quick last word.

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

Absolutely quick. It's a challenge actually to the committee. I agree that these slides are great. I think the increasing clarity with which we're all understanding what the S&I framework is really all about is really good. Unfortunately, what keeps me awake at night is the same thing that's kept me awake for the last couple of years, and that's worrying about implementation. When I look at this, what I start to twit about is how do we take all this from the 1,200 people who work on it every day and understand the standards and make it implementable, make it broadly applicable, disseminate the information, show implementation is a success. By design the S&I framework takes it through prototype. It doesn't take it to full implementation. And so one of the things I want to throw out to the team is what should we do about that? Is this something that, Cris was nodding, so the Implementation Workgroup could take on and look at more specific implementation specifications, if you will, not about the standard itself but how you take it and actually integrate it in and use it within meaningful use. There's no answer to this. To me it's the next step of the challenge because out there in the world, I know many of you know this, they're struggling with the standards, and I think it's because we have to figure out a better way to communicate and disseminate the information.

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

Judy? Judy?

M

... Implementation Workgroup did. That's been a focus for the Implementation Workgroup for sure, and I think we got absorbed in MU2 for the 2014 standards.

Judy Murphy – ONC – Deputy National Coordinator for Programs and Policy

Yes.

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

This is Wes. I'm sorry to interrupt, but if you could just take my comments that I made previously about implementation support dealing with the standards and we put them under this setting, I think it's absolutely critical that somewhere within the ONC you find a home for implementation support. And it's not a kind thing to say when budgets are getting tighter, but it's not going to be cheap.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I think that is a good place to not close, but really tee up perhaps some conversations between but certainly at the next meeting. I think, Wes, you hit the nail on the head, this was really the most succinct and terrific presentation of S&I and I think a good discussion on that, a great meeting. I want to be

respectful of the public process for input and so we'll stop here with thanks to all of the committee members for your work. And let's move, Mary Jo, to a public comment period.

Public Comment

Mary Jo Deering – ONC – Senior Policy Advisor

Operator, would you please open the lines for public comment? And if you are in the room and would like to make a comment please come forward and take a seat at the table and limit your remarks to 3 minutes and please pronounce your name and organization very clearly. So we will start with people in the room.

Lindsay Hoggle – American Dietetic Association – Independent Consultant

Thank you. And thank you for the work of this committee. My name is Lindsay Hoggle and I am commenting today on behalf of the Academy on Nutrition and Dietetics, the former American Dietetic Association — too many ADAs so we changed our name. It's an organization of 72,000 nutrition experts in the United States and we've been involved in following HITECH since its inception in 2009, specifically, to make sure that we are able to follow nutrition in electronic health record moving forward. I'm only the facilitator, there are over two dozen people who work on standards, HL7, S&I framework, and other initiatives to assure that we are doing it right going forward. I have several comments just for your consideration.

I'm going to reuse some of the comments that were made today. One of those is Dr. Mostashari's comment that meaningful use is the floor. I'd just like to ask that nutrition and diet orders be included above that floor. And the reason is that, to quote another comment made today, "no one size fits all." For what may be a regular diet for some of us or no restrictions, there are restrictions for patients that are very important. Some of the patients go home on enteral feedings, on parenteral feedings, and we follow all of those. Any omission in a transition of care or any other exchange of data of that information can be critical.

The other comment is in terms of our work to make sure that we have structured nutrition terms in the electronic health record. One of those reasons is so that going forward we can have clinical decision support that includes nutrition, evidence-based medicine.

The final part is in terms of inclusion in stage 2 is that in terms of consumer engagement nutrition and diet and exercise are one of the main topic areas that patients search online, they have apps and look for information on that. We've participated in S&I framework in the transitions of care and the query health initiative for a reason, mainly because those transitions of care are very critical in terms of nutrition. One of those is in terms of long term care. We have many anecdotal reports which are not good in terms of patients getting to their location and not having the information that they need.

The last part is in terms of allergies we've commented several times in terms of including food allergies we understand that standards are a myth in that area and we have collaborated with several other experts in the area and now are working on HL7 Patient Care Committee Allergy Workgroup, and that informative ballot is supposed to be submitted in August of this year. There may be better standards out there, but we just want to assure that all the allergies are kept together and that we have a standard for food allergies going forward to assure that no mishaps occur from using electronic health records. Thank you very much.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you.

Tom Bizzaro – First DataBank – VP Health Policy & Industry Relations

My name is Tom Bizzaro. I'm Vice President of Health Policy for First DataBank and a pharmacist. As a provider of the script that is in the clinical drug knowledge basis FTB has an intense interest in the designation and use of national standards and national standard related vocabularies. My comments today are related to the codification of drug allergens and specifying a standard vocabulary for those allergens. It makes sense that the codification of allergies to dispensable drugs, drug ingredients, and

recipient ingredients use RxNorm, and I would endorse that. We also want to support the interoperable transfer of allergy drug class information in a standard vocabulary for drug class is required to support the interchange of this critical health information. I was happy to hear members of this committee raise this issue earlier today and thank the committee for the opportunity to comment.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you.

Robin Raiford – Allscripts – Executive Director, Federal Affairs

This is Robin Raiford from the Advisory Board. I'd like to present probably the largest single piece of paper in a public comment of what keeps nurses up at night is when it's explained in so much paper you can't see it, you can't see it, so here is the final standards rule from stage1, the 2014 criteria, the stage 2 NPRM of measures, objectives, numerators, denominators, exclusions, and thresholds in one piece of paper that I will send to Jon, I'll send a link and we'll get it out to everyone. It's intended to be public for everyone to see it and use it, and if you've created the floor then I've created half the wall.

(Applause)

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you. I have a feeling new wallpaper will be showing up –

Robin Raiford – Allscripts – Executive Director, Federal Affairs

We've got to get the paper out of this.

Mary Jo Deering – ONC – Senior Policy Advisor

Operator, do we have any comments on the phone?

Operator

(Instructions given.)

Jonathan Perlin – Hospital Corporation of America – CMO & President

Hearing no comments on line I want to thank all those people that made comments today and really to all the people involved with this work to quote the famous philosopher, Yogi Berra, "The future ain't what it used to be." In this instance I'd say it's much better and your work really deserves great accolades. Thanks very much. We stand adjourned.

M

Thank you.