

**HIT Standards Committee
Transcript
March 26, 2014**

Attendance

The following members attended the meeting:

- Dixie Baker
- Steve Brown
- Anne Castro
- Jeremy Delinsky
- John Derr
- Floyd Eisenberg
- James Ferguson
- Elizabeth Grippo for Keith Figlioli
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- C. Martin Harris
- Stanley Huff
- Elizabeth Johnson
- Anne LeMaistre
- Arien Malec
- David McCallie, Jr.
- Nancy Orvis
- Jonathan Perlin
- Wes Rishel
- Kamie Roberts for Charles Romine
- Eric Rose
- Sharon Terry
- Andrew Wiesenthal

The following members were absent:

- Lorraine Doo
- Rebecca Kush
- Kim Nolen
- Christopher Ross

Presentation

Operator

All lines are bridged with the public.

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

Hi everyone; this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is the 55th meeting of the Standards Committee. This is a public call and there will be time for public comment at the end of today's call. As a reminder to those making comments comment is limited to three minutes and also as a reminder to Standards Committee members and anyone speaking if you could please state your name as this meeting is being transcribed and recorded. For those of you on Twitter the handle for today's meeting is #HITSC, and with that I will now take roll. Jon Perlin?

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

Good morning.

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

Good morning Jon. John Halamka?

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

I'm here.

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

Hi John. Anne LeMaistre?

Anne LeMaistre, MD – Senior Director, Clinical Information Systems & Chief Medical Information Officer – Ascension Health

I'm here.

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

Hi Anne. Andy Wiesenthal?

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

Here.

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

Anne Castro?

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

I'm here.

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

Hi Anne. Arien Malec?

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

Hello.

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

Hi Arien. Marty Harris?

C. Martin Harris, MD, MBA – Chief Information Officer - Cleveland Clinic Foundation

I'm here.

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

Hi Marty. Charles Romine?

Kamie Roberts – Associate Director – National Institute of Standards and Technology

This is Kamie Roberts for Charles Romine.

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

Thank you. Cris Ross? Dave McCallie?

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

Here.

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

Hi Dave. Dixie Baker?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm here.

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

Hi Dixie. Liz Johnson?

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

I'm here.

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

Hi Liz. Eric Rose? Floyd Eisenberg?

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

Here.

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

Hi Floyd. Jamie Ferguson?

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

Here.

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

Jeremy Delinsky?

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

I'm here.

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

John Derr?

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

I'm here.

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

Keith Figlioli?

Elizabeth Grippo – Executive Coordinator – Premier Healthcare Alliance, Inc.

This is Elizabeth Grippo for Keith Figlioli.

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

Kim Nolen? Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

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

Lisa Gallagher?

Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy & Security – Healthcare Information & Management Systems Society

Here.

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

Lorraine Doo? Nancy Orvis? Becky Kush? Sharon Terry?

Sharon F. Terry, MA – President & Chief Executive Officer – Genetic Alliance

I'm here.

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

Hi Sharon. Stan Huff?

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

Here.

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

Steve Brown?

Steven H. Brown, MD, MS – Director, Compensation & Pension Exam Program (CPEP) – Veterans Health Administration

Good morning.

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

And Wes Rishel?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Here.

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

Hi Wes and with that I will turn it to you Karen.

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

Well, good morning everybody and thank you all for joining us on the call today. We have been quite busy here at ONC and are looking forward to an in-person meeting in April and we'll have a chance to talk in more detail about work plans going forward but it doesn't stop the fact that we have expectations this year around seeing if we get the 2015 NPRM is something that we received some comment back on from folks and some dialogue.

And then we are, as you all know, in open season for Meaningful Use Stage 3. So, beginning the process of thinking through in a structured way what makes sense to advance the HIT community through the Meaningful Use Program and more importantly to advance patient health and care.

So, I look forward to both of those discussions today on the agenda and to meeting everybody in person in April and that's all I have.

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

Great, well thanks Karen and appreciate your leadership and indeed the season is off to a very energetic start all around probably a good anecdote for all of that snow in the area to keep us warm with all of the activity and certainly it is a busy time for everybody who is at work not only contemplating the future, but in the present, Stage 2 is an exciting period as we transition from really laying the foundation of technology to using it, to net process I believe working on increasing the usability task, important task for providers, patients and vendors alike.

Let's start right in with the minutes. I know that Jamie Ferguson has an amendment he would like the sentence that says that many of the continuous specifications have yet to be considered by FDA to be changed instead to say that many of the Continua specifications have yet to consider new FDA guidance. And we have that in writing Michelle so an important but subtle distinction.

With that, are there any other amendments or implications, corrections to the minutes that anyone would like to suggest? Hearing none we'll assume consensus on those and move forward.

And many thanks, Michelle, and to the ONC team for your thoughtful capture of our deliberations at the last Standards Committee meeting. And welcome, everybody to, hard to believe, the 55th meeting of the Health IT Standards Committee.

Appreciate all of your hard work and as Karen said, we have an important agenda an inflection point during the work that continues on for Stage 2 as we contemplate Stage 3 and the 2015 NPRM. In fact, I think this set of materials is really a very important set of materials.

The references for this meeting are really quite encyclopedic and a resource in particular on the S&I Initiatives. In fact, as we think about the agenda this morning Doug will be providing a snapshot of the status for S&I Initiatives and more insight into the clinical quality initiatives and we'll hear more about that as well as the Prescription Drug Monitoring Program.

Continuing in the realm of really encyclopedic references, Steve Posnack has terrific contributions around helping us understand the requirements in the law and the really necessity for progress with rulemaking and the recommendation for the 2015 edition NPRM.

We'll also be thinking forward from that point to requirements and necessities for 2017 and toward that end there's a lot going on in the Workgroups. The Standards Committee Workgroups will be providing comment by the next Standards Committee meeting on April 24th on implementation which has been doing just a huge amount, clinical quality which will have input on specific items related to clinical quality measures and clinical decision support and the privacy and security will be contemplating areas in its area of expertise.

One of the other areas that's again a terrific reference and encyclopedic in terms of contemplating really the framework for consideration of standards going forward in terms of maturity and provider effort and development effort is that the work that John Halamka and the Standards Task Force has done and rather than my provide introduction to that at this juncture let me perhaps segue at this point to Co-Chair John Halamka for introduction of that topic and our segue into the bulk of the agenda, so with that, John?

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

Well, great, thanks so much, John and as you said there's much going on out in the trenches. Beth Israel Deaconess just finished its Meaningful Use Stage 2 certification. I think we may be the first hospital in the country to self-certify all of our systems.

So, I got to live the dream of what the Stage 2 regulations actually required and all the demonstrations that we had to go through as both a provider and in effect a vendor organization creating our own software. So I tried to be exquisitely sensitive to the impact of everything that the Federal Advisory Committee recommends.

And Jon to your point, as we reviewed the 19 different segments of the Meaningful Use Stage 3 recommendations we tried to use objective criteria to understand the provider effort actually using, in a novel workflow, said recommendations what was the standards maturity and we tried to use the Dixie Baker back in the day when she ran the NwHIN Power Team and developed a set of standards maturity rubrics so that we could really look at what was the stage of a standard and where was it adopted and what was its ease of implementation and try to objectively make some conclusions but also look at the total development effort of integrating that particular function into an EHR.

I am confident that our Implementation Workgroup will also do additional hearings and get additional feedback. And of course as we today go through our presentations, I mean, we'll hear Doug telling us where the standards interoperability framework is going. That's going to help us all understand how some standards gaps are going to be filled.

For those of you who've read the GAO report identifying some barriers to interoperability are reflective of a maturity of standards, we know there's additional work to do. The NPRM, as John said, will give us in effect a roadmap as we go to 2017 how we're going to get to some of these standards gaps implemented in products.

And as I go through the 19 points in my presentation what I hope you understand is how hard it is to actually take a moving target like a standard that is balloted and piloted but not yet widely implemented and make some judgments about how it is appropriate or not appropriate for 2017 inclusion.

So my promise to you, Karen, is that I'm going to try to argue both sides of every story and therefore the committee can, based on objective data, draw some summary conclusions.

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

Thank you, John.

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

So, certainly look forward to the discussion ahead.

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

Well, thank you for that John and notwithstanding any other comments from Karen we will dive right in with Doug Fridsma. And Doug really just a – I'm going to have your slides not only available for this call but actually will, I think, be a reference for all of us who as John Halamka said are living the dream because it really provides great insight into all of the different domains of activity.

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

Great, well, listen, thank you so much Jon and John for all your leadership on the HIT Standards Committee here.

What I included in the packet of information that was sent out was actually a comprehensive list of many of the initiatives that are currently underway in large part just to sort of give people some visibility into the breadth and number of activities that are ongoing.

It's important to note that many of the things that are being supported within the standards interoperability framework support not only Meaningful Use but are also supporting many of our federal partners that have particular needs that they're trying to do and so while there's a whole host of activities that are going on many of them are being funded or being sponsored by some of our other federal partners. But I think it's just really important to try to give that transparency and the visibility into the work that's going on and to solicit any feedback that we might have about how we can fold all of this work together into a cohesive picture.

I'm only going to spend a little bit of time to introduce two of the more recent initiatives. I've included a lot of materials in the appendix, which I highly recommend if you are feeling – if you're having some insomnia and you want to get to bed that would be a good thing to go through. There's a lot of information and detail there. But I really hope that if there are additional questions or the like around that I'm happy to answer those questions as well. So, if we can go to the next slide? And we'll go to the next slide after that. There you go. Okay.

So, as I always like to do is just give you some updates on kind of where we are with participation within the community and really to highlight that this is a community driven process that ONC supports to try to accelerate the development of these standards.

We now have over 3000 registrants that are tracking the work that's going on and contributing to the work there. We've got about 750 people that are committed members. And what a committed member is someone who's really sort of showing up on the calls that is participating on an active basis and is committed to really taking the information and the standards and trying to get them out there and pilot them.

We're at about 2100 working sessions so far since we started. And we have – we've received 5600 different ballot comments on the various standards that are there and we've resolved all but about 300 right now and so that means working with the community to help facilitate that process has been important.

If we go to the next slide, just as this is my kind of multi-graph view of all of the activities that are going on, each one of these bar graphs, if you will, has a corresponding PowerPoint slide that's been included in the appendix that talks a little bit in more detail about what it is that we have going on.

Transitions of care is one of those that has recently gone through a ballot to update the templates that are there as well as some of the additional elements that are needed. We're working right now with HL7. There are significant – there is backward compatibility although there is a challenge in the way in which they identify some of the identifiers that they used for the templates. And there's a couple of proposed solutions for how to solve that and we're working with HL7 over the course of the next couple months to make sure that we can solve and resolve that issue.

Laboratory results is one that we have published some errata and updated that, that's also in progress as we're going forward. The Query Health Project actually has been folded into what we consider the data access framework and it's really part of that, but it also has contributions that will fit into the newly launched quality – clinical quality framework initiative that we'll talk about as well.

Data segmentation for privacy is normative and what we mean by normative it means that it's passed sort of the international community's seal of approval and so it has sort of the highest level of acceptance and has actually been implemented in some of the production systems.

With public health reporting we're creating kind of an umbrella organization that helps integrate much of the work but what we're finding is that within the public health community there are a tremendous number of use cases that are useful within our structure data capture activities and our data access framework and so we are working very closely with the CDC and others of the public health community to sort of create a community that has this umbrella but to get the work done in the various initiatives that are within the S&I Framework as well.

esMD is our collaboration with CMS related to digital signatures and really trying to make sure that administrative side of things, that CMS and the work that Melanie Combs-Dyer is doing is integrated with the other kinds of clinical standards that we've got as well.

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

Doug, this is Michelle, I'm sorry your line is kind of terrible. We're getting a lot of feedback from it. I don't know if there's anything that you can do on your end.

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

How about this? I'll try this instead. If we go to the next slide which I guess is the third slide, yeah, there we go. The longitudinal care coordination that is a project that is being really community lead, but we're getting some additional resources to try to make sure that we can work on things like care plans and doing some pilot work.

They've added some templates into the Consolidated CDA suite of templates. I think that's another activity that we really have to look at in terms of how we can support those providers that are not typically part of Meaningful Use but could potentially work within this larger ecosystem. Laboratory orders interface has completed their work.

So we've got two additional activities within the laboratory ordering interface. One is that we've identified an electronic specification for orderables so that you could put into a registry or into a resource all of the things that a particular lab had the capability to order and interface that into your EHR systems.

We're also working very closely with LOINC right now to identify a common subset of laboratory orders that cover 99.5% of all of the labs out there. It represents a number of LOINC codes that's probably less than 700 or 800 depending on how you look at it and all the remaining codes really fall into that much more uncommon set of orderables.

The Health eDecisions group is going to be kind of closing their activities and merging into this clinical quality framework initiative and we'll talk a bit more about that in just a bit. The Blue Button activity –

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

Doug, I'm sorry, this is Michelle. We're just getting a lot of feedback online and on the phone. Is there another phone in your office you could call in from or something else that you could try?

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

I am on a landline.

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

Okay.

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

The beeping is tolerable though Michelle. I mean, at least from what I hear. I can hear it still.

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

Okay, we've gotten a lot of complaints online from people listening in that they can't hear.

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

So that's –

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

Well, it's really not the beeping.

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

My guess is it's probably somebody else who is interfering with the communications. I'm on a landline here there is –

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

Doug, every time you talk it beeps and when you stop it doesn't. So, it's something close to your computer or something like that, but it's tolerable I can hear, this is Andy.

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

Oh.

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

Michelle, what I would suggest is everybody mute their line because it could very well be feedback that is happening. So at least we try that.

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

I can hang up and call in if you think that would improve things.

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

Sure why not try that?

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

Okay. Do you want to go on with the meeting and then come back to me?

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

Well, I mean, this will take one minute just go ahead and dial in again and we'll all mute and we will hope that it gets resolved.

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

Okay, I'm hanging up and I'll call back in.

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

Okay.

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

Thank you, Doug.

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

And if you guys have one minute to spare Michelle has sent out significant numbers of letters from public health entities offering us advice. So you can use the free time to read those letters.

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

Do we have Doug back yet?

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

I'm here.

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

It sounds much better. Thank you, Doug.

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

Okay. So, where were we, I think we were on slide three?

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

I think you had just finished Health eDecisions or started it.

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

Yeah. So, we to work on the Blue Button activities this is really about extending our transport standards around more RESTful ways of doing things and adding that to our portfolio of standards. It really is there to help support consumer engagement and making sure that we don't put in unnecessary barriers.

With regard to structure data capture we're continuing to work very closely with HL7 and with IHE. We've completed a content profile with IHE and we're working very closely with HL7 to see if we can't use the structured data capture to identify the first FHIR resource or this new sort of standard that's being – that's emerging from HL7 and use that as a way of getting a specification on highly granular data. We expect to go into the May meeting in HL7 with a project scope plan. And we will then hopefully ballot that come September.

The EU/US eHealth Cooperation continues to work on developing mappings or understanding the relationship between the standards that are used in Europe, those that are used in the UK, and those that are used in the US. And we've completed a very detailed analysis of the standards between the US and the UK or I'm sorry the EU around the transitions of care activities.

We are expanding that to include now some analysis around the UK and we hope that this will help guide the work that we're doing to try to create a more constrained version of the transitions of care that can be internationally recognized for exchange for patients that may be traveling across international borders.

The data access framework, we talked just a bit about that. They've got use cases developed and they're working on developing really what should be the first API and how we might be able to access information.

Again, there's a lot of interest from the CDC and other organizations to try to make sure that we can do case finding and that combined with the work of the structure data capture activities provide the mechanism not only to get data into the electronic health record but also to get data out.

The last two, the Prescription Drug Monitoring Program, as well as the clinical quality measures we'll talk a little bit more about those in the next section. So let's go to slide four.

So, one of the things that I think is important to recognize is that when you think about quality both the measurement of quality and the improvement of quality you realize that there's a lot of similarities in the ways in which that information can be represented.

So, if you take a look at the way that you would measure quality and the standards to support that you need some sort of metadata around the quality measure. What kind of quality measure it is, where is it applicable, what kind of organization has developed it, whether or not it fits into a particular approach with either Meaningful Use or other programs within the quality assessment.

You also need to have some way of describing the data. So, the way that the data is represented in that quality measure, whether it is a diabetic set of values set around diabetes or whether it's the ways in which the data would be necessary to calculate things.

And then finally, you need to have an expression logic that sort of says, here's how you calculate the numerator and denominator. What we found is that if you take a look at the corresponding clinical decision support you need to have similar kinds of things, you need to have metadata about the applicability of that particular clinical decision support tool, you need to have data that is used to sort of trigger the clinical decision support event and then you need an expression logic that sort of fits behind the "if" of the "if then" statement that says "if the following conditions are true" then do some sort of action or some sort of prompt.

And what we've realized is that if what our goal is in terms of doing measurement of quality is we want to be able to measure it and improve, having standards that are aligned in that way so that there's common ways of describing the metadata, common ways of describing the data that's used to calculate and common ways of having a logical expression that put those pieces together in either an "if then" statement or in terms of a numerator/denominator would be tremendously valuable.

And so, if we go to the next slide, we've just launched this initiative last week. And the goal is to identify, define and harmonize the standards that promote the integration between clinical decision support and quality measures and to take a look at that metadata, the patient data models and the logical expressions that are shared across those two different kinds of standards.

We also believe that as we get more sophisticated on our ability to do calculations around quality measures or to be able to trigger clinical decision support separating out these pieces, the metadata, the data model and the logical expression allows those three components to mature at different rates and allows us to make sure that they are consistent across the different groups.

So, we want to be able to pilot them, we want to make sure that we are harmonized in this and so this is an opportunity for us to bring together both the measurement community as well as the clinical decision support or improvement community to really sort of get all of these pieces together and to see if we can't work with HL7 and others to sort of come up with that formalism.

So that's an activity that's just got launched and I certainly encourage people if they want to go and take a look at that activity to engage and provide us some feedback and to see if there's ways that they can help us get to a place in which clinical quality measurement and improvement are used and use a consistent set of standards. Next slide.

So, this is the last slide I want to talk about and then obviously there's an appendix that includes many, many other activities that are in there. The Prescription Drug Monitoring Program and HIT integration really is being – is work that's being funded through SAMHSA to help us make sure that we can approach the problem of prescription drug monitoring not just from law enforcement but to make sure that we do this from a safety perspective and to do that we have to make it easy for patients who are prescribing information or for providers who are prescribing medications to be able to check to see if that particular patient is on other narcotic medications or that maybe have had multiple prescriptions or things like that.

And so we are focused on trying to make sure that we can connect the clinical community to these prescription drug monitoring systems that many states have stood up to make sure that they can monitor the narcotic medications that are out there.

Our goal really is to make it possible for there to be a suite of standards that help us manage information around prescriptions and prescription drugs that makes it easy for us to integrate that information into clinical decision support or to be able to do medication reconciliation and other things like that.

And so part of our work is going to be to try to map the existing standards that we have on the clinical side into those standards that are used in the PDMP communities as well. And so this is another, I think, very important set of activities that will, I think, improve the safety for patients and make it easier for providers to get that additional information that is so important to making sure that patients don't have excessive narcotic or to identify those patients that may potentially be at risk.

So with that we'll go to the next slide. And I just put that up there, if there are particular questions I'm happy to answer them but I'm not going to go through the remainder of the slides those are really there for people's enjoyment. And hopefully if people have other questions I'm happy to answer them as well.

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

Doug, thank you very much. Let me first turn to John for any comments and then we'll work through questions.

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

Certainly, well, Doug absolutely applaud the co-mingling of clinical quality measurement and CDS because they should be two sides of the same coin. In fact a doctor is told to do the right thing and then there's a measurement made as to whether or not the right thing ultimately was accomplished. So, I think that's great alignment.

I'm a user of the Prescription Drug Monitoring Program. And of course clinicians really would love a unified workflow. While I'm in an EHR one click and I have context to the patient preserved, username, password or credentials preserved and then the data from the Prescription Drug Monitoring Program appears either as a service that's a different UI or somehow data is incorporated into my system.

And of course our challenge that you've outlined has been identifying the patient between an EHR and the Prescription Drug Monitoring Program and establishing a fabric of trust so that there isn't another login and then the question is it a view or data transfer and if it is a data transfer then how is updating done, etcetera.

So, I do think it's a very noble goal and there are a number of physicians in Massachusetts who would thank you if you could establish that level of integration. Not a specific question, just an observation. So, Jon, back to you.

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

Thanks, John.

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

Jon, this is Michelle, can I recommend that we use the hand raising feature? And we do have – somebody has already proactively used it. So, David McCallie does have a question.

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

Terrific, let's go to David McCallie. And others have to use the hand raising feature or otherwise if you don't get through that, just, you know, state your name and we'll get you in the queue. So, David?

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

Yeah, this is David McCallie it's really unusual for me to be proactive. I'm impressed. Doug, my comment is one you're familiar with hearing from me, but I just wanted to update you a little bit on the Health eDecisions and structured data capture efforts with respect to FHIR, HL7's FHIR and just letting you know that a number of us who are concerned that FHIR may be a better long-range solution than the current approaches, both structured data capture and the Health eDecisions, have had some good conversations off-line with those Workgroups.

I guess in particular the structured data capture when – to, you know, kind of question them about thinking of using, you know, FHIR instead of the form definition language that they had been working on, you know, the FHIR questionnaire that you mentioned.

And then in the Health eDecisions it's not been so much with that group but with some of the members, Bob Greene and some others who have been working on that group questioning whether FHIR might be a better model than the VMR for defining some of the data elements.

So, I just want to say I've gotten good feedback from both those conversations that FHIR looks promising. I think it's the future facing standard from HL7. Some of the other work is more backward facing I would say.

So, I just want to bring your attention to that. I'm sure you're aware of these conversations but I think some of this has not yet landed from the point-of-view of where we want to be in four or five years. So, I'll just add that comment. You've heard it from me before but I want to reregister it.

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

And Jacob has a comment.

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

Jacob go ahead and Doug just feel free to chime in when you like.

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

Jacob Reider responding to Dave McCallie. Dave we agree and I think that if you've not spoken with them, please feel free to engage directly with the team, Ken Kawamoto especially, and perhaps he's on the on the line listening has asked this question explicitly and is working on mapping VMR to FHIR and what resources would need to be added to FHIR in order to do that. And so I think we are aligned with your strategic direction and guidance David.

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

Yeah, Jacob this is David, thank you for that feedback. Yeah, I think my main concern is that the VMR mix has concerns, it's got business logic down embedded in the data access logic and FHIR makes for a much cleaner separation.

So, I would say the goal is to avoid creating new resources but to create any necessary business logic in a different layer. And of course, I also have concerns about the expression logic but I will save that for another conversation.

But, yeah, I think we should engage. Josh Mandel, Stan Huff and I had this conversation with SDC and I think a similar one would be worthwhile with the VMR effort.

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

Michelle, are there any other hands up on the online feature?

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

Yes, Jamie Ferguson just raised his hand.

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

Yes, hi, I have a question for Doug. On the EU/US Cooperation, I know you're aware of the Trillium Bridge Project which is the European Commission funded sort of side of the EU/US interoperability that is aiming at a demonstration soon I think in a couple of months of different methods for both patient mediated as well as provider mediated exchange of summaries between epSOS and the US.

And so I'm wondering if you can talk about what you see as the opportunities for collaboration and synergy between the sort of the S&I Project versus the European Commission Project?

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

So, thanks, Jamie. All the work that we're doing for the US/EU activities are actually being coordinated through this S&I Framework activity. As you know, we have a weekly call with DG Connect folks in Brussels and so we have tried very hard to sort of keep things aligned.

There are some challenges in the sense that the Trillium Bridge Contract often has some deliverables that are time sensitive that have made some of that coordination somewhat challenging. I think also the hope is in the Athens meeting in May to demonstrate a sort of web accessible mapping tool that you upload a US version and it spits back an epSOS version and vice versa. We obviously have learned a lot in terms of the mapping and I think that this particular service will help demonstrate our understanding of how to move between one and the other.

I think, ultimately though our feedback has been that establishing internationally recognized standards would kind of, if you will, cut out the middleman with that and allow someone to generate in native form that particular specification regardless of kind of what side of the Atlantic you might be on.

So we are working through those activities as well and trying to make sure that the Trillium Bridge folks have been included in everything that we're doing. And making sure that we are aligned with where we want to go. I spent a tremendous number of hours at the last HL7 meeting and will likely do that again in May with Kathryn and others to make sure that we are moving in the same direction.

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

So thank you and if I can just follow up, it sounds like the web service for bidirectional translation is a particular element that, you know, there's no sense in having two parallel developments and if you've got that going maybe Trillium Bridge can use that and just have it be done once.

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

No, it is only being done once. We have been contributing to the project by understanding what the mapping should be. We've done a lot of that analysis. They're the ones that are actually developing the demonstration or the pilot that has this web service for upload and download.

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

Great, thank you.

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

Thanks, Michelle, are there any other hands up?

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

No, no one else.

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

Okay, let's open it up here if anyone didn't weigh in and would like to offer any comments or input please speak. Okay, Doug, any closing comments before we move forward?

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

No, I just want to thank both the committee and all of their comments and certainly if, as people review the material that has been given to the committee in anticipation of this meeting, if there are any other particular comments or questions that come up, by all means, let me know, send me an e-mail and I'll try to do my very best to answer.

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

Okay, well, we certainly appreciate the hard work and again, just a terrific resource both in terms of the work itself and the documentation you provided for this meeting.

In a similar vein and apropos of Karen's comments and John Halamka's comments about creating a roadmap looking forward, hard to believe to 2017, and creating a certification foundation for that roadmap, we now need to move to the discussion that we introduced earlier about the 2015 edition proposed rulemaking. And so with that Steve Posnack are you ready to go?

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

I'm ready. How is the beeping or any other type of interference?

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

You're not beeping unless if we're beeping.

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

I'm not beeping right now. All right, very good. So thank you very much for having me to give a quick rundown of the 2015 edition certification criteria Notice of Proposed Rulemaking. The rule has been out for almost a month now since it was published in late February. I'd like to just do the first public service announcement that, please submit comments and the comment period closes on April 28th. And next slide, please.

So, I'm briefly going to cover why a 2015 edition both at the 30,000-foot level as well as into some of the details that I know all of you have now dug into. Briefly, go over a little bit of the certification policy perspective, the past, present and the future, and some specific highlights relative to 2015 edition proposals and 2017 edition topics under consideration. Next.

So, big picture, why certification? From a Meaningful Use EHR Incentive Program's perspective it's required by law. Eligible professionals, eligible hospitals, critical access hospitals are required to have certified EHR technology to demonstrate Meaningful Use.

But in a general sense you could ask yourself what's the real purpose of certification and in most cases it serves as a kind of consumer protection oriented approach, provides assurance and accountability to purchasers that the products or services that they're acquiring have met certain requirements. And that in most cases there is a third-party assessor that is objective, impartial and is part of the process to add a level of trust that would be beyond self-attestation or kind of self-testing.

So, in a sense this really creates a gold baseline for a lot of programs and it can be a starting point not necessarily the end for a number of policy activities that could occur.

So, when we think about certification and we look at what ONC's role is as well in this bigger picture we do have one preeminently, as the coordinator, as a convener and in this case with certification one could see how we could be an enabler relative to appropriate and well-honed policies related to certification as that gold baseline.

So, we've been doing a lot of thinking and exploring and coordination with our other federal colleagues and I'll touch on a number of these points as they relate to the 2015 edition rulemaking and to the future that we're looking at in terms of how the certification program and its policy can be of service to others and that's really where I think this will warm all of your hearts.

I've described this, in my own speak, as kind of a policy API as a method for convergence and a way in which we can work with industry stakeholders as well as our federal colleagues to find ways in which we can explore mutually beneficial outcomes and where certification can provide some acceleration and some means to enhance the regulatory structure in which we work, as well as, and, you know, maybe this is a hope of mine, ways in which we can reduce overall regulatory burden, setting up some areas where there could be instances where I put in quotes "compliance fast-track" not necessarily guaranteeing through certification that a regulation has been met but there could be certain elements under other regulatory frameworks where certification can provide a jumpstart and that's where we may need to take a first step in our certification program to allow others to then build on and use that API that we've created. Next slide.

So, here's a best guesstimate of the next three year's worth of work and breaking down by the calendar year. So, we are currently in the black kind of line worth of work early on in 2015 edition NPRM that was published in Q1 of this year meaning for Q3 to have that final rule out.

And the unique thing about shifting to a more incremental rulemaking process, and I think you may have heard Jacob mentioned this in his prior attendance at one of these meetings, is that it gives us an opportunity to solicit public comment and give the industry advance notice and advance input, and advanced time to think about some of the issues that we're considering and to tell us apropos to the discussion earlier, when things might be right, when things might be fully baked, where there could be other areas of exploration that we need to take into account before we would we include something in a regulatory process.

And so as we look to the future what I'm mostly thinking about in terms of rulemaking approach is that it gives us two opportunities going forward to get input on our rules going forward. So, we've got the 2015 edition proposed rule but within it is really what we would call an advanced Notice of Proposed Rulemaking for issues that we are currently thinking about relative to the 2017 edition.

And you'll notice that the proximity of these two rulemakings are very close together creates a little bit of a challenge for us to, you know, make sure that all those pieces fit together. But, I think timing-wise it couldn't be any better because the public comments that we get on this rulemaking, which again I'll emphasize, are very important, please do so, will feed directly into the policy discussions and drafting processes that my team will take on as we aim to get the 2017 edition NPRM out in quarter four of this year. So, it's a real opportunity to give a first round of feedback before you normally would be able to as both the Standards Committee and the industry at large.

And then the rest of the roadmap shows how we would intend to replicate this process to make our rulemakings a little bit more nimble and more adaptable and accommodate updates to standards and implementation guides over time. Next slide.

You can animate through this, please, until the four dots are populated. All right, so the animation didn't quite – there's one more, I lost some of the colors but that's okay. So just a couple of milestones for reflection and to show, you know, where we've gone in the past three years.

So, the major certification edition timelines in rulemaking is really in January 2010 we published what we now call the 2011 edition that was part of the interim final rule that we issued, but for all intents and purposes it generally served as a Notice of Proposed Rulemaking. And we published that rulemaking in January 2010, two years later we published the 2014 edition which everyone is now intimately familiar with in implementing. And two years later now, in February 2014, we've published the 2015 edition as this incremental update to the 2014 edition.

Sprinkled in there was the final rule for the permanent certification program, which is now the ONC HIT Certification Program and that is the kind of current methodology that we use for the testing and certification processes.

So, I just wanted to give a high-level overview both of, you know, where we've been and where we are right now present state and how long it's been since we've waited to include in a rulemaking updates to our standards and certification criteria.

So, putting again in perspective that it's really been two years since we've tried to advance policy relative to what I would call "standards" policy in a rulemaking and to push forward with some of the updates that have occurred. Next slide.

So, as I mentioned, I've used this framing of incremental rulemaking. I'll touch on these briefly again. I think we think that this will make our rulemaking processes more nimble, it will enable us to better keep up with industry updates. There have been some instances where we've done a whole lot of work the rulemaking has come out and then six months later something that would have really complimented something that we've included a regulation comes out, comes out of ballot gets, you know, worked on by the industry and then we have this period of waiting whereby until the next regulatory train is starting to leave the station then we get to include that information.

So, we see if we could issue smaller scoped regulatory actions that it could enable us to in a more incremental way with – by shrinking the changes that would occur between additions and certification criteria, that it would allow for us to keep our rulemaking more current and fresher as well as allow the industry to see where we're going in an earlier way.

There's a more important kind of regulatory construct which I'm going to touch on in a little bit more detail relative to what we call "gap certification." And as there becomes less change between editions that means that there is less retesting of potential and more efficient and quicker certifications that could occur through the certification process and finally, as I mentioned, ample opportunity for public comment and early visibility, so I've touched on that numerous times. Next slide, please.

So, gap certification just because I'm going to go through this in a visual next, the important part of gap certification is that as we adopt a new edition of certification criteria there are certain criteria that we designate as "unchanged" and when certification criteria is designated as unchanged it means that previously issued test results can be used toward meeting that next edition certification criterion.

And so where there's an "as is" adoption of a certification criterion in the new edition, gap certification would be available and we think that this would significantly expedite certification going forward. And I'm going to show you a visual as to why this might be the case. Next slide.

So, working our way downward chronologically we start with the 2011 edition and that was the first edition that was published to support what was the original Stage 1 Meaningful Use, I call it MU Stage 1 Classic. That was our baseline of certification criteria. So all of them were new which is what that N stands for.

As we move down to the 2014 edition, when you look at the composition of that edition, it was made up of 20% unchanged from the 2011 edition, 50% revised and 30% new and I'm looking at the ambulatory as my point of reference here.

And so the reason why I think in my mind there's a steep hill to climb for EHR technology developers as they were getting their products tested and certified to the 2014 edition was because 80% of the 2011 edition criteria including some new ones were added, were revised and new, as part of the 2014 edition. So, there was a lot of change that occurred.

If you look at the difference between the 2014 edition and 2015 edition, the composition of the 2015 edition is roughly 64% unchanged from the 2014 edition. Meaning that 64% of the certification criteria in the 2015 edition, as proposed, would be eligible for gap certification and essentially kind of carrying forward the previously issued test results as a means to get credit for 2015 edition certification.

So, that means it's possible for any HIT developer to get a 2015 edition certification without any additional retesting if they were to focus a scoped product within those 34 criteria in the unchanged category they would not necessarily have any changes that they would need to make and they may be able to bring forward their 2014 edition test results as a means to getting credit toward the 2015 and as you can see the shrinking of the change between additions as well.

So, as we go forward and I can't forecast what the 2017 edition composition may look like, but I would venture a guess that both between the 2014 edition and 2017, as well as the 2015 and 2017, that there would be less of a revised and new composition when we compare the 2011 to 2014. So next slide, please.

I also was reading on a plane flight that visuals help with retention. So I've been using a lot of visuals in terms of the policy communications that I've included here. So, I have two slides that are compare and contrast in terms of what the approach would look like had we not included this 2015 edition rulemaking. We would have been on this path that's in front of you today with the slide where we published a rule for the 2011 edition that supported MU Stage 1. That's that blue kind of hump there.

And then the corresponding HIT developer resource allocation to get the products tested, get through certification, get it out is that red line. And one could argue in terms of the peaks and valleys relative to the resources and how I've gotten there, it's not necessarily drawn to scale, but for illustrative purposes, and also as I've been given my talks tried to ask folks to visualize a third curve that would follow the red one which would really be the implementation on the provider's side.

And so you could see three peaks, one for the rulemaking, one for developers to get tested and certified and then a subsequent one which would be the actual implementation by eligible professionals and eligible hospitals. And you can see how all of that work starts to fill the voids between the rulemaking and the time going forward.

So now we're going to have a little bit of an interesting sequence here with the animations that I build in that I'm not driving. So you can go forward. The stars here, and as we go forward and I'll have them tab through, because I think I'll just go through the concept once is that, you know, all those stars or development efforts between, you know, SDOs that then get mushed into the big star that represents our rulemaking.

And then another, you know, large gap of time where we're kind of under the impulse to get as much as we can into a rulemaking so that we can capture everything, all the good work that's occurred thus far, as well as forecast a little bit into the future so that our rule doesn't become immediately obsolete as soon as it gets published, and as soon as the industry implements toward it.

So, that's what the kind of stars, the little stars into the big star was meant to illustrate in terms of the flow and capture of industry activity right before rulemaking and then the subsequent events afterwards. Next slide, please.

So as we look at the resource allocation relative to the rulemaking compared to developers with incremental rulemaking, again not drawn to scale, but you could see how with less changes between editions an assumption or an estimate could be that the HIT developer resource allocations would lower to a different level, not necessarily flat line but have smaller peaks and valleys and have more of an expected trajectory going forward with respect to the amount of effort that would be necessary to move from edition to edition. And I have my stars animation that follows here next. So, you can go through that please. Keep going, one more. All right, next slide.

So getting into 2015 edition highlights now down at the 10-foot level, as I mentioned earlier, using our regulatory process as a point of convergence, as a way to engage other stakeholders and other federal partners that we have, there are a number of activities that are represented in proposals in the 2015 edition proposed rule that have been informed by our work with our other federal colleagues.

And so with respect to lab orders we've proposed a split to the CPOE certification criterion to have three separate certification criteria, one for each of the specific ordering workflows. The lab one being the most specific where we've worked with our colleagues over at CMS and the survey and certification area to have a greater focus on where there could be some CLIA compliance efficiencies that could be built in as part of certification that would then enable subsequent action on the part of CMS. And that's explained in our preamble of our regulation.

We've proposed the adoption of the Health eDecision's work, which I know there are some discussion of already, as part of continuing to improve the clinical decision support capabilities.

We've proposed a new certification criterion for the capturing of patient's implantable devices. And that was due to coordination and collaboration with our colleagues at FDA and they're rulemakings that have put forward the unique device identifier rules. I know you guys have been briefed on that before. So I'm not going to cover that in any detail.

It's also a good reminder I think from a broader policy perspective that there's a lot more policy out there for which certification can be helpful besides Meaningful Use and it's not to say that Meaningful Use isn't important, but it is one tool in the toolbox that the department has as well as one tool that ONC can support through a variety of mechanisms and more so through the certification process which I'm focusing on today. Next slide, please.

One of the ones that I know has already generated a lot of debate which is probably the most comprehensive revision to the certification criteria from 2014 to 2015 edition has to do with transitions of care. And we've proposed, based on a lot of industry feedback and our own analysis, to separately test and certify the content capabilities from the transport capabilities.

Today, just to give you the compare and contrast in order to meet the certification criterion for 2014 edition certification an EHR technology developer needs to demonstrate both the content and transport capabilities in one shot through testing and as part of getting certified. So to say it in the negative, you can't get certified to just doing transport today you also have to do the content capabilities as well.

As we look going forward, as we look to make sure that our rules are extensible, as we look to other content capabilities as well as other transport capabilities that may exist, that may develop on different timelines, and that may have different purposes and be fit for use for other reasons, it makes sense to split content and transport from a testing and certification perspective so that they are more modular as Doug would say and that we can accommodate changes without having to entirely revise and up heave the structure of our certification criteria.

We also included a proposal, given the separation of content and transport to make sure that on the content generation side there was a way for the EHR technology which would really be the one communicating in this case for Direct Project purposes to another health information service provider via some type of edge.

And so the Direct Project folks have been working on an edge implementation guide and we reference that as a proposal. I know that's also generated a lot of public comment and feedback thus far. So I would encourage you, those of you who are out there listening, as well as on the Standards Committee, to very much engage in a dialogue about that.

Another proposal that we included that would be new is relative to a performance standard. A lot of the focus that we have had thus far in certification has been on the creation and the transmission outbound of the content.

And we haven't necessarily focused on the receipt and Postel's Principal type of commentary that Doug brings up very often and the resiliency really of EHR technology to be able to receive, in this case a Consolidated CDA, and perhaps unanticipated or unexpected implementations or ways in which certain optionality might have been implemented by the sender and be able to accommodate that variability and not necessarily implode upon receiving something that was unexpected.

And so we've proposed what we think is a performance standard that could advance both coordination in the industry to galvanize around making sure that there is the appropriate constraints on the Consolidated CDA for particular purposes as well as to create a greater focus on not only the ability to send but the ability to receive in a resilient way.

The last one I'll touch on here which is the bottom bullet had to do with, as many of you are aware, we had an issue going on related to patient matching. There are a number of areas in the industry of which I'm sure many of you are engaged relative to patient matching still.

And so we looked at a point where the EHR technology could be helpful here and that would be improving upon the outbound creation of a Consolidated CDA the quality of certain data elements relative to patient matching and those elements that might be used by recipients to do their matching and so trying to add in some specific constraints that would allow for some additional consistency. Next slide.

There's another one which represents collaboration between ourselves and our CMS colleagues, specifically across both CCSQ, the Clinical Standards and Quality Group, and the CMMI folks, innovation folks related to clinical quality measures and in this case more broadly speaking kind of population management and the ability to filter clinical quality measures by different types of patient populations and so that's been a need expressed to us as an area where the certification program could provide some assurance, could provide some baseline and could be something that could be built on by other programmatic needs.

The last one here I'll touch on has to do with syndromic surveillance. This is one of the exceptions here where we've actually gone back in response to feedback to revise the 2014 edition certification criterion as well as mirror a 2015 edition proposal that retains those revisions.

This would be done in order to provide greater flexibility specifically on the ambulatory side for eligible professionals that may be engaged in other activities that would allow for them to conduct syndromic surveillance but not according to the HL7 2.5.1 standard that we've adopted that they are currently limited to using for the purposes of achieving Meaningful Use.

So, this would be a way to open up the performance to this Meaningful Use menu set objective and measure through the certification process as opposed to modifications to the Meaningful Use rules. Next slide, please.

Okay, I'm not going to touch on these too directly to keep time here I know I'm probably over already. I'll just touch on this last bullet related to transmission, with the split of content and transport relative to the transitions of care certification criterion we have proposed to adopt four separate certification criteria for transmissions, so pulling the three sub-capabilities out of the current 2014 edition certification criterion and making them their own, as well as adding new certification criterion which is the Direct specification plus the implementation guide for delivery notification, which also has some relevance to CLIA compliance. Next slide.

We've also included some changes to the certification program policy overall. The first and probably one of the main or major revisions is to discontinue the use and the issuance of complete EHR certification. We're proposing to discontinue this going forward with the 2015 edition certification.

It's really outlived its intent and I should stop here and say that the rule expresses a point by point eloquent rationale for this that I'm not going to be able to do in the time allotted here, but to go over the high points, it's really outlived its original intent.

It's really served as a misnomer that's made it harder to communicate our regulatory policy and in that way the certifications as they're issued today only apply to the scope of capabilities for which certification was assessed and awarded in terms of its evaluation and not to an entire product and often I found that when a complete EHR certificate is issued, and this is more so on the provider side, the purchaser's side, there's some assumption which has to do with a communication issue on our side in choosing this approach that complete EHR was applied to the entire product including capabilities for which certification is not required or assessed. And that's again, as I mentioned, the misnomer.

We also have areas where the complete EHR definition encourages EHR technology developers to exceed the flexibility that's now provided in the certified EHR technology definition and so in this way this is a little bit of a nudge toward focusing on capability specific analyses toward the scopes of certification that might best fit different groups of eligible providers and eligible hospitals.

And finally, which I think is really the most important point here, is that it's not necessarily complete anymore. For those of you that are familiar with our base EHR definition, one component of the definition is that the eligible provider or hospital has EHR technology that's been certified to a certain minimum number of clinical quality measures and one can get a complete EHR certificate issued if the product is certified to all of the relevant certification criteria as well as a minimum number of clinical quality measures.

And so that creates an instance where, to use the inpatient setting side, I can get a complete EHR certification issued to a product if it's been certified to 16, which is the minimum number of CQMs that exist and, you know, market and sell that scope of that product as having met the complete EHR certification.

But if someone wanted to implement clinical quality measure number 21, it wouldn't be part of that complete EHR certification and so then they would ask, well if it was complete, wouldn't it have included the 21st clinical quality measures?

So, those are different discussions and potential areas of confusion going forward that I think would only continue to be exacerbated by other types of flexibilities that we would try to introduce in a certification program just to accommodate the intricacies of the complete EHR definition.

So, we've proposed going forward to remove that and discontinue its use and only have "EHR module scoped certification" which I think has a lot of benefits going forward to simplify our regulatory framework and our communications as well as the understanding of what the scope of the product certification that was issued. Next slide.

Here's another area where a visual will help. I've explained this before and I've noticed that my verbal explanation has not been as helpful as a picture. So in the overall context of discontinuing the complete EHR definition certification we've moved to a proposal where we are including a concept that there would be "MU EHR modules" as well as "Non-MU EHR modules."

And the reason for this is that, you know, focus on our broader policy perspectives, focusing on care across the continuum there are other providers for which certification and developers – for which certification is available today.

And the one thing that might be holding them back is that under our current certification policy approach, which is the kind of black dash box, the path for certification is step one demonstrate that you can perform the actual capability, the functional capability described.

And step two is if that capability supports a Meaningful Use specific percentage-based measure, then you also need to show some capabilities around calculating the percentage-based measure and our hypothesis, which we are seeking public comment on, is that requiring EHR technology developers who focus on providers that are ineligible for EHR incentives to understand the full scope and nuances of Meaningful Use policy, numerator/denominator calculations and build that into their products just to get certified through that step number 2 would be an unnecessary burden and wouldn't necessarily provide value to the specific stakeholders that don't have to meet Meaningful Use measures.

It's not to say that they couldn't go ahead and get certified as it is today but this is one area where as we look to make the certification program more extensible over time, create a regulatory structure that is accommodating of different product certifications, we wanted to be careful not to impose Meaningful Use specific certification requirements on all products when that might not necessarily be the best, in the interest of the program. So I wanted to show those kinds of two proposals and how they relate to each other and the steps that are required today and what we've proposed. Next slide.

I think I'm getting close to the end. All right, here we go, so here are a bunch of 2017 edition topics under consideration. We've included public comment requests on additional patient data collection, not to say that this would be part of a Meaningful Use policy specifically, but to say that we have gotten a lot of feedback relative to stakeholders in terms of how disability information could be collected, how US military service information through coordination with our colleagues at the VA could be collected, how work information and industry occupation data could be collected also with both VA and NIOSH at CDC, a number of other areas where greater coordination with some of our other colleagues across the department, disaster preparedness, there's a write up there where we worked with our colleagues at the Assistant Secretary for Preparedness and Response on feedback that they've gotten from emergency responders and their use and experience with electronic health records and some of the capabilities that they feel are lacking or could be improved or would really make their work more efficient and support their response to disaster preparedness.

And I think that will end the whirlwind tour that I have been allotted and probably exceeded of my time here. So, you can go to the next slide, which I think is our general, you know, stay connected slide.

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

So, Steve, thank you for a terrific report. I'm sure this is an area that has elicited a lot of interest. So let me open it to comments. John, is there anything you'd like to start with?

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

Well, I wonder, Jon Perlin, the Implementation Workgroup is going to actually do a very rigorous analysis of all of these recommendations, evaluating impact on workflow and EHR, and provider readiness and that sort of thing.

And so I know that there are many of these that we would have lots of debates about. Wes Rishel, for example, raised a very interesting impedance mismatch question. If you have two EHRs, one is certified with 2014 edition and the other with 2015 edition, can they send and receive data from each other given that criteria for certification have changed?

These are the kinds of rich comments we're going to have to capture. I would hope maybe we would take one or two general comments and then return to this at our next meeting once the Implementation Workgroup has done that thorough review.

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

I think that sounds like a perfect approach. So, the floor is open and Michelle are there any electronic hands raised?

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

Lots of them. So, Wes Rishel is the first and there are five more after that.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Okay. So I hear the message to keep it short and have almost as much difficulty as Steve has in presenting the material in that regard. I will keep it general.

First off, I want to recognize – I think we need to recognize the limits, the practical limits of certification, which is to say that certification, certainly in the area of interoperability and probably in the area of functional certification, very seldom or I could almost say never represents a level of testing necessary to provide assurance that the capability works.

There's an economic force at work in the construction of certification testing criteria that limits the amount of time that can be spent in testing on a specific product because that gets reflected in the fee that the testing bodies have to charge in order to recover their costs.

In addition, we know from recent experience that the testing needs testing, that criteria that are put out and begun in testing often have significant holes in them that need to be patched and that vendors are dealing with revisions to the testing criteria during testing and I don't know what the particular patches for dealing with revisions after testing but that must be an issue too.

I'm happy to see – I'm now going to focus mostly on interoperability testing because that's an area that I pay a lot of attention to and I see that Steve has acknowledged that there is a hole in the 2015 approach when it's a voluntary approach because there is a requirement, which is not obvious, but is there that says a 2015 edition product must be able to receive and parse and extract information from the standards that were present in the 2014 edition or in the 2015 edition they're just listed there in lists of things that are omitted with three asterisks in the publication format of the NPRM. That's an important capability, because it means that a 2015 edition product receiving a transition of care from a 2014 edition product has clearly to be certified that it can do that.

In the world where we're talking about something more than certification, some sort of assurance process that would work, we would retest EHRs that had previously been certified on C-CDA 1.1. We test them now that both 2.0 and 1.1 instead of assuming that because they were tested two years ago in a different version on 1.1 it still works. That's not likely to happen and it's one of several areas where there's a difference between certification and readiness for widespread implementation.

Steve acknowledges that the reverse transmission, when a 2015 edition product sends a transition of care to a 2014 edition product is problematic because while it's possible to write a product that can look at what's coming in and decide which parser to use and which data to capture it's not possible for something that was written with no awareness of C-CDA version 2, it's not possible to expect it to do something reasonable with that whatever it is.

So unless a fix is put into the 2015 NPRM we will be in a situation where any vendor who seeks and gets 2015 edition approval for a specific version of their product must implement it without that feature in order to be sure to be interoperable with other products and their own clients then may fail to make a Meaningful Use attestation measure using the new product. We have a fundamental problem here that has to be addressed somehow.

I would like to emphasize that there are testing procedures known that can be used that exceed the level of testing associated with certification right now and at least I know HL7 is experimenting with one such set of testing procedures.

I think that our ability to create some public resource for the vendors and other developers to freely test their implementations, not only on the happy path, but on the error path, and not only on one example of a thing but N examples of a thing. If we don't find a way somehow through policy to make that capability available to the industry, we will – we are in danger of having new versions collapse under their own weight.

Finally, I want to give Steve credit for a discussion he and I had through e-mail last week. I became aware that I was misreading the NPRM because of this issue of, there's a point where there's three asterisks and you have to go back to the old regulation, translate any changes and section numbers, and decide what goes in there in order to read the proposed regulation.

And I just kind of almost joking said “boy, wouldn't it be nice if we used basic web publishing capabilities to publish NPRMs” so that we could see the NPRM as a red line against the existing regulation and that when we had a reference, as all regulations are full of, a citation to another section of the regulation we could click on that and see what that citation was all about. I threw it out just to be ironic, but I understand, from Steve, that there are efforts going on in the government and it's consistent that this administration has been quite aggressive about making better use of the Internet.

If we can find a way, even if it costs a little more of the taxpayer's dollars to publish proposed Regs as a red line with hotspots for citations, I think we could get a lot better comments back to the NPRM. Thanks.

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

Well, thanks Wes, that's a fairly comprehensive comment and likely stands alone. I don't know, Steve, if you want to take additional questions and perhaps hit them in group if it makes sense?

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

Sure, yeah, let's, I know we're up against other parts of the agenda so why don't we make sure that everyone else can be heard as well and then if I have any, you know, closing remarks I can bottle them all together?

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

Terrific. So Michelle, why don't you go through the list?

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

Arien Malec did have his hand raised, he was next, but I think Arien, did you change your mind?

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

Thank you, no I'm still here and first of all thanks Steve and to Wes, my only obligation during this call was to drive my daughter to high school and I did that while Steve and Wes were concluding their comments.

So, there are some very laudable things in the 2015 approach or in the incremental approach, particularly errata and fixing regulatory bugs as well as fixing minor revisions to interoperability specifications, I'd mention in this regard the separation of content and transport which I think everyone acknowledges was a bug in the 2014 edition.

I think we need to hear from the Implementation Workgroup on the broader policy goals. My conclusion, observing the rate of change in this industry, is that the three-year cycles in many ways may be too fast. And I'm speaking as somebody who generally prefers more incremental approaches that the complexity of getting an entire ecosystem upgraded is high enough that the three-year cycle may in fact be too fast and we may actually not – we may suffer from trying to upgrade the ecosystem faster than that.

So it maybe that a three-year cycle while unfortunately slow is also realistic to achieve and I think it would be useful to hear – get some evidence in terms of the tolerance and ability of particularly providers as well as HIT vendors to accommodate faster cycles of upgrade.

The second major comment that I have is that I think in some areas the attempt to get additional clarity and signaling for 2017 has run against the policy making timeline and what I mean by that is that for example Health eDecisions as a possible inclusion for 2015 went out at the same time that the Policy Committee was actively debating decision-support for 2017. And it also came out at the same time, as Doug mentioned, that the S&I Framework was spitting up a new quality initiative. And I think the net effect is to make the policy actually less clear and more chaotic, and harder to read than it is to make it clear signals.

It might be more appropriate to ask for RFI-like approaches. I think that's been very successful for ONC in the past in areas where there's a desire to do regulatory signaling or probing for 2017 as opposed to putting it as proposed criteria or to clearly signal, or separate the RFI components from the regulatory components potentially as different documents.

And there are some areas in this NPRM that have policy goals that I don't believe have been clearly articulated and certainly not expressed by the Policy Committee or by the Standards Committee. And, you know, clearly ONC can address policy goals that don't come from those two bodies, but I do believe that in general, we should be asking for the community as represented through the Policy Committee and the Standards Committee to get evidence that particular policy goals need to be met.

I'll mention in this regard, the inclusion of mandatory interfaces, edge protocols for Direct that appears to be a response to a policy that EHR vendors must offer choice of their underlying HISP and I'm not aware that there's been evidence that that's been a factor for provider organizations, that they have desired in cases where that capability has been bundled that they've desired to unbundle it. And I think it would be useful in those cases to gather evidence prior to putting policy recommendations or manifesting policy recommendations as actual certification criteria. Thank you.

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

Thanks and we'll continue on. These are terrific comments. And I think work very well for Steve to have some comments at the end. So, Michelle?

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

David McCallie.

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

Yes, it's David, Wes and Arien covered most of the things I was thinking about. So I will just endorse their comments but at one minor footnote – that the – backward compatibility –

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

Hey, David, can you use a handset? You're breaking up pretty badly.

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

I'm sorry, is that any better?

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

A little bit.

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

Okay – I – just the backward compatibility question will apply to the incentive measures as well so that if the rules for what are acceptable technology changes in the middle of an incentive measurement period that has to be factored in as well and that could complicate reporting on the incentive side considerably. So, just factor that in as well. And I will take it off. Thanks.

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

Thanks, David.

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

Leslie Kelly Hall.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks and building on some of the comments earlier, I would just like to add that as we integrate the consumer into this ecosystem, we'll always have this natural tension between is there a consumer ready standard or a healthcare ready standard needing to be used or named? Is this mature in the provider area but as a standard emerging in the patient area?

And John Halamka gave us some really great direction in our patient generated health data team and work that we did and it was using a phrase "directionally appropriate." And I think that that has very strong potential to help in this new area. So we avoid some of the confusion we've seen now as we've developed the structure and standards in the provider world.

What can we do in this timeframe and in the structure that you've laid out, Steve, really well to say, when do we know something might be directionally appropriate for use but we're not yet ready to name it in a regulation. However, that directional signal provides strength for the industry to respond to, to test and to pilot that could be one option.

Another is to name on some of these new and emerging standards that have tremendous opportunity, like FHIR, like smart platform, how those might be seen as directionally appropriate for the consumer as they integrate into this ecosystem. So I'd just like us to learn from our efforts and also provide some signals without creating confusion and overburden when it's not necessary.

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

Thanks and Michelle we'll continue on down the list.

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

Andy Wiesenthal.

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

Yes, hi, I'll try to be brief, Jon. Steve thanks very much, very coherent presentation and of course everybody else's comments were much to the point.

The one concern I have in this is once we reach a steady state when we're beyond monetary incentives but practitioners are still thinking about buying systems or replacing systems, in the absence of saying something is complete, if I want to get something from my office or my department or my hospital, what's the guidance to me that helps me in a very simple way understand whether a product will meet most or all of my workflow needs? So, you know, I think we – I didn't hear in any of this the way the buyer is supposed to not beware and I'll stop there.

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

Eric Rose. Eric, if you're speaking you're on mute. Okay, I'm going to go to Dixie Baker.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Thank you, Michelle. As everybody on this call I'm sure already knows the Privacy and Security Workgroup expressed significant concern with respect to the 2014 decision to not require EHR modules to be certified against any security criteria, certification criteria and the standards. And it sounds like no change to this policy is proposed for the 2015 edition and a change is only under consideration for 2017.

I want to stress that the privacy and security certification criteria are very basic capabilities that anyone who cares at all about security would implement. And the Privacy and Security Workgroup recommended either requiring either that the module implement these capabilities or that the module implement an interface that would enable the services to be obtained from another module or external service or justify why the privacy and security requirements are not applicable to that module.

Again, I want to stress that this is very minimal. So you can expect, Steve, to receive from the Privacy and Security Workgroup the same recommendation that you received with respect to the 2014 edition and which I would add was endorsed by this Standards Committee as well.

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

Terrific and Michelle is anyone else in the queue?

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

No, no one else.

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

Okay and Eric, you've not come back online? Okay, well, absolutely terrific thoughtful comments. Let's go back to Steve for any reaction.

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

Sure, sure thanks and I'll try to take on folks. I think I appreciate everyone's comments getting a little bit of echo and I think are fair points, there's a depth and breadth that, you know, is part of this dialogue that I think is really important and the Implementation Workgroup my team will be supporting in every step along the journey. So rest assured that we will be with you trying to provide any insight and support as needed. I think the points that everyone brought up were very helpful.

To the one related to the complete EHR comment, I think it was John, if I heard the name correctly, we do have another proposal that I didn't touch on related to a concept we call "certification packages" and so those would be a shorthand way to logically group a certain set of certification criteria that could describe a particular workflow or need or purpose.

So you could see a certification package and we have these two in the rule relative to one related to care coordination which includes the transition of care certification criteria and then another "package" title related to patient engagement which includes the VDT and secure messaging if I'm not mistaken.

So we're exploring that as well as public comments to help make it easier and quicker from a communication perspective for providers in this case to understand in a more direct manner certain capabilities or purposes that they would be able to get out of or uses out of EHR technology that's been certified.

In general though we do have available in the certified HIT products list a listing of the certification criteria to which each product is certified and EHR technology developers need to disclose that information as well.

The one thing in response to Dixie's comment, I don't think it's necessary for you to reissue your recommendation. The point of including it in this rulemaking here was to provide an opportunity for the public and the industry at large to comment on the approach that was recommended. This is the first immediate vehicle that we had to implement.

I would note that we also include some data based on the certifications that have been issued thus far to the 2014 edition relative to the policy issues that we made, as of December 31st, which is when we crunched the numbers, 70% of the EHR modules had been certified to at least one of the privacy and security criteria voluntarily and 51% had been certified to four or more.

So, I think we also need to take into account the empirical evidence that we have that people are actually doing it out of the benefit that you just mentioned without the imperative from a certification policy perspective.

And there were also a number of reasons that we included in our prior rules related to regulatory burden and duplicative implementations and the enterprise as a whole and in terms of security approaches and that's not to say I disagree with your point.

And I think, you know, we included the full write up of the extent of the recommendations that were issued as well as questions relative to EHR technology developers in terms of how they would approach this from a certification perspective.

So I think we're very much interested in what the feedback may include and I would encourage the Privacy and Security Workgroup to focus on the implementation of those recommendations instead of, you know, reissuing them.

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

Great, well, thank you very much. This will still be, as John mentioned, a topic that will be threading through our conversations particularly in our next in person meeting and I imagine likely have some implications in the continuing discussion of three recommendations on the Standards Task Force activities.

So, with that as a segue, let me suggest that given that we will have additional conversation on this topic and terrific comments that were offered really suggest further discussion. Let's segue now to Dr. Halamka and review of Meaningful Use Stage 3 recommendations from the Standards Task Force. So, I'll ask John both to present and moderate this session of the agenda. John?

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

Well, thanks so much, Jon. So, just a quick review and that is the process we used was to gather a set of experts, those experts were given a set of rubrics. We also sought external experts and as we gathered votes we did stratify members of the Task Force votes versus external expert input.

So we used external experts really not to sway our vote but more or less to validate and compare as to how our internal committee and Task Force experts ranked the criteria, provider use efforts, standards, maturity and development effort for each of the 19 Meaningful Use Stage 3 recommendations. So let us dive in.

Michelle, if we go to the third slide, improving quality of care, clinical decision support. So I'm going to try for each of these slides to capture the nature of our discussion to tell you the pros, the cons and both sides and why we ranked, in a particular way, these criteria.

So, on this one the certification criteria and a review were that CDS, which was deemed actionable, would be tracked so that user actions or inactions would be stored in an audit trail and could be reported upon. You might imagine that as root cause analysis is done of an adverse event that audit trail could be helpful in understanding what was done or not done. Also as certification criteria to perform age-appropriate maximum daily dose weight calculations.

So the nature of the discussion was that the burden of tracking every decision support element that exists in an EHR and the response to it could be quite significant. The standards that would support creation of such an audit trail, the nature of having a semantically controlled vocabulary as to nature of a response, a full response, a partial response standards didn't really exist. And that the provider being forced, at every single intervention, to take an action could be burdensome.

And so there was no question that the notion of achieving good outcomes, improving quality and safety was very desirable but the nature of the discussion was, might there be a different way to achieve this and that is through incentives that were related to the measurement of quality related to an outcome rather than having a prescriptive set of decision support rules with what could be very burdensome workflow, lack of standards and significant development involved in tracking.

So, hence provider use effort ranked high, maturity of standards low, and development effort high with a suggestion, above our pay grade, that maybe we look at a policy approach rather than a technology approach to achieve this one. That's how we ranked it. I'll pause for a moment, Michelle, to see if there are others who would offer feedback on the CDS Meaningful Use Stage 3 element?

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

It's David.

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

Dave McCallie has a comment.

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

Yes, David, please?

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

Yeah, John, I totally agree with your recommendations. I'm sorry we've got such a bad connection. I think it would be extremely difficult to implement. And it would fly in the face of our attempt to make decision support less intrusive. Focus on the outcome not the process.

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

Thank you. Other comments? Okay, well, Michelle let me – of course we are going to have multiple discussions of these over multiple meetings but let me move onto the next one. Slide four, improving quality of care and safety order tracking.

So the challenge with this one is that it mixes and matches many different workflows in a single criteria. So on the one hand it suggests for a laboratory or diagnostic that a display should have an abnormal flag and that certainly seems very reasonable. But it also suggests that the same criteria might be usable for closed loop consult workflow from PCP to specialist and back.

And so hence the notion of notification when some action has not been available or completed, date and time of closed loop between an initiation of a referral, a response to the referral, etcetera and of course matching of the patient and the events across conceivably disparate electronic health records in different practices and different locations.

So in effect, I'll go through the grades in a moment, but we said if you constrain this one to something like a laboratory such that an order would be resulted and then there would be capture as to whether or not that result was acknowledged that such a constrained closed loop order set of events would be a whole lot more mature and easier to implement than a more global one of what might be multidisciplinary, not standard supported workflows between PCP and specialists.

So at the moment, depending on how you look at this, whether it's the lab or whether it's the specialty referral, the provider use effort would be medium. But standards maturity for such things as all of the steps involved in closed loop referral tracking quite low.

Harvard actually have a multidisciplinary group look at all the workflow involved and found 11 discrete steps in transitions in closed loop referral tracking that need to be supported and therefore development effort depending on how you phrase this one could be quite high.

And so our suggestion, again a little bit above our pay grade, is maybe constrain this to the lab use case and then we would be able to give grades that were more positive and supportive. Again, let me open it up to the group for comments. Well, Michelle, I trust no hands are raised?

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

No hands raised.

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

Okay. Well, thank you. Let us now move onto demographics and patient information. So the notion that we would capture, in certification in an EHR, the patient preferred method of communication, occupation and industry codes, sexual orientation, gender identity, disability status and that the end result of communication preferences would be applied to visit summary reminders and patient education.

So here we have an interesting quandary that there are some controlled vocabularies like occupation and industry codes which are well described. Sexual orientation and gender identity there is a rich literature, I would call this very much emerging of not so much categorical sexual orientation and gender identity but a set of questions that a registration clerk or clinician would ask of the patient and then record answers to questions, the answers of which really give us more complete knowledge of the patient's sexual orientation and gender identity which then might have implications in decision support, patient educational materials or other parts of the EHR.

And of course communication preferences, we imagine would be constrained to those technologies which are supported by the institution or doctor. It might include such things as a patient portal, secure e-mail, phone call, but might not enumerate Twitter, Facebook and Instagram though those might be a preference, they wouldn't be supported.

So, with that as a preamble, we thought provider use effort here, again, depending on the implication of the demographic gathered, could impact the provider workflow in the presentation of educational material or the way in which a doctor might order or execute based on patient preferences.

Where the maturity could be high on occupation and industry codes, but evolving on these others and therefore development efforts could be medium if all we're doing is gathering the answers to questions but could be very high if what we needed to do was modify a variety of other elements of the EHR.

You could imagine for example all the places in EHR where administrative gender might be used for patient identification, decision support, patient educational materials, etcetera, and if every one of those places had to be altered based on patients answering questions about gender identity that could certainly be a significant amount of development effort. So again, let me open it up to comments and questions.

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

Eric Rose has a comment.

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

Yes, please, Eric?

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

Okay, I'm having some audio problems, can you hear me now?

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

We can hear you now.

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

Yeah, John, I think your comments on this one are right on the money. The other thing that occurs to me is that this might actually have essentially a punitive effect on EHR vendors that have sort of gone above and beyond in terms of representing this data in a way that's meaningful and applicable to healthcare and consistent with emerging best practices in terms of for instance identifying sexual orientation, not as a unified data element, but by just a question of, you know, whom have you had sex with and what are their genders and so forth?

And so what would concern me is that EHR vendors might actually have to dumb down the functionality they have for capturing kind of the rich tapestry of information that's inherent in these seemingly simple data elements and so there ought to be – the requirements ought to be able – ought to allow for that, by for instance requiring that the system be able to output some kind of synthesis of data that might be captured in a more granular or nuanced level.

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

Great, well, thank you very much for that comment. And I did review the literature on sexual orientation, gender identity standards and I did forward to ONC an important paper in this regard. So, Michelle, you know, as we have further discussion, I think capturing this notion that Eric mentioned that it is really not categorical.

You know there are many questions that could be asked of the patient and many ways to ensure across the care team that we appropriately communicate sexual orientation and gender identity and this may be one where being too prescriptive on certification could do a disservice to those impacted.

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

Thank you.

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

So let us move on now to advance directive. This one I think could be very not controversial. Yay! Where if the intent of the Policy Committee is to use in effect a checkbox and a URL was an advance directive captured, if so, here is a link to something. It could be a scanned document, it could be, you know, a free text, it could be, you know, some sort of media that recorded a conversation, all kinds of things.

So what we suggest is that the EHR captures a “yes/no” state and a pointer to something. Then we would call the provider use effort low, the standards maturity of a checkbox and a URL high and development effort low.

However, we know that there’s huge state variation as to what constitutes the appropriate structured data capture around advance directives and patient preferences for care and that the C-CDA, you know, at the moment does not have highly structured mechanisms for capturing this in a uniform way that might be acceptable to all state regulators.

So if, by chance, the Policy Committee meant use C-CDA to transmit structured advance directives that could be parsable in systems that receive them, you know, then that would be a very different evaluation.

So for the moment, we have constrained this problem and call it high maturity, low effort. Comments?

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

David McCallie.

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

It’s David.

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

Yes, David?

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

I like the simplicity of the model. I just would point out the trust issues around that URL are nontrivial but it’s something we need to solve anyway.

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

Right, you know, absolutely certain to ensure that both the document is non-repudiable, digitally signed, accessible through a secure means, etcetera, that’s a very good point.

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

Yeah, that’s hard.

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

Yeah. Other comments? Okay, well, let us move onto electronic notes. So electronic notes, this one thankfully was revised by the Policy Committee because it used to include the notion of what I'm going to call edit track changes and a complete journaling of every change made to every note by every person. And at this point it does not include such criteria. The specific criteria are that there is a note authored by an eligible professional and that the note should be text searchable.

Michelle, I know there was a question here as to whether or not the intent of the Policy Committee was to search across all notes by patient as opposed to search within a note which already is a Stage 1 and 2 capability. Do you have any comments on that?

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

This is Michelle. No I haven't shared this back with the Policy Committee yet but the question is still included and we'll bring it back to them.

John Houston, JD – Vice President – University of Pittsburgh Medical Center – NCVHS

Thank you. So with this one, the fact that there may need to be novel workflows that may very well be that hospitals do have hybrid technologies using electronic systems for ordering, problem lists, medication management, but handwritten notes could impose a new burden on providers. We do have to recognize that.

The standards maturity question here was what is the nature of the note? Is it pure free text? Is it a combination of structure and non-structure? Is it supposed to be incorporated in transition of care summaries and other exports from the EHR now that it is available? And then this question I raise about capacity to search across multiple notes within a patient throughout the EHR.

So the standard maturity here again could be graded in a couple of different ways and certainly would be medium if what you wanted was a combination of structured and unstructured text and conceivably, as is mentioned in the development effort, if this now needs to be incorporated in all C-CDA transition of care documents, that could propose a development burden. So we would rank that high dependent on the intent of this one.

The last thing I will just mention is that Liz Johnson highlighted that the threshold on this one is listed as high. Meaning that as Meaningful Use criteria go, this might be stated as a 50% threshold. So going from zero to 50% with the very first suggestion of this as a criteria did certainly seem like a very substantial change that might be hard to implement rapidly.

So let me open it up to the floor. Any questions of folks or comments? Okay. Well, I think Michelle, we must have stunned them. Let us move on then to hospital labs.

Hospital labs, we know that in this country that our commercial laboratory providers such as LabCorp and Quest have adopted LOINC codes very significantly and they are in the business as reference labs of providing results electronically to EHRs using controlled vocabularies.

However, a very significant number of laboratories have used small hospitals serving as reference laboratories for communities. And the concern of the Task Force was that the adoption of LOINC in small hospital reference laboratories was not as high as in our commercial reference laboratories.

So I don't there's a lot of question that HL7 2.5.1 laboratory results using the LRI implementation guide has high maturity, the development effort however, conceivably to make sure that LOINC is embedded in all hospital information systems and implemented could be high.

Now, Arien Malec was given the homework assignment of trying to do some investigation based on his vendor experience with hospital labs and Arien any comment you would make on what you might have found so far?

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

I apologize, I am behind on my homework assignment.

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

No problem. So, that is the only concern we raised, not about standards maturity and certainly not about our commercial laboratory development readiness. So comments on this one?

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

Dixie has a comment.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, I have a comment.

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

I'm sorry, was there a comment?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes, I have a comment, this is Dixie.

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

Yes, please, Dixie?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I have my hand – okay. I just wanted to point out that your center column, your standards maturity, the maturity was just one dimension of the two that the NWHIN Power Team used to judge readiness, one was maturity and one was implement ability.

So, number one I think that center should be readiness instead of maturity. But I think that this is a good example of where you would say readiness would be low in fact. Standards readiness would be low because of the lack of its really broad use.

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

Right and so you're absolutely correct in the notion that when we look at maturity we tried to use the criteria you had outlined as to, is there a well understood implementation guide, has it been deployed in the field in meaningful ways to be volume and scale and those kinds of things.

So, in a funny way, you're right and in this one, pending Arien's analysis, we might find that maturity is high because of the well understood nature of LOINC and the LRI implementation spec, but readiness among our hospitals, especially community hospital systems, could be low. So your point is well taken.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Is that the same as development effort or – I'm kind of confused because you've just, you know, captured just one dimension of the readiness.

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

Right, so in effect, we corrected for that oversight by looking at development effort and saying that for our community hospitals to implement this mature standard would be high.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay, thank you.

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

Sure, okay, well, let us move on to the universal device identifier. We all –

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

John?

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

Yes, please?

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

John, I'm sorry, Eric Rose had a comment.

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

Oh, yes, Eric, please go ahead?

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

Oh, yeah, sorry, real quick on the hospital lab one, if that's referring to the entire implementation specification, the other thing to call out on that is that it requires or actually it's unclear to me whether it requires or simply requests that the result values themselves be coded in SNOMED including organisms.

And it's worth calling out that this is – I think would be quite a bit of work for hospitals to take what may be thousands of organism terms and start associating SNOMED organism concept ideas with them.

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

Very good, so –

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

And John, this is Liz, is that what you think is implied? Because, you're absolutely right that would be a huge amount of work. I don't think we talked about that in the Standards Workgroup.

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

Yeah, we did not and so this one Michelle is probably again good for us to clarify with Policy Committee intent is that our discussion was really limited to the LRI spec and LOINC encoding not specifically SNOMED encoding...okay, let us move onto UDI.

And so UDI, there was no question among the Task Force discussions that the idea of capturing a unique device identifier for patients with implanted devices seemed like a very noble goal. Again, we look at scope on this one and we asked the question, if the idea is a free text field will be made available that a physician would hand type a universal or unique device identifier into a free text field and it would sit statically in the record, the development effort to create one new free text field is low, but the utility of that would also be low.

And one wonders, again as one looks at policy intent and desired workflow, you know, might there be something additionally clarified like that should be searchable across the entire population of patients so that a cohort could be identified in the event of device defect or recall and action could be taken. Should there be some mechanism of checking the integrity of that UDI against an external database to validate that it is not a missed typed UDI or something of that nature?

So, again, depending on this one scoped, a physician typing a UDI, effort is low. The UDI specification is well described, but Dixie to your comments about maturity, has not been widely deployed in the field, in actual products and software, and the development effort could be low to high depending on the nature of workflow that is desired once UDI is recorded. Comments on this one?

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

Leslie Kelly Hall has a comment.

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

Yes, Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, John, one of the use cases that was discussed was the UDI availability to a patient who has had an implantable device now knowing what that product number and that specific unit could be. So, in the case of future recall or issues they had that information and actually potentially making that available in VDT at the end of a surgical event.

So the use case wasn't just strictly around the provider, but how we could help with safety issues for consumers and patients.

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

Correct, I think that's very well taken. Thank you. Any other comments on UDI?

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

Andy Wiesenthal has a comment.

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

Yes, Andy, go ahead?

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

Just a brief one, John, there is actually the confluence of two things that may be helpful here, one is if 2-D bar coding is really on our roadmap that would be extremely helpful because device manufacturers I think along with pharmaceutical companies are actually ready to embrace incorporation of that on the external packaging as well as on the devices themselves.

And the second thing is that there is a global medical device nomenclature that's being incorporated and harmonize with SNOMED CT so that as you implement SNOMED CT you will actually have the GMDM in your software or at least as a service to your software.

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

Great, well, thank you and I should mention as we go through each of these, you know, there are areas of passion and this particular UDI item has many passionate supporters at the FDA which would like to really see their good work on standards be implemented in products and to help patients and to help with recall.

So, I just – as we go through these you'll see another area of passion will be public health. And I'll just highlight that because sometimes as we as a committee debate technology we may not fully appreciate the community that is behind that technology. So thanks very much, Andy. So moving on.

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

John, Wes also had a comment.

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

Oh, yes, go ahead?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

John, I wanted to be sure I understood what you meant by talking about validating the UDI. Are you talking about validating its form such as a check digit or some other form of redundancy in its form? Are you talking about validating that this specific number has in fact been issued already through some sort of master service that tracks all UDI instances?

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

And it's exactly those kinds of issues we raised. We didn't specify which ones. So, if it's a free text field with zero error checking as to the length of the string, a check digit computation, a going out to an external service, as Andy Wiesenthal suggested, a look up against GMDN, you know, something you would then worry that if a recall occurred you wouldn't discover a patient who had such a number because it had simply been mistyped.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Right.

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

The development effort could be certainly more than low depending on the nature of what that validation might be.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

I got it. So it wasn't necessarily high?

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

Right.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

It was unknown, but potentially high?

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

Right.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Got it, thank you.

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

Let us then move onto view, download, transmit. And so this of course, we have view, download, transmit in Stage 2 already but the changes to this one that the information would be available to patients within 24 hours if generated during the course of a visit.

And the information for VDT would include potentially items like labs that would not be immediately available upon discharge and those were four days availability rather than 24 hours availability and that added to it as a new criteria were family history to be available.

So our comments here were that depending on the nature of the workflow you might actually need a physician or care team member to generate information using a novel workflow that is currently not in place today to hit that 24 hour VDT criteria and so conceivably, you could have provider use effort high.

And I'll give you an example there, that as discharge summaries are developed at Beth Israel Deaconess we actually have two kinds of discharge summaries. One which is to be made available to patients and families immediately that nurses, doctors, social workers, pharmacists, everyone contributes to this patient friendly kind of summary but then the actual formal discharge summary may sometimes be even a week or two away by the time that it's dictated, edited, signed off, etcetera. So, there may be some workflow implications there.

And the standards maturity if you're talking about C-CDA we know is pretty good, but if structured family history, and that could be either the HL7 pedigree or SNOMED CT structured history, that's still a bit of a work in process and if you needed that incorporated into VDT as family history the standards maturity would be low.

And then development effort, to the point I was making about operational issues, you could see developers creating whole new kinds of discharge Apps to get the data in a more timely fashion to that 24 hour timeline. So we ranked that one as medium. So let me open up to the floor on comments?

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

Jamie Ferguson has a comment.

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

Yes, Jamie?

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

Yes, hi, John. So, the day before yesterday, I spent the day in our Los Angeles Regional Reference Lab and they report over 50,000 test results per day every day. So, it's a pretty big comprehensive lab and I unexpectedly got a real earful from the lab director on this timing requirement and the burden on clinicians who ordered tests.

And the issue is that the folks who ordered tests may be required by state law to contact patients and discuss the results with them before releasing the – before the lab can release the report. And so, you know, the idea is that while this is a low threshold item and the low threshold may work on average over large numbers but it may still place an undue burden on individual providers where, you know, these state requirements may apply to a higher percentage of their patients.

So, I think that, you know, it's possible perhaps without changing the policy that this could be addressed in the standards if any specific test results that had these conflicting jurisdictional requirements for patient contact and notification could be excluded from the standard. But, I don't what you think of that.

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

Yeah and so a very good point because although CLIA has been modified to allow the direct transmission of data to patients without necessarily provider review or approval there are state laws that as you – HIV testing for one, you know, you might have viral load or other things for which the workflows maybe much more complicated.

And so I think that's sort of an interesting Steve Posnack issue of how do we try to adhere to the policy spirit but recognize that time limitations on complex workflows may not be implementable in accordance with certain state regulations?

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

Yeah, John, this is Liz, the other thing we may need to think about and Dixie would certainly be the expert, is how we deal with minors and pregnancy tests and that sort of thing because we're fighting that now.

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

Right.

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

Just to make life more complicated.

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

Exactly, well very good comments. Okay, well patient generated health data. So one of the challenges that all of us have is whenever we create a certification rule we sometimes, because we know standards are evolving and workflows are heterogeneous like to put in the word “or” you could do it this way or that way.

And as Arien and Dave McCallie and others will remind us, every time we say “or” to the vendor we mean “and” that two totally separate sets of software, two totally separate workflows need to be created because the certification must demonstrate both.

So, here with the patient generated healthcare data there are two options that a structured or semi-structured questionnaire such as screening sheet or medication adherence survey, a form would be delivered to the patient and then given back to the provider for incorporation into the EHR or a secure messaging mechanism would, in effect a free text blob, might be sent back to the provider as a patient responds in effect via secure e-mail or message kind of infrastructure.

So the nature of how this would be done has different workflow implications for the provider in terms of receiving the message, incorporating the message, acting on the message and although, we know, things like C-CDA do have templates that might include a text blob, the idea of having completely structured query and response is something that S&I Framework is actively pursuing per Doug’s presentation earlier today.

So, based on the fact that we have a couple of different workflows and the standards are at various levels of maturity we graded this as provider use high and maturity low, and development effort to implement both strategies and then figuring out how to incorporate either structured or unstructured data into the EHR and act on it could be significantly high for developers, but we love patient generated healthcare data that wasn’t the question. So, comments folks would make?

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

Yeah, this is David again.

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

David McCallie –

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

So, yeah, I heard David and I think I heard Leslie. But please go ahead David?

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

Yes, this is one where I think we should focus on the outcome and less on the process. I don’t think it’s an interoperability issue here because a particular provider could choose to enter a – to capture that data from his or her patients in whatever mechanism works best for his particular tools and the incentive should be the fact that he captured it rather than that he used a particular technology to do it.

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

And so David’s comment would be very similar to what we said about CDS which is let’s achieve a policy goal and that actually might be through a P for P or merit-based program as opposed to being very descriptive as to how it’s done. And I bet Jamie, you know, given that Kaiser has such a rich patient engagement strategy, you might make somewhat similar comments?

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

Yes.

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

And Leslie Kelly Hall, I think that was your voice?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, thanks. So, I would add to it when we did the work on the team we talked about for the use case that is not part of the tethered PHR, like someone coming in with maybe a third-party PHR or collaborative care product and that having named standards like the Consolidated CDA that we went forward with and maybe Direct for transport that those things were directionally appropriate.

And this comes back to my earlier question. How do we distinguish or provide things that can give good directional signals that may be for industries that sits out of direct HIT but can be interoperable and integrated and to promote the patient's adoption of patient generated health data as well as integration into the ecosystem?

So, how do we accommodate that? Because, in this case it's the recommendations we put forward for the untethered system are considered mature enough in the provider world for Regs, but emerging and not yet used in some cases on the consumer side.

So we want to make sure we're not in a situation where we continually promote a chicken and the egg for patients integrating into the ecosystem and promote third-party Apps that can start to enter into this world and provide very good and meaningful use of HIT in nontraditional ways.

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

So let me echo what Leslie has said and align it with what Jamie has said in the past which is that if you have in effect it's not a PHR an EHR but a fully integrated shared record that doctors and patients can use that the idea of having a very prescriptive means of how to communicate patient generated data may not make sense.

But if you had loosely coupled, I have an App on my iPhone and I want to get that data to an EHR, there may be some statement made about how to be able to receive such transmissions.

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

This is –

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

But we have to be careful with the descriptive nature of this as opposed to the outcome. Was there another comment?

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

Hi, this is Stan Huff, I can't connect to the WebEx so I can't raise my hand, but I'd like to make a comment if it's possible?

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

Please, Stan?

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

I just want to echo what many I think have said or implied. I like the fact that we're questioning or at least trying to clarify some of these items and that – I mean, what's in my mind is really the approach I'd like to see for all of these is that we focus on measuring outcomes and we ask people to adhere to standards.

And all of the things that are invasive in terms of workflow and other things are things that are left at the discretion of implementers. I mean, as a – not specifically to this, but almost every one of these items that we're reviewing I can just see a number of unintended consequences that could arise because these things haven't been done in real working systems and their impact on workflows are not known and the ways they might be interpreted in the certification – I mean I really am in trepidation about what this could mean in terms of stifling other better innovative ways of doing these things and we're locked into a highly prescriptive way that people have envisioned.

And so I really, in the strongest way would say, I hope we can move towards a position where we're requiring, in this case have a way of measuring an outcome of whether, you know, we've been able to create patient data and incorporate it in the system without being prescriptive about how that happens or maybe even knowing whether that's a more important activity than other things that we should be doing for the patient and doing this thing would take, you know, time away from that.

So that's a general comment and I apologize for getting on a soapbox, but I just – I'm almost terrified of the impact that a lot of these things could have because we're being so prescriptive about the workflow and the implementation and the discretion that system developers should have but won't have.

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

All right, well, thank you very much and in fact your theme will actually be exactly what we are discussing in the next element, secure messaging which is, you know, Stan, to your comment, in secure messaging, there are a set of certification criteria that delineate precisely and prescriptively how secure messaging between clinicians, patients and families should work.

It specifically states the capability to indicate whether a patient is expecting a response or not and the capability of tracking a response to a patient message, no response, secure message reply, telephone reply. Now we look across our communities and Kaiser has implemented a set of workflows.

Beth Israel Deaconess has implemented a set of workflows. RelayHealth has implemented a set of workflows. Some of us have been doing this for 20 years and have achieved a level of maturity and patient/clinician communications, which is quite high and very satisfactory.

And in fact, being too prescriptive, as this one seems to be, could actually quash innovation and force us to reengineer and reverse systems that work quite well today.

And so in this theme of what Stan has suggested on secure messaging what we have said is if you're going to be prescriptive you're not really going to be dealing with any mature standards around closed loop messaging with feedback and somehow a vocabulary that delineates where in the hole closed loop messaging process a message may sit. The development effort would be high but the industry already has implemented solutions that work well so let us be extraordinarily supportive of the concept but remove the prescriptive specificity.

So comments in general on secure messaging that just have built upon the comment that Stan made on patient generated health data?

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

John, this is Michelle, Dixie did have a comment about patient generated health data. I'm not sure if she's still on.

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

Oh, yes, please go ahead, Dixie?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

No, Stan said it way more clearly than I would have. So, I agree with Stan completely.

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

Great. Comments on secure messaging?

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

David McCallie.

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

Yes, David? Can you hear us David? I think we've lost David. So let us move on to visit summary/clinical summary. So the wording change in this one which we found particularly problematic is that office visit summaries to patients or patient authorized representatives would include relevant actionable information and instructions pertaining to the visit in the form media preferred by the patient and that EHRs would be completely configurable so that the summary data would be relevant and actionable that was admitted from a visit.

Our challenge was none of us on the Task Force could define the terms relevant and actionable in a way that would be certifiable or measurable. And so hence, the provider effort at least would be medium. The standards maturity is low because there is no definition for actionable in a standard. And the usability is not something that has ever been standardized. And the development effort could be quite high for two reasons. One, providing a user configurable screen where the user would be able to decide on the data elements that were relevant and actionable to a given situation, as well as, it's not just a form of communication, it could be media that is presented to the patient.

Our recommendation is maybe, since we have an existent patient delivery mechanism, VDT, that if we did implement this that we use VDT and somehow we need to, as Stan and others have said in the last two, adhere to the spirit as opposed to prescriptively describe what is relevant and actionable. So, I'll open it up to comments? Okay.

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

Jeremy Delinsky has a comment.

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

Yes, please go ahead?

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

This is one where we continue to get a tremendous amount of feedback from our providers about the utility of these summaries, questions about the content that should be there, strong feelings about the content that should be there.

And I wonder if this is an area where it would best be informed by sort of listening to the market and asking sort of – understanding whether there are problems from the patient perspective about what they're getting, but trying – I'm struggling with this one a little bit on the problem that we're trying to solve because I think that the behavior change has happened in the market where providers are doing this over sort of lots of heartache.

But I don't know the gap between what we've already done and what would be helpful for patients and it's hard to think about – I think as you pointed out how to take these sort of objectives and turn them into things that are measurable and that you can build standards around without knowing what the problem is that we're trying to solve for here.

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

Right and you wonder if there are other market mechanisms to correct for this such as patient feedback, patient satisfaction scores, likelihood to refer all those other sorts of things.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.
That's right.

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

You know, all those other sorts of things.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.
That's right.

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

This is Nancy Orvis from DoD I have a comment when able, a question on this one.

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

Yes, Nancy go ahead.

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

I have had personal experience in the last month from having a sports injury in Colorado and then coming back with actionable information to give a new consultant for a ski injury and to me it seems what we need actionable in that summary is are there clear patient instructions or next steps, or is there a particular summary direction that the patient is to follow orders to give to another doctor? That's what I think is what is actionable and clear.

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

Right, so well stated and again this gets into a question of policy versus technology which is how would we certify that or measure it and so it's sort of we hope that as others have said that we adhere to a spirit of a policy.

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

Well, I mean, it's a legal obligation like from an emergency room visit that there are patient instructions given to the patient am I correct on that? That's my – that's my understanding on how I've see, it's always been an emergency room is obligated to give a patient, patient instructions. It's never been clear on a normal outpatient encounter that that's true.

So I ask that same question. Are there clear instructions for a physical therapist where I'm working on my knee? What do I do before the next visit? It's always verbal but it's never written, hardly ever written unless I insist on it.

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

So, I wonder if, as we follow up on this, we ask if Steve Posnack could find, are there other existent regulations that describe, as you point out, that for a kind of encounter, instructions may be given? Is there some language that we could lift that would be a little bit less prescriptive?

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

Right and less amorphous, right.

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

Yeah, okay, so let us move onto patient education. The one element of this one that's novel is that EHRs have the capability for the provider to give patients education materials in at least one non-English language.

And sort of two concerns about this is we weren't quite certain, and maybe Leslie you could research this for us, if InfoButton currently include a parameter for language of patient's preference –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

So that if all you had to do was take existent InfoButton and include a parameter, maybe the standards maturity was reasonably high or if it was just a small tweaked InfoButton then it would be medium.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's actually very –

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

But we do –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's actually in there John you have both the provider language and the patient language so the provider can select education in English and have an output in Spanish or another language for the patient.

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

So, this one, you know, and probably, as you say, it's in the standard and probably not widely implemented yet, but, you know, certainly is getting – it would definitely be a standards maturity of high to medium somewhere.

But the development effort, we wonder is that – Beth Israel Deaconess for example has 37 languages commonly used within our institution. If one certifies that one Non-English-speaking language is offered as an alternative in an EHR, is ultimately that going to accomplish a policy goal or really be helpful to our patients?

I mean, maybe the certification criteria is I can do English and Spanish but I happen to be in an area where there's little Spanish spoken. Is that a certified EHR that's useful in my community? Does it achieve a goal?

So, development effort depending on how you support this, where you support it in EHR could be medium to high and we would just seek Policy Committee clarity on really what is the intent here? Other comments? Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

John, I can add to that, this is Leslie, I can just add to that a little bit, it's currently the language is offered out of NLM and others, there are other languages. It is a pretty high use case. When discussing do we name a specific language and policy that was a harder thing to gather because of your points exactly.

In Wisconsin, there's a high degree of Hmong for instance and in Seattle we might have a lot of Cantonese and so there was a discussion about how do you name those languages and potentially is it starting an effort where another language is recognized and then moving beyond that, could that be useful?

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

Right.

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

So, John, this is Andy. One of the things that might come out of the EU/US Cooperation is that there's lots and lots of translation efforts going on in the EU. And I don't know that the United States has to invent the translations for all of these things.

So I'm not suggesting that the standards effort might still not be high depending on how the InfoButton actually works, but that documents could be translated by real native speakers in other countries and be again available to US consumers as a service rather than us having to have a library in every EHR of every language.

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

Very good point. So I think what we have on this one is just it needs some further discussion on the policy side and then probably a restatement. So, next one is summary of care and this is of course transition of care and the kinds of transitions of care from PCP to specialist, from hospital to SNF, consult request back to PCP.

This one was stated as they're actually data elements that can be at the discretion of provider. However, a narrative synopsis expectation, results of a consult is required. Other elements would be optional. And then there was a clarification from the Policy Committee that structured data is very helpful but free text is completely acceptable.

So the question here is, C-CDA, choose an appropriate template, ensure what is incorporated into that template is either structured, semi-structured or unstructured, that it is a representation of that narrative the standards maturity would be medium. I mean, it's described in the template, just not widely used in production today.

And the development effort could be medium if all you're doing is taking an existent blob from a fully dictated note that is going to be resulting in the EHR anyway and putting it into C-CDA or it could be high if you had workflow changes that required more timely interaction and required maybe a capsule summary to be written in a novel way and a novel application that then would go in the C-CDA off to a recipient.

So, you see it's probably high impact on providers, standards maturity medium and then development could be medium to high. Any comments on that?

Okay, well, let's move onto notifications, this one is entirely new and specifically requires that arrival at emergency department, admission to a hospital, discharge from an ED or death be sent to a next provider of care, a care team member, could be sent to a place where it's the, you know, patient's caregiver and patient consent, etcetera.

Our comments on this is the HL7 2.5.1 A03, A04, A08, you know, all the various kinds of A-messages are actually quite mature, but the notion of capturing at registration or other part of the workflow who are the designated care team members and their Direct addresses and where is consent given and what should be sent to whom and what circumstance there are very poor standards for capturing care team structured Direct addresses at the moment and so the development effort of this one would be quite high and it's a totally novel set of workflows not on the HL7 and ADT kinds of messages, but on the delivery of this notification to an end-point where currently no such workflow exists. So, comments on this one?

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

This is David.

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

Yes?

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

Trying again, hopefully on a better connection, I think your comments are good. I think a fair amount of this kind of activity already occurs in notification of like admissions to the hospital being sent out to the physician's office, but its ad hoc in every case and there aren't any standards to govern it as you point out. It's not the message that's the problem it's knowing who to send it to is the problem.

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

Very well stated. Any other comments? Okay, well we're –

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

–

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

Yes, was that a comment?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, this is Dixie, I wasn't back at my holding – holding my arm up. In general, you know, a lot of our comments here and a lot of my thoughts have to do with being less prescriptive. Is there a requirement somewhere that every one of these Meaningful Use measures must be incorporated into certified EHRs or can you have a Meaningful Use measure that isn't implemented necessarily in the certified EHR?

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

And so, for example, I mean, as Steve Posnack has told us, you might have a certified EHR that isn't used for Meaningful Use and therefore the restructuring of the NPRM is to allow you to sort of pick and choose what criteria might be certified to give you the comfort that the function exists but not to attest to Meaningful Use. So, there is sort of a decoupling between Meaningful Use and function.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

And certification, I mean, because they have – it seems to me the having – in order to get the incentive payment you have to have a certified EHR, okay, they have that, plus you have a Meaningful Use – has met the Meaningful Use measures, but I don't think I've ever seen where it says every single one of the Meaningful Use measures must be implemented in the certified EHRs. I have never seen that written.

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

And, so, it is true that when I did certification for Beth Israel Deaconess there were a variety of menu set Meaningful Use requirements for which I did not certify functionality because I never had the intent to attest to such functionality.

So, yes, you'd be correct that it is quite fine to achieve attestation and not have every single potential menu set function certified in the EHR.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right, well, some – a lot of these that we're discussing today are of that nature that we keep – I keep hearing us say, they're being too prescriptive by putting this directly in the EHR just like David just pointed out, doctors do this in other ways besides using their EHRs.

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

Right.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

And I think that's a general acknowledgment and maybe even a general statement that your Task Force might want to make, that, you know, don't be overly prescriptive.

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

That's a very good point. Well, we are running short on time and I'll tell you in the remaining slides there's actually only one that has any controversy. So, let me just tell you the next slide, which is medication reconciliation is actually already a Stage 2 criteria. There is nothing new. There is no new standards and there is no development effort. So, there is nothing to discuss there it is already Stage 2.

This next one, immunization history I want to very thoughtfully discuss, reflect on the input we've received and seek comment from those on the phone. The notion here is that an EHR should be able to receive and present a set of standard structured, externally generated immunization records and capture the act and date of the review of them within an eligible professional or eligible hospital practice and as well, through some mechanism, be able to receive the results of externally generated clinical decision support related to the patient immunization.

Our comments were we certainly believe the HL7 2.5.1 message that the CDC has enumerated in its implementation guide, for the last couple of years, is actually very well described and used by many in production. The CBX vocabulary for vaccinations well described in Meaningful Use Stage 1 criteria absolutely used in production.

Where I think there is lack of consensus, but there is much passion, is on the transport mechanism that is used to deliver the package of an immunization's history being given to an immunization registry and to be able to do query response of that immunization registry to incorporate a result into the EHR.

So, there is no question that the CDC has created a SOAP-based implementation guide that as of 2011 very clearly described a WSDL and a query response mechanism it's all SOAP-based and it has been piloted in many sites, a couple of dozen sites.

However, what many vendors have told me, and again, would welcome comments from Eric, from Arien, from David, as they go to implement immunization transactions in their locality that there seems to be great heterogeneity among public health organizations at the transport level.

Some want FTP, some want REST, some want SOAP, some do Direct and that Stage 1 and 2 did not attempt to restrict transport, even though there are all these implementation guides that are SOAP-based because of heterogeneity in practice.

And it is purely because of that experience that a number of us have had of the heterogeneity that we declared the standards maturity, you know, again, Dixie, to your point, the implementation guides exist and are very well described and are well piloted but there just seems to be this heterogeneity of the way that the standards are used in the field and therefore the development effort on this one could be high if we did decide that every EHR had to use the CDC's SOAP implementation guide as opposed to Direct it would require the developers to have two kinds of transport, one for transitions of care, one for submission to registries and then a SOAP-based approach for query response.

So, again, not trying to provide any adjudication here just trying to reflect the conversation that we had and a lot of the very passionate input we've had from the public health community. So, open it up to your discussion?

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

Arien has a comment.

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

Yes, Arien?

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

Thank you, yes, I served on the CDC Task Force that selected that particular transport and at the time there is the Wisconsin Immunization Registry that's actually used by a number of states and I believe that the vendors behind the Wisconsin Immunization Registry were the "were" were planning on supporting that specification, but I'm not sure of the exact state of it, but there are very clearly a significant plurality that do not use that. And so you're absolutely correct there is huge variability in terms of support.

In terms of why SOAP was ultimately selected the concern was that for an immunization submission use case Direct is perfectly appropriate, for a query response use case and in particular for a more real-time query response use case where you wanted to look up the immunization registry at point of care the thought at the time was that Direct would not be sufficient for that use case, you could do two pushes, but there would be some degree of latency associated with it. So, I just want to provide some context there. I would agree with all the rest of your comments.

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

Right and in fact that was in our letters, the comment which said, okay, if you said Direct was going to be used for the submission of data to registries the problem then is that it would not be sufficient for query response so you would then be creating two standards anyway, so why not just do SOAP for everything related to public health.

Now we could get very edgy as a committee and say, well, we like Direct a lot and we actually think SOAP is appropriate but wouldn't REST, as we look forward to 2017, actually meet everybody's needs for every use case?

There has been a lot of discussion in Dixie's committee about the use of REST for health in combination with OAuth or OpenID for use in both push and pull real-time query response kinds of approaches.

So, I mean, this is an issue we're probably not going to solve today, but I certainly, thank you Arien for your comments and context.

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

You would also, just as a follow-up to that you would also imagine which way I voted on that particular case, the thought at the time was that EHR vendors were more comfortable in a SOAP-based approach then in a REST-based approach, that may or may not have changed.

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

Yes. Other comments?

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

Eric Rose.

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

Hi –

John Houston, JD – Vice President – University of Pittsburgh Medical Center – NCVHS

Yes, Eric?

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

Hi, this is Eric, yeah, I know your question was regarding the transport standards, my comment is actually about the terminology implications because transport standards I'm certainly not an expert in, but I think it's worth calling out that there is a terminology wrinkle here in that the terminology used to identify immunizations that's been embraced by HHS is of course CBX which comes from HL7 and it's a living terminology and is updated as new immunization types are introduced and when you're talking about outbound, sending information outbound from the EHR that's not such a big deal as it is when you're trying to be able to ingest inbound data, of course, I think most people on the call have had that experience, so you can get into a situation where the EHR doesn't have for instance the latest CBX codes and their need to be – this requirement implies the ability to manage the terminology on the EHR side and also to manage exceptions when inbound messages come in and so forth and so I think it merits being – you know, that being called out as a non-trivial implication of the proposed certification requirement.

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

Great, thank you for that. So, I think it's important that what we summarize to ONC is, in a balanced way, that we think content is mature, vocabulary has certain implications as Eric has just described but CBX, you know, certainly is something we're familiar with and transport has some controversy and there are many ways to slice it, it could be SOAP as CDC has suggested, it could be REST in the future, there are ways to use Direct but Direct won't be useful for query response. So, this is one, whereas in many standards making activities, the answer is not completely black and white there are pros and cons to each of the variations. Other comments?

Okay, well, I know we're getting near time so very, very quick the registries Meaningful Use criteria suggest that an individual user should be able to choose arbitrary data elements that they wish to configure and submit to a registry and so our comments there is we love the idea of registries and we certainly think the things like cancer registries are so important but the idea that you would be able to supply data from an EHR to any registry based on a user's capacity to upload an arbitrary number of data elements requires standards that don't exist and development which could be exceedingly difficult. Comments on that?

Okay and then the last two they all exist in Meaningful Use Stage 2 electronic lab reporting and syndromic surveillance both exist in Meaningful Use Stage 2 as certification criteria they've already both been developed, the standards maturity is high, development effort is low they're just moving from menu set to core so we didn't have any issues there.

And the very last comment we'll make on slide 22 is that in the spirit of looking at implementation burden a number of folks said, if we are forced for every CQM to stratify every numerator and every denominator by a very large number of potential disparities that we're going to end up with a certification nightmare, a data quality nightmare, we're going to end up with numerators and denominators that are going to probably at times be vanishingly small so maybe we should rethink that and say, you know, can we constrain this in some fashion that reduces the burden of certification and the burden of use.

And that, Jon Perlin, is everything in record time.

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

That was extraordinarily well done, great conversation, great presentation many, many thanks. I know, because Michelle has told us, that there is already interest in public comment and apologies to our colleagues who've been waiting to participate that's so much an important part of this type of committee, the Federal Advisory Committee, so Michelle without further ado let's open the floor for public comment.

Public Comments

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

Thanks Jon, operator can you please open the line and while we wait for the operator to open the lines just a reminder for those making a public comment it is limited to 3 minutes and it is purely for comment only not for question and answers.

Caitlin Collins – Project Coordinator – Altarum Institute

If you are listening via your computer speakers you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment please press *1 at this time. We do have a comment from Alison, please proceed.

Alison Chi, MPH – Program Manager – American Immunization Registry Association

I'm speaking for the American Immunization Registry Association and I just want to point out the numbers on uptake of SOAP in the IAS world, the December 2013 quarterly IAS Meaningful Use survey conducted by the CDC, the initial numbers from that show that 39 of 54 respondents are engaged in SOAP as our transport for immunization. Another 39/32 are in production and 24 are working directly with the CDC WSDL. And given that time is short I thank everyone for their attention and I would refer you to the written comments submitted by AIRA. Thank you.

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

Well, many thanks for that. Michelle?

Caitlin Collins – Project Coordinator – Altarum Institute

Our next comment is from Tom Bizzaro.

Thomas R. Bizzaro – Vice President Health Policy & Industry Relations – First DataBank

Yes, thank you. I would like to comment on the S&I Framework PDMP HIT Integration Workgroup. I commend this group for the work they are doing and the work that has been done by states in developing PDMPs. I have participated in this initiative and would like to comment on its limited scope.

The scope of this initiative was limited to examining improvements possible using the current formats and methods for the exchange of PDMP data. It did not look at the use of standards such as the NCPDP Script and telecommunication standards that would allow real-time exchange of PDMP data from the pharmacy and physician management systems and within the workflow. I am hopeful the discussions could take place in the future.

The issue of prescription drug abuse is a national problem and the current state specific programs and the need to access information outside of the workflow is cumbersome and difficult to manage.

I am very hopeful that additional work will take place to look at a long-term solution to a national problem as was expressed this morning by Doug Fridsma. Millions of transactions between physicians, pharmacies and third-party happen in real-time every day. The same type of technology should be incorporated to transfer PDMP data.

Finally, this is often seen as a law enforcement issue, it should be viewed as a patient safety issue and I thank the committee for the opportunity to comment.

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

Thanks for that. Michelle?

Caitlin Collins – Project Coordinator – Altarum Institute

Our next comment is from Angel.

Angel Aponte – Computer Software Specialist – Immunization Registry New York City

Hi, my name is Angel Aponte I'm a Computer Specialist at the Immunization Registry in New York City. I want to thank Arien for providing some of the context to the decision of using SOAP web services over Direct and what I wanted to add was a comment about the standards maturity and about the development effort.

If the rule required that the CDC transport layer expert panel WSDL be used and that SOAP web services would be used the standards maturity would be high especially given what Alison said a minute ago about how many of us have implemented that. We should simply require that everyone use that as the transport standards and implement that in order to meet this.

And the development effort would be low because once it's implemented once they would simply be able to change the URL and the credentials and then they'd be able to connect to a different service. Thank you.

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

All right, thank you very much. Michelle anyone else on the line?

Caitlin Collins – Project Coordinator – Altarum Institute

We do have a comment from Kristen.

Kristen Forney, MPH – Project Director – Citywide Immunization Registry New York City

Hi, my name Kristen Forney and I'm the Interoperability Director for the New York City Immunization Registry along with Angel and so I just wanted to share a bit about the experience that the New York City Immunization Registry has had with bidirectional exchange of immunization data with EHRs.

We've been doing bidirectional communication using the HL7 standards since 2009 and during that time really the only transport standard that we've accepted is SOAP web services and we currently have 455 practices in total who are submitting data to us through SOAP and 190 of those practices have a bidirectional connection so they're both sending us data and doing queried response. And overall we get about 1.1 million HL7 query messages every year.

And the feedback from providers who are using the bidirectional interface has been uniformly positive both in that it improves their workflow and accuracy, and completeness of the immunization data in their patient records and it's one of the most requested features that we get from providers.

In many cases providers have called to ask us which EHR products have a bidirectional connection with us in production because it's such a critical component of their practice that it's actually one of the kind of deciding factors of which EHR system that they're going to adopt.

So, I just wanted to kind of provide a little bit of, you know, empirical support as well for the inclusion of, you know, real-time bidirectional exchange in the certification criteria. Columbia Presbyterian was the first hospital the developed a bidirectional connection with the New York City Immunization Registry and they did a small study to look at how the inclusion of registry data into their electronic health record improved their up-to-date rates for immunizations.

So, they looked at different age groups and found that in each age group by adding the – data that they were missing from their electronic health records they were able to statistically significantly improve their immunization coverage rates.

So, for the age appropriate series for 7 to 23-month-olds their coverage went up from 79 to 86%, for 24 to 36-month-olds it went up from 79 to 86% as well and looking at adolescent immunizations for Tdap coverage went up from 75% to 79%.

So, you know, given that Stage 3 of Meaningful Use is about improved health outcomes I think that, you know, including bidirectional communication as a requirement and, you know, requiring that it be done through SOAP web services is, you know, in line with the improved health outcomes. Thank you.

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

Terrific, thank you very much. Michelle?

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

I think that's everyone.

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

All right, well let me thank all of the members of the committee for your hard work, clearly there was a lot of work between meetings. John Halamka just a tour de force, Doug and Steve just really encyclopedic in terms of both the S&I Framework and the regulatory frame around it.

And as always want to thank the public for their input it's so much a part of the democratic process and of course the National Coordinator's Office for really just heroic work.

I don't know if Karen is still on the line, but certainly Karen if there are any closing comments we'd welcome them. Okay, I'm imagining that she may have had to have gone to next activity, but with that let us – actually Michelle can you just give us a word on our next meeting?

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

I'm sorry, Jon, I didn't make out what you said?

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

So, Michelle, the April meeting schedule?

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

Oh, it's April 24th at the Washington Plaza Hotel, we'll be meeting in person.

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

Okay and more details to follow I am sure. So, with that we standards adjourned and thanks to everybody for all of your hard work.

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

Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

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

Have a good day.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Bye.

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

Thank you.