

# HIT Standards Committee Transcript February 18, 2014

## Attendance

The following members attended the meeting:

- Dixie Baker
- Steve Brown
- Anne Castro
- Jeremy Delinsky
- John Derr
- Lorraine Doo
- Floyd Eisenberg
- Jamie Ferguson
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Jonathan Perlin
- Wes Rishel
- Kamie Roberts for Charles Romine
- Eric Rose
- Christopher Ross
- Sharon Terry
- Andrew Wiesenthal

The following members were absent:

- Keith Figlioli
- C. Martin Harris
- Anne LeMaistre
- Nancy Orvis

## Presentation

### Operator

All lines are bridged with the public.

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

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is the 54<sup>th</sup> meeting of the Health IT Standards Committee. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. If you are Tweeting today the Hashtag for today's meeting is #HITSC.

To all the members on the phone we will be using the raise the hand feature when we come time to ask questions. So, if you're looking for where that is it's on the top of your screen next to the microphone you'll see a little icon with a man using his hand to raise it. So, when we get to portions of today's discussion where you'd like to ask a question please use that feature and it will put you in the queue and I'll just call on you in the order that you have raised your hand just like when we are in person and you raise your tent card. 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 – 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 – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi John.

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

Hello.

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

Andy Wiesenthal?

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

Here.

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

Hi Andy. Anne Castro?

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

I'm here.

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

Hi Anne. Anne LeMaistre, LeMaistre? Arien Malec?

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

I'm here.

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

Hi Arien. Marty Harris? Charles Romine?

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

This is Kamie Roberts for Charles Romine.

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

Cris Ross?

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

I'm here.

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

Hi Cris. Dave McCallie?

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

Good morning.

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

Good morning Dave. Dixie Baker?

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

I'm here.

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

Hi Liz. Eric Rose?

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

Here.

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

Good morning. Floyd Eisenberg?

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

Here.

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

Good morning. Jamie Ferguson?

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

Here.

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

Hi Jamie. Jeremy Delinsky?

**Jeremy Delinsky, MBA - Senior Vice President, Chief Technical Officer – athenahealth, Inc.**

Here.

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

Hi Jeremy. John Derr?

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

Here.

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

Hi John. Keith Figlioli? Kim Nolen?

**Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.**

Hi Michelle I'm here.

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

Hi Kim. Leslie Kelly Hall?

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

Here.

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

Hi Leslie. Lisa Gallagher?

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

Here good morning.

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

Good morning Lisa. Lorraine Doo?

**Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services**

Here good morning.

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

Hi Lorraine. Nancy Orvis? Becky Kush?

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yes, I'm here.

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

Hi Becky. Sharon Terry?

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

I'm here.

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

Hi Stan.

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

Hi.

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

Steve Brown? Hi Steve. And Wes Rishel? All right, thank you everyone. Just a couple of comments before we get started I do want to make sure that everyone is aware we have published a number of openings for membership to the Health IT Standards Committee there was a blog published and you can also access a place to apply to be a member of the Standards Committee. We are accepting applications until March 3<sup>rd</sup> and more details can be found on the healthit.gov website.

And I also want to note that we are working to implement two year term limits for our committees so that would be for a total of 6 years for committee members. We are working on a waiver to the Secretary and to hopefully update the charter to include that information.

And there also are a number of committee members that we are working to extend their membership by one additional year. Those members should know who they are but just wanted to make everyone aware and we'll keep you updated as we work through the process.

So, with that I will turn it over to – I think Karen is on, but Karen if you are able to speak I know that you're en route please let us know if not I think Jon Perlin is all set to also take over if you aren't able to.

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

We'll give a second to Karen. Okay, well she may not be – I know that she is flying and traveling this morning and will join us as soon as she can. Welcome everybody to the first meeting of 2014 our 54<sup>th</sup> meeting. I want to thank you for all that you do.

I think this is a huge and exciting moment in Health Information Technology. I think it's exciting for a number of reasons, three reasons. First and with respect to all of us, we are not doing what Karen is doing we are not on an airplane traveling across the Snowbelt of the polar vortex and have the privilege to meet virtually.

So, thanks everybody for adapting your schedules actually I do hope it was of some help to you not to have to travel given the challenges of travel at the moment but thank you very much for getting together virtually.

Just by – it does take a lot more attention for us to focus collectively and thanks to all who joined. We are a very large group today. We look forward to robust discussion and in lieu of the tent cards do let John or myself, or Michelle know if you're trying to weigh in. Always please say your name so that everyone knows your voice and look forward to a robust discussion.

The second reason I'm excited about this meeting is that as we look to this point as we look back across 54 meetings, as we look back across four years plus of activity so much of what we've been able to participate in has built an infrastructure that is increasingly remarkable. Is it perfect, is it complete, does it all fit together, of course not.

But I just see in organizations that I have the privilege of visiting and recognize in my own organization the opportunity for information to be available from site to site across time and geography and among members of a team increasingly by virtue of what has occurred over the last few years and that's really exciting going from the implementation aspect to really cultivating the informatics and service of better health, better care, better policy, better decision-making and that is just rewarding and exciting, look forward to hearing stories of your organizations and how you're actually realizing the products of increasing interoperability.

And third I'm hugely excited about our new National Coordinator for Health Information Technology whom I'll introduce in absentia. She is someone that...

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

Jon?

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

Succeeds a number of eminence –

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Hey Jon, Jon?

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

Jon?

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Pause a second I think she's here.

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

Jon, I've been on the phone I just couldn't tell if you all could hear me, apparently the operator can but maybe there's something amiss with my phone. Can you all hear me okay?

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

We can now.

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

Okay, apologize for that, I've been trying to jump on and –

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

Well, Karen, actually, if I can take the Chair's prerogative and just a few words of introduction then turn it right over to you?

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

Absolutely, sounds good.

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

Well, I have had the privilege of knowing Dr. DeSalvo for a number of years. I came to know her in the wake of Katrina and learned more not only about her public service and passion for public health and health care and healthcare of the vulnerable, commitment to medical education and health professions education, but really her leadership and passion for Health IT and using technology in conjunction with all of her other skills to help stand up in real time support services for those who had been so terribly affected by hurricane Katrina.

Following Katrina she created an innovative model of neighborhood-based primary care and mental health services for low income uninsured and other vulnerable individuals. And she has also served as Professor of Medicine by State and Community Affairs and Health Policy at Tulane University School of Medicine.

And as mentioned, the subject of her work has been in these areas of the interface between public health and health services of the multiply vulnerable. She's not only been a leader in Louisiana as the Lead for the Health Information Exchange and Steering Committee for the Crescent City Beacon Community Grant but a national leader in the Board of the Society of General Internal Medicine and elsewhere.

I had the privilege of actually asking Karen to speak at the National Patient Safety Foundation Congress last year and her vision for the use of IT in the extreme circumstances of Katrina as well as in the more routine circumstances of healthcare in 2014 and beyond was really compelling and inspiring.

And I think all of us welcome the practicality and passion that Dr. DeSalvo brings along with formidable intellect and skills to lead the Office of the National Coordinator. So, please join me in giving a warm virtual welcome to our new National Coordinator for Health IT, Dr. Karen DeSalvo.

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

Thank you Jon that's really very nice and I just want to thank you for your support and all of your intellectual and other capital that you lent to New Orleans. A lot of the thinking of the work that you had done at the VA went into our thinking and rebuilding and you were personally engaged and so we really appreciated that.

And I want to thank you and John for all of your leadership with ONC for the Standards Committee. I know it is a lot of work and I appreciate your willingness to continue on and help us as we move into a new decade of ONC. Don't worry I'm not keeping you for a decade but it is wonderful for you to be with me in transition especially because you are familiar. And John Halamka has been someone I've so enjoyed getting to know and really appreciate the insights and input from both you all.

And then I just want to say hello to the Standards Committee who some of you I have met but not everyone and I just want to thank you all for what you have been doing to serve the country and appreciate your willingness to continue to do that in a variety of capacities.

I'm going to be brief. I have had a chance to talk with the chairs of both committees now a couple of times. I'm just beginning my sixth week at ONC and it's a really exciting time here. We're ending a decade of important work where there is framework laid out to move towards widespread adoption of electronic health records in particular and some of the opportunities therein for the good use cases and I think there has been great progress in the country honestly.

And we have much work ahead using levers like Meaningful Use including next chapter of that which we're planning for three right now but also thinking of all the other opportunities we have to enhance standards and interoperability systems and make sure that they're capable of doing the things that we want them to do for all the patients that we want them to serve.

To that end I think as we are looking at where we go forward as an agency and as a field the Policy Committee is taking a step back from their agenda and really beginning to look forward at a multiyear trajectory of the big policy questions that they want to see answered. And they think that they can help inform HHS about how to move the field forward to a place where we get to a really nice learning system with a great feedback loop where the patient's data is there across the care continuum and can be used in all the ways not just for care delivery but to improve safety and quality and the evidence base of healthcare services.

To that end we'll be working on that some more in the next couple of weeks. Paul Tang has really been great about it and we had a good discussion at the Policy Committee where we got some general input from them and we'll be talking about a strawman for a broad approach and working on their Workgroups, our Workgroups there to see that it's going to set forward the building blocks so that we can achieve the answers to those policy goals.

Standards in a similar way has been very focused on the work at hand of Meaningful Use and some of the other high priority projects that we've had that I think that what I would like to see this committee do is start to really look out into the future and make sure we are keeping our head up about what's coming down the pike and how first of all we can make sure that the Policy Committee dreams but does that within the context of what is realistic and also that we're – can you hold on one second. Sorry you guys. This commuting thing is not going as smoothly as I'd hoped.

So, as far as the work plans go and the Workgroups go I think that we're going to be looking in the next few weeks to see can we start to do a better job of harmonizing and aligning the efforts of both committees to make sure we're getting as much bang for our buck as we can.

And also make sure we're thinking as proactively as possible and minimizing any kind of reactive work. I think that is important for the staff because it's easy for them to get pulled in a lot of directions but also for you guys and I just want to make sure that we stay as focused as possible the important priorities the American people want from us and that HHS thinks that we need to have to deliver on this promise really of better care, lower cost and better health.

So, it's a general comment about some changes and I think that you guys will feel with the FACAs both the Policy and Standards Committee as we're working first with the Chairs and the team and then with you all to harmonize the few efforts that policy is first more proactive in its thinking on a longer term horizon not losing sight of important responsibilities in the short run obviously, but that we also have the chance for standards to communicate well and inform Policy Committee and then there is a really good feedback loop so that you all who have a greater appreciation of some of the opportunities around innovation in standards etcetera can make sure the Policy Committee is not losing sight of some of the new things that might be coming along that would be important to deal with and incorporate and develop policy around.

I would happy if you have – well I can't them now Michelle, but if there are questions and public comments – folks have feedback and to that end also I guess I would say that in March when we're all – I'm expecting we'll all be together in person we'll have a chance to lay that out a little bit more explicitly for everybody.

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

Well, thank you very much, Karen, for your inspiring vision and also giving us some guidance in terms of the practicalities of the next few months in terms of taking stock, being aspirational with the Policy Committee bounded by real-world inputs from the Standards Committee and others in terms of possibility and then prioritized by commitment to that magical combination of improved care, improved health and improved value.

Our agenda formally lists that we would go through the review of the agenda and some comments and then into the Standards Committee but you've offered an opportunity for some questions. We do have a section on work plan but why don't we actually right here see if anybody has any questions or comments.

I would just, in terms of setting the stage, refer people to the minutes of the last meeting where there were five categories four of which were new, privacy and security continuing on and one set of questions obviously relate to the sequence of activities and we'll come to that momentarily.

But let's just get one administrative order of business out of way. Are there amendments or corrections to the minutes of our last meeting? If so please speak up.

Okay, hearing none we'll consider consensus and those approved with all thanks to Michelle Consolazio and a great team at ONC for your very thoughtful capturing of our discussions before and let's open for a second here and it's a topic we'll come back to in terms of work plan.

But, as I heard it really you want to work with us and with the Policy Committee to have a look at our environment, a look at the future and a look over the next few weeks to make sure that work is aspirational that there is a long-term horizon, that immediate efforts do get filled and toward that end that there is information flowing back and forth vigorously between standards and policy informing the Policy Committee in terms of possibility, in terms of the maturity and adoptability of standards and also feedback as to frankly where we need to do work and identify opportunities for development.

And so this is what I believe I heard. Let me open the floor for any questions or comments? And certainly –

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

This is Michelle, Arien Malec has a question.

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

Go ahead Arien.

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

Hello, thank you very much and Karen, thank you so much for the opening comments. This is a set of comments I've made a number of times so I apologize for repeating myself. But I'm very encouraged by your words.

I strongly believe that the future that we should be working towards is a future increasingly organized around alternative payment models where Meaningful Use may be a precursor but where, you know, what I like to think about it is if I'm achieving the Triple Aim do I need to be – have somebody looking over my shoulder to make sure that I have entered all of the problems in my problem list for example but that's a programmatic that may be a necessary prelude to achieving quality and cost consideration. But if I'm achieving those considerations maybe I don't need to be worrying so much about the micro-details that are currently part of the Meaningful Use Program.

On the other hand it is imperative that I use an interoperable electronic health record which suggests that the certification criteria should be much more heavily focused on the interoperability and standards associated with the EHR technology that I'm using.

Finally, there may be a set of Meaningful Use criteria that don't get captured in quality measures, that don't get captured in improving cost consideration that may be good approaches for Meaningful Use. Those may include for example reporting to public health or some aspects of patient engagement that aren't already captured in improving quality, decreasing costs and improving the health of the nation.

And so just a plea really that we keep our minds focused less on the programmatics of the Meaningful Use Program and more on the prerequisites for true value-based care supported by an alternative payment model scheme that supports and embraces true patient centered care. So I guess that's comment number one and I'm hopeful that that's the direction that we will move in.

Comment number two –

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

Arien there is going to be an awful lot there –

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

No, no –

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

Maybe –

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

I think it will be really quick.

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

It's not fair to Karen and – get some discussion around that and we'll come back.

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

Can I just throw one more quick thing in because it's an observation that we're two years from the publication of the NPRM for Meaningful Use Stage 2 and it's an observation that we need 2.5 to 3 years between the publication of an NPRM and the expression of that NPRM in terms of a standard supported EHR that's used by providers. So, just another plea to him look at the timelines associated with the activities that we have underway.

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

Okay, well thanks Arien, great comments and I heard four specific comments and I can either recapitulate or Karen if you want to make any comments please feel free. She may be muted.

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

I think we might have lost Karen I know she is in transit so she'll probably be reconnecting soon.

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

Okay, so well Arien let's hold those. I think we heard, you know, your eloquent plea that Meaningful Use is a precursor and that there is activity for quality and cost that goes beyond what's captured in the standards themselves and beyond the interoperability standards there's a lot of work that's going on and that you were interested, I just want to make sure we synthesize this for when Karen returns, that we're working also toward a model that supports really value-based healthcare and alternate payment models more broadly.

We also heard you plea for a time cycle between – that really allows for the development of product that's closer towards a three-year cycle then the two-year cycle.

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

Exactly. Thank you.

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

Okay, well appreciate those. Let's take this moment and Karen will rejoin as actually per the published schedule –

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Hey Jon?

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

Yes?

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

This is Jacob Karen is here and has actually dialed in its been – I guess for some reason hard for us to hear what she's saying, but she is here.

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

Hi Jon.

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

Terrific.

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

I came down to Jacob's office for some reason the conference line in my office isn't really working. So, I'm able to hear you all, I'm just not able to respond and I was just going to generally say, thank you for the comments and definitely for thinking big about the potential for other tools and levers to get us to goals beyond Meaningful Use as a capital M, capital U and also for, you know, just recognizing that we have to be thoughtful as we go forward about making sure that we want to do aspirational and good things but we have to balance that with burden as appropriate.

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

Well, thank you. All right are there additional comments that anyone would like to offer at this time? Very quiet group this morning.

Okay, well then let us – I suspect there will be more discussion as we proceed through our agenda. Please do keep your December materials as a reference point for the work plan as it's been we're going to enter a discussion momentarily about the work plan evolution given these preparatory comments that Dr. DeSalvo has offered.

Let's take a look at the agenda and additional comments from John Halamka. So, let me turn to you John for any stage setting you'd like to do and your comments on today's other activities?

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

Well, great, thanks so much and I do want to echo my welcome to Karen and in my time with her and Jacob so far I have found that Karen is a great listener, understands many of the issues that Arien has raised about timelines and balance, looking at where we want to be a few years from now and trying to work backwards and decide how the Policy Committee and the Standards Committee working together can achieve our future goals.

So, I did post a blog about the new optimism, you know, so that all of us who have felt that sometimes the pace of Meaningful Use and sometimes, as Arien described, the overprescribed nature of some of the tasks felt so daunting and yet I do feel this optimism that as we go forward as a Standards Committee and work with Karen and Jacob and others at ONC that there will be opportunity to polish and I think to that point Jon Perlin we're going to hear from ONC, Jodi Daniel, commenting on an NPRM looking at the certification criteria for FY 15 and thinking about how you might, without disrupting the certification that has already been done or is already in process, offer some revisions, some corrections, some polishing and improvement that would be voluntarily accepted by some vendors as some relief to some of the challenges they accomplished in the 2014 certification criteria. So, I do certainly look forward to those ONC updates.

Jon, as you said, the work plan is going to be interesting to formulate because on the one hand there are many standards gaps that we all want to fill. We're all aware every day in our operational roles of how standards could improve data flows in many domains, but also as Arien told us, I mean there is this new payment model as fee-for-service gets replaced with global capitated risk and if we are going to get to where we want to be in a few years are there some forward thinking standards that we're going to have to work on along that path.

And so I look forward Jon to the discussion of the work plan and how the Policy Committee and the Standards Committee, its Workgroups and Taskforces, and Power Teams are best going to be organized, prioritized and staffed in the future.

And speaking of staffing, as Michelle said, I am very relieved to know that there are likely the one year additional time available for some of our extraordinarily valuable contributors because as you did the math and you figured out we were all working for 2009 to the present that's five years not six. So, I look forward to working with you all as we reformulate our Workgroups.

So, we'll go through some of this work plan discussion. We will hear the ONC updates, look at some transmittal letters that have come from the Policy Committee and figuring out how best to assign those to get that work done.

And then Leslie Kelly Hall and I have been involved in many presentations of the patient generated healthcare data question and many of you on the call and Jamie and others have been intimately involved in that set of scope definition of what is it we can do in the short-term in the long-term and what's most appropriate to include in the next round of certification criteria.

So, Leslie will present to you a detailed analysis of both patient generated healthcare data as text and that which may come from devices and where is standard's readiness and maturity, so look forward to that discussion.

So, overall Jon Perlin I would just say that 2014 is going to be yet another very important year for the Standards Committee and with a new National Coordinator we do have an opportunity to refine our focus and don't worry all the change ahead will be good. So Jon, turn it back to you.

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

Well, thanks John, it is, you know, I do know there is some degree of facetiousness in terms of John's challenge that all change is good but this really is a hugely exciting time and as I opened the comments at the beginning the increasing capability of interoperable information is really compelling and I think all of us in our various professional lives are seeing the benefit of that.

And this is why when we look at the ecosystem, the ecosystem of possibility there is need to really prioritize opportunities where are the greatest lifts, where are the greatest gaps, where are the greatest capabilities in terms of technology.

Dixie Baker has offered for us a scheme for thinking about the maturity and adoptability of standards and how does that understanding of what's possible interface with the task of the Policy Committee in terms of what's desirable in terms of elevating healthcare and value.

And this means that in addition to the logistic opportunity to avoid travel in the midst of cities recovering from snow it means that this month our agenda is a little bit compressed and we think about the future rather than completely defining our work plan.

However, we've had a trajectory of thinking about a number of different categories of work as you recall from before. The global areas of one quality and safety to health information exchange, three consumer related activity, four accountable care and population health, and care management, some areas that were defined freshly the last time and continuing activity that Dixie Baker has been so much a part of leading in terms of privacy and security.

Now it's hard to imagine that the categorical areas change but given the fresh perspective that Dr. DeSalvo brings and just the opportunity for reflection on the forward trajectory of interoperable health information technology and the state of Meaningful Use currently it does give us some opportunity for reflection on where we are and the opportunity to provide any feedback to the Office of the National Coordinator on this moment where we do have, I think, really for the first time an opportunity to take a quick breath and look at the environment around us and work with the Office of the National Coordinator and provide input.

Now Arien you started on that thread and you had comments both about the content what's in it in terms of Meaningful Use, the approach that is things that actually meet the intent of Meaningful Use but aren't specifically captured by standards or measures, quality measures specifically, as well as the sequence for material development and that's a good thread on which to start.

But let me stop here for a moment and let me ask Dr. DeSalvo if there are additional comments she'd like to make to reengage in this discussion and if not we'll just go on into comments for the committee. So, Karen?

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

It sounds like we can't hear her again. Oh, here she comes down the hall. Is she coming?

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

We'll wait for her to come back to your office.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Here she comes.

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

All right. Giving new meaning to the sneakernet.

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

I'm getting my steps in today. I'm going to try one more time for you all. No really, thanks everybody for the comments. I think they're in keeping with the kinds of principles that we've laid out for ourselves, you know, in thinking about the importance of the data liquidity to make sure it's available for the use cases that we, I think all envision and that we see happening in some aspirational places around the country.

And there is work to do but I think focus is a good word and I heard it a few times from folks. So I think we have to get really thoughtful about how to sequence appropriately so that we're not sort of building on our work and it is a good time to take a breath because we're at the 10 year mark, a lot of great success but important for us to now get really focused on how to go forward.

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

Thanks, let us open the lines, any committee members who have any comments?

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

This is –

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

Jon, this is Leslie Kelly Hall. I just had a comment and Karen, welcome and really look forward to hearing about your vision for patients and consumers and how they can help to transform healthcare as well as coproduce their health.

You and I were in a panel in the National Patient Safety Forum last year and I was so impressed by what length everyone had to go to in New Orleans to make sure that patients were put first and were cared for well over tremendous challenges. So I'm just eager to learn more about your direction and help to support that.

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

This is Michelle. Stan Huff has a question.

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

Please, go ahead Stan? And thanks Leslie for your kind words.

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

Yeah, you know, I think one of the important things that occurs to me is again the idea as we're in this, you know, a new opportunity to look at things that we plan and take some time to do strategic thinking about what we would like the future to look like and how we can aid and support that as opposed to just, you know, thinking about what is here and now and maybe filling gaps in with known problems.

But, again really thinking that we can add value if we get back to some of the ideas that were in the PCAST Report and think about, you know, a much more open usable services strategy that would incorporate, you know, potentially new kinds of thinking about security and new kinds of thinking about how we access and use data and would like to see that kind of – have an opportunity in the sense to think about some strategy together rather than maybe just always react to an unknown road map.

So just a hope and a goal may be to have a chance together as, I think, a very bright set of people to talk about ways that we can make things different that would be a long-term goal as opposed to the best thing that we need in the next six months or a year and that's all I needed to say for now. Thanks.

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

Appreciate that, you're open Karen for any comments or I may offer a comment. Karen, go ahead?

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

Oh, no I think that was great, and I appreciate what you said and the same kind of somatic things that there is an opportunity to be more proactive and to focus more our work to be as strategic as possible. So, I love the somatic sense of what I'm hearing.

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

And maybe an opportunity to work off-line about how we might envision some generative activity that supports the Policy Committee and your office in thinking about more open services and strategy, and security and access and use some of the comments that I heard Stan make because it's interesting.

I think your notion of taking a pause to look at some of these things is really critical because, you know, when we started not only was there far less use of IT in healthcare and it's really quite extraordinary to look at the ONC statistics on attestation to Meaningful Use Stage 1 both among hospitals, which are called about 84% as of December of 2013 and over 60% for eligible providers as of the same time, but the technologies have evolved as well and so let's put our heads together and think about how we can support you and the Policy Committee in terms of thinking about the new capabilities and how they may play out.

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

Yeah, I think that's exactly the kind of feedback loop that I hope we can engage in, again not with overworking ourselves but just to say, hey 3-D printing is happening are you all thinking about that in the Policy Committee or are there any implications, I mean, that may be completely out of the box, but just those sorts of interesting things that maybe we miss and just speaking for – you know I would reiterate this point which is that this it's very easy for us to get into the work of the day because we have real responsibilities – so we really, you know, I'm going to really count on the FACAs, the Policy Committee and Standards to make sure that they are looking up and out and bring information to us to make sure we don't miss anything strategic that's happening out in the field.

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

Great, that's really encouraging. Let's hear from other members of the committee.

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

This is Michelle, Floyd Eisenberg and then Dixie Baker have comments.

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

Great. Go ahead Floyd?

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

Hi, so I wanted to follow on Stan's comment and I think that it's a great idea to rethink a little bit just to bring some information from a full week meeting last week that ONC and CMS sponsored a Kaizen to look at the whole measure development and clinical decision support enterprise.

It was clear and a recommendation from that group to look at all standards around the area of quality and decision support to see that they coordinate in efforts that go on both in standard's development and in measure and CDS development all align rather than just individual standards for individual components of the process. So, I think that would be a terrific approach.

I also think there are some areas from learning in measurement that apply to decision support as well that have been problematic and perhaps some recommendations to simplify as an example consider exceptions in measures of something that perhaps is going to take a long time and maybe could be avoided. So that's my comment. Thank you.

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

Great.

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

This is Dixie.

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

Go ahead.

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

Several of us on this committee are also involved in the new Patient Centered Outcomes Research Institute Initiative, PCORI, that are building a PCORnet that is directly related to what Karen has mentioned about the, you know, enabling the learning health system and it's – I'm on the – for that initiative I'm on the Data Standards Taskforce and I find myself discussing the same issues again.

And I would love to see there be a closer working relationship between what PCORI is doing and what this committee is doing. It's great that three of – you know, several of us at least are engaged with that initiative but it would be really nice to have a facilitated transfer and engagement between the two groups.

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

Well, thanks for your comments on that just I might note that an area of some intersection of some of the folks here is there is a health system's leader workshop being built, a national research network, that will occur at the Institute of Medicine sponsored by PCORI and that is April 24<sup>th</sup> just note that because Dixie your point that there are a number of convergences on these questions and approaches.

And Karen let me turn to you for any comments either on harmonization of approaches to clinical recommendations and clinical decision support, Floyd's comments and Dixie's comments interfaces potentially with PCORI and the activities of PCORI.

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

Thanks, Dixie. Thank you Jon, I'm actually sitting here were Jacob and, you know, he is our content expert around all these areas. I'll make a general comment which is that the PCORI and PCOR and PCORnet are opportunities to enhance the learning environment of healthcare and that HHS has a variety of ways of interacting with PCOR and its various versions.

And so, you know, I think there's a lot of opportunity and certainly within HHS we're doing our best to make sure there is a strong interface so that we're thinking through, you know, how do we leverage those funds to see that we're thinking about the kind of at the point of care clinical decision support that's going to not only help – Jacob do you have anything that you want to add about that?

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Nothing to add.

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

Nothing to add.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Good points Floyd.

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

Yes.

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

Okay, other comments? The floor is open for continuing discussion.

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

Hello, this is Eric Rose, I'm not on line so wasn't able to raise my hand, but can you hear me?

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

Yeah, hey, Eric.

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

Oh, hi, Karen, Dr. DeSalvo thanks very much for joining the meeting and welcome aboard we're delighted to have you. I fill – I'm sorry?

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

I just said, thank you.

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

Oh, thanks, so I'm in a bit of a noisy environment. I fill one of the slots allocated for practicing physicians and one of the things that I try to make sure were mindful of is the fact that in particular small practice physicians are kind of hanging by a thread in terms of the administrative and logistical burdens of caring for their communities and I think we have to try to really walk that tightrope between policy initiatives that appropriately push us forward and we can't just accept the status quo and at the same time we've got to make sure that we don't leave behind these folks who may not be that visible, especially in urban centers but really are the backbone of healthcare for their communities.

So, I think it's really important for us to be not just making good policy about standards and so forth to create systems that can do awesome things but ask questions like why are 20% of the doctors who attested for Year 1 of Stage 1 not attesting for Year 2 of Stage 1 when it should be theoretically not that much more difficult and really reaching out and seeing what is it about these – about the Meaningful Use Program in particular that is making things more not less difficult because we should be all about solving problems and patient care and removing obstacles that are helping be healthy which I'm sure is your goal as well.

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

Thanks, Eric, I – yes, this is about every man and I don't mean that to be gender specific, I mean, this is about all Americans, patients, doctors, etcetera and coming from a State like Louisiana where many of our doctors are still in small practices, heavy rural population not a very managed environment we don't really have any clinically integrated networks, we are not the kind of healthcare infrastructure that I think lends itself to some of this easier implementation.

So I get it. I've lived it. I understand it completely and it's on my mind because I think that we have to make sure that we enable medicine but maintain the practice of medicine and joy of medicine and we don't put burden over expectations and policy.

But, you know, everybody wants to push and everybody wants to advance and I know that about all the doctors and small systems on the ground but we have to be thoughtful about making sure we're doing it in such a way that it is really getting us to three part aim but doing it with everyone in mind.

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

Thank you.

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

Other comments? John Halamka?

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

Jonathan, this is John Derr, I had my hand up.

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

Hey, John.

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

Thank you Karen for everything, I met you at the ONC meeting, I just wanted to speak up for the non-incentivized providers who are not included in the HITECH Act which is long-term post-acute care, behavioral, outpatient surgery and then also to speak up for pharmacy for true medication management and not just reconciliation of a medication list.

We really appreciate everything that ONC has done for us and Doug Fridsma and Liz and the rest of your staff, because we know how hard it was since we weren't in the legislation to pull us into the whole spectrum of care but yet how important it is since 40 to 60% of the people are discharged from hospitals into a nursing home or home care or hospice agency.

So I just want to thank you and I know you helped out a lot of the long-term post-acute care in Katrina in Louisiana and we really appreciated that. Thank you.

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

Sure, John, thank you, you know, that raises an important point that I tried to articulate earlier which is that the Meaningful Use Program is a powerful tool and it's a good tool but it's only one of many tools that we have and if we want to have a really inclusive continuum of care where the data moves to all the places where the patients go we're going to have to look at other tools in our toolbox to get you guys in. So, yes, I agree.

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

Jon Perlin this is John Halamka, you asked for my comments and so as I think we've talked about what will likely happen over the next 30 to 60 days, as Karen and her team begin to look at their agenda, we'll I'm guessing, see a set of policy goals that will in many ways define the structure of both the Policy Committee and the Standards Committee Workgroups going forward and we'll divide up the work that we all think is appropriate to get to those policy outcomes and goals some of which may be very 2 to 3 year forward thinking kinds of activities.

I wrote a blog piece the other day where I looked at the theme that everyone's talking about, you know, what is it we need to solve tomorrow and the things like our transition of care summary work, a number of the S&I framework activities have been absolutely wonderful and coming to consensus on those things that are of more short-term urgent nature.

But then where do we want to be a year or two from now. And we look at FHIR and we look at REST and we look at OAuth as trust fabric creators and then even beyond that to some of the things that Stan was talking about with PCAST like detailed clinical models and APIs with universal exchange languages or the things that Gary Dickinson often tells us about, well what if there was this notion that schemas, although underlying logical schemas may be different, that you might have some common definitions that would allow a data integrity to be insured between the point of data capture and its ultimate use because it didn't go through a whole variety of imprecise mappings between A and B.

And these are the sorts of – you look to the point that folks have made about the national pace of things, you know, what are we going to do one year from now, three years from now, six years from now because some of the work has to be started today if we're going to get to these more forward thinking eventualities.

So, I would think Jon the first step we next month convene and we start seeing some of the ONC policy goals and some of the organizational structures suggested and then we map together how we are going to do the short, medium and long-term once we have that input.

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

I think that sounds like a very practical and also inspiring approach because in that we can map to not only the sort of domains of activity but the horizon for those activities.

You know it is interesting because I will tell you that outside of these calls I know all of us do a lot of work in the interest of the committee and there are those who would say it's moving too fast, there are others who would say it's moving too slow. There are those who would say a lot has been harmonized and there are those who would complain that not enough is identical.

Just one point of convergence with the IOM and the PCORI work is at a recent meeting Professor Mary Shaw from Carnegie Mellon University noted that there is no way to move to interoperability to implement new standards other than sort of by accretion. The alternative is massive rip and replace and that's not feasible.

I'm going to close this section where we started which is with tremendous excitement because what is most gratifying to me is to hear the use cases of patient care from hyper-rural, really frontier environments that are now linked with less mile technology but more importantly interoperable information to really opportunities for linking care continuity and the changing delivery and payment model to finally the capability for interoperability providing a platform for research, to things that are really being tested in workshops.

And those certainly are not only the one to two-year activities but even beyond and ONC's support of for example the SMArt platform making APIs available and new models that open information and really allow us to think ahead in terms of new flexibilities which are just extraordinarily exciting.

And I think that our task, our work ahead will be in parallel very exciting but in between we'll have some opportunity to work with the Policy Committee and work with ONC in terms of recommending a structure to think in the near, and John as you've laid out so eloquently, the near-term what's necessary tomorrow, what's necessary most immediately, one to two years, and what really is aspirational, and beyond and then the very speculative portfolio even further out. I think those are great conventions.

And to Stan Huff's point will allow us to also segue between conversations that are really focused on those immediate must do's and those things that are generative in terms of thinking about the system in terms of its broader aspirations for healthcare and value. John or Karen any other comments on this section?

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

No, I'm good, thank you guys.

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

Good summary.

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

All right, well, very exciting and let us transition then with thanks for the continuing work and support of ONC, all the terrific teams that I know Karen you're beginning to get to know on a daily basis and see the great skills and talent and we appreciate the leadership and inspiration that you bring.

But with that said, then a pleasure to turn over to the ONC report and we have Jodi Daniel and Doug Fridsma to provide that but as we do that, John Halamka any introductory comments you'd like to offer?

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

Just that to the point I made about ONC really listening, I think it's just so exciting to look at the slides they'll present and recognize that we've already heard that there have been a few adjustments to timelines here and there to try to make things more tolerable, to Eric Rose's comment about making sure we get as much attestation as possible and now with this presentation today I hope folks just feel this optimism that, you know, there are opportunities to offer input and refinement. So, look forward to Jodi and Doug's comments.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Great, so this is Jodi Daniel I will start and we decided today that Doug and I would do a tag team to kind of keep things a little bit shorter today given the virtual nature of our meeting and to show that we do in fact work hand-in-hand through all of this both in coordinating the work of the Policy and Standards Committee as well as the policy and technical aspects of our work.

So, today we're going to just touch on four issues that we we're going to give you updates on, first is talking a little bit about the learning healthcare system which Doug will take the lead on and his thinking about the learning healthcare system and the connection about standards and policies and the like.

Next we'll talk about the transmittal letters from the Health IT Policy Committee. There are a couple that will be of interest to you, the Standards Committee, and Doug will talk you through those.

Then third we wanted to talk a little bit about the Meaningful Use feedback that we're getting from the Policy Committee and a proposal for how we take those on with the Standards Committee and how we get your input on those.

And then finally just a quick update on our 2015 edition NPRM for standards and certification criteria which I will take on. So, I will turn it over to Doug and I'll catch the end of the presentation. Go ahead Doug.

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

Great, thanks so much Jodi.

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

This is Michelle, sorry Doug, just quickly we're getting a little bit of feedback so if you aren't speaking if you could please mute your lines it would be appreciated. Sorry, Doug, thank you.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

And can we put up the slides as well I don't see the slides up on the screen. There we go. You can go ahead two slides. Great.

**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, thanks so much Michelle, what I wanted to do and this kind of goes back to some of the comments that we've heard with Arien and others about kind of thinking ahead not being quite so tactical in our approach and thinking kind of where is the gold state and how do we view the ecosystem that's out there that we'd like to have supported by standards that provide the value to the patients and the health care system.

And so, this particular slide sort of takes a look at the learning healthcare system, which is one of the things that we've been talking about. We've had those discussions early in the process and I think it's important to remind ourselves of those conversations, particularly as we're looking ahead to Meaningful Use Stage 3.

And I see that they're going to fill in all of the slides for us, which is a little bit more challenging but I will talk you through this particular set of slides. So the thing is that if we think about the range of activities that we have both within ONC and we think about where we are now and where we'd like to be, we have focused to a large degree on this notion of the practice, so EHRs and support for patients who are on the frontlines delivering care.

But if we think about orders of magnitude we've got patients, we've got practice, we've got populations and we've got the public. And so patients are one, practices are about 1000, a population could be about 1 million and when we think of the public at large, you know, we're starting to talk about numbers in the billions.

And so in fact in each of those orders of scale, we need to think about how we can provide an ecosystem and a set of building blocks that will provide support for personal health records, electronic health records, health information exchange organizations and for national and international health analytics.

The thing about that is as you start to think about these continuums, this continuum of care all the way from patients all the way up to public we start to realize that there are lots of connections that we can draw. And in this particular slide, there's a whole host of different connections. I could draw a whole bunch of other arrows other than the ones that I've described.

But if you take a look at the relationship between a patient and their individual experience and how we want to try to do value-based purchasing, the way that we get there is we measure that individual patient outcome, we aggregate that and we determine a quality metric, if you will, for how that patient and that practice is delivering care.

If we think about connections between practice and population, we really start talking about public health. These could be quality registries, they could be disease registries, they could be public health and it's really about population and public health support. That's going to require us to be able to look at how we share information not just within an organization but between different organizations and perhaps across organizations that don't necessarily have business relationships but are there to help support the public and public health.

Finally, when we think about clinical research there is this relationship between sort of patients, practice and population as it pertains to clinical research and Dixie Baker I think mentioned the notion of PCOR and the Patient Centered Outcome Research activity.

We clearly need to make sure that we engage in some of the PCOR activities and certainly Avinash Shanbhag in my team, as well as some of the work that we've been doing working with ASPE, we've been really trying to focus on how can support the data infrastructure activities that are supported with PCOR.

If you take a look at the arrows at the bottom of this slide there's a whole series of other things that we can talk about. So, if we've done some research we've identified a cost-effective way to improve quality that often times can be represented in clinical guidelines or in other ways that if we're thinking ahead about how we disseminate this information we may realize that an academic medical journal may not be the best way to be able to take that knowledge and to integrate it to this burgeoning electronic health information technology.

Population and practice is really about public health policies and how we can link case findings from diseases that are identified and when we think about the relationship between practice and patient it's really those decision support rules that fire or that are triggered within an electronic health record that then are applicable to a particular patient at a particular time based on their unique condition.

So, if we think about patient, practice, population and public the various orders of magnitude in which we need to engage and we think about the work that's going on in the personal health record and the Blue Button activities, Meaningful Use and quality measures around electronic health records, the work on health information exchange, registries and public health and then the activities that we have around clinical research and PCOR you can see already that ONC is trying to figure out how we can engage across this entire spectrum.

If you think about the things that ONC's been doing, you know, all of these interoperability, all of the things across this learning healthcare system are supported by standards and interoperability, the technical specifications that help all of these pieces fit together. There is certification that assures that people have the capability to be able to interact across that spectrum.

There are policies that hopefully will make it easier to share information or that will make it possible to drive forward in terms of incentivizing the exchange and use of this information. Privacy and security needs to be an important part of this and I think throughout we need to be able to measure, monitor and evaluate the progress that we've had.

And so when we think about where we want to go and we think very broadly trying to get to this learning healthcare system is something that's going to take years. This is not something that is, you know, a one to two-year framework.

But clearly, if we think about the broad aspects and where we can identify high-value activity to support patient practice population and public it becomes really important that we can then look at the ONC portfolio of standards, certification activities, policy, privacy and security and measurement monitoring and evaluation to see if we're moving in the same direction.

So, I wanted to put that out there. I hope that will help us think as we go forward in a couple of follow-up meetings about how we can be more strategic in reaching those particular activities. Let's go to the next slide.

So, now I'm going to, yeah just flip those all the way through, there, good. So, now I'm going to kind of move further down because even though we're starting to talk about this very high level one of the things that I wanted to be able to do in terms of thinking about health information exchange and the work that's going on in the Privacy and Security Tiger Team is that we do have to continue to move forward on the work ahead.

And I think over the course of the next couple of months we have a number of things coming down the pike and this is going to serve to help us organize our work, get these things taken care of and off our plate while we think about these broader issues going into the spring and fall.

So there is a transmittal letter that was received from the HIT Policy Committee Information Exchange Workgroup and there are sort of three different areas that they wanted us to take a look at. The first is querying for a patient record, which is really about how do we search for patient information and respond to searches for patient information.

We have in the past talked about this in terms of a targeted query where you know the patient was seen in the emergency room the night before and you want to be able to see what the final CT was on that particular study. We received that in November and this is one of those activities that may fit into the NwHIN Power Team. We've put some proposed assignments, but I think part of our conversation today is to figure out exactly what's the right place for these things to happen.

We are beginning some work on the query for patient records in our data access framework. There is a use case two which is really about targeted query and so we have an opportunity to sort of provide an update to the Workgroup about where we are with that and then provide some feedback and guidance about how best to proceed.

Second topic is around provider directories which is the ability to search for a provider and to respond to a search. This is really about how do I know, how can I identify the endpoint or how to send something securely. Clearly within Meaningful Use Stage 2 there is the use of Direct for transitions of care and so how do you find a person's Direct address and be able to send that information to them securely?

We've already begun that work. We've got some work with the IHE in a federated provider directory and have had tremendous collaboration and support from IHE in terms of driving that forward. That connect-a-thon was just at the end of January and have learned a great deal about that. Have some pilots with some key stakeholders in the community and that may be another thing that we can update the NwHIN Power Team on and provide some feedback.

Finally, for the Information Exchange Workgroup they wanted us to explore provider data migration and patient portability and this really has sort of two use cases. The first is that if a patient is moving from one provider to another they want to be able to move that information in an electronic format from one vendor product to another vendor product given that the patient is moving to a different provider.

The second use case is to make sure that providers have the opportunity to change between EHR systems and to lower the cost it would take for being able to make those migrations. And so as this data becomes increasingly electronic one wonders if there is a way that we can streamline that process as well.

Now we do have again some work within the data access framework primarily around patient portability not so much around practice but around the patient portability and again that would be an important conversation to have the HIT Standards Committee weigh in both in terms of the ability of the standards to support those use cases and if they're not quite there what additional work is necessary to get them there? If we go to the next slide.

The second transmittal letter that we've received is from the Health IT Policy Committee Privacy and Security Tiger Team. And they have three topics that they wanted us to explore. The first was on testing authentication and how we would test two factor authentication in the certification criteria and so getting a jump on that to make sure that our testing methods are aligned with what our policy outcomes are and having the Implementation Workgroup take a look at that and see what are different methods that we can do for that and what would be the standards that could help support that two factor authentication.

Certainly, looking at things like OpenID and OAuth and some of the existing standards become important, as well as a reference to NSTIC, the National Strategy for Trusted Identities in Cyberspace becomes important to consider.

Second is around standalone certification so that the question is, should ONC permit certification of both the standalone EHR and an EHR along with the third-party authentic service provider? So, is there a way to sort of separate those two and provide an ecosystem in which those would interact?

And finally, patient authorization requirements or policy. So, what technical methods do we have for giving providers the capability to comply with applicable patient authorization requests or policies? And so we thought that's something that could go to the Privacy and Security Workgroup as well.

So, those were the transmittal letters and the activities, our proposed Workgroup assignments that were in there. What I would propose is that we go through the remainder of these slides and I'll turn it over to Jodi to step through slides six and seven and then at that point perhaps we can open it up for other conversations. So, with that Jodi? And the next slide.

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

Jodi, if you're speaking you're on mute.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

I was on mute. Thank you very much. So, as we mentioned the Policy Committee has been talking about Meaningful Use Stage 3 and they will be producing or the Workgroup will be making final recommendations to the Policy Committee at the March meeting.

This has been – there have been a lot of conversations about this and a lot of refinements to their recommendations and we have gotten some initial feedback from some Standards Committee members. But what we'd really like is to get feedback from the entire Standards Committee and so given the timeframe we had a proposed approach and would look forward to folks comments on this.

We thought it would be helpful – we would present at the next meeting after we get the final recommendations from the Policy Committee and provide all the Health IT Standards Committee members with a copy of those recommendations.

What we'd like to propose is that we poll the Standards Committee for input on those recommendations but we form a small taskforce, it doesn't have to be five or six, but, you know, a few folks from the Standards Committee to sort of take a look more closely at the recommendations as well as the feedback that we get from all of the members and then present that back to the Standards Committee so that we can have a rich discussion at the Standards Committee at the following meeting on March 26<sup>th</sup>.

At that point – so we would work behind the scenes with the folks from the taskforce to try to pull that all together so rest assured we'll help you. But really to have some folks who can identify where there might be some issues, where there might be some things that – where we can – the Standards Committee might have some general agreement and if there are some things that we need to take a deeper dive look at from the Standards Committee perspective we can identify those in March so that we're not putting all of the recommendations to Workgroups but only those where we feel like there is a need for further diving in and discussing about the standards and functionality capabilities that would support the Meaningful Use recommendations from the Policy Committee.

So, we can come back to that when we get into the discussion period. But I'd love to hear folks feedback if that works as well as looking for volunteers who would like to take the first stab at consolidating the feedback we have in making some – and facilitating the conversation for the full Standards Committee in March. Okay, next slide.

So, the one update I wanted to provide you on was about – I don't think I've spoken about this at the Standards Committee since we made the announcement about the 2015 edition of certified EHR technology. So, I just wanted to give you guys a summary of what we're proposing to do without getting into the details.

You'll see our NPRM when it comes out I think we've actually publically said we're shooting for getting it out in February. So, stay tuned. It did already go over to OMB. So, stay tuned. We're working on getting that out as soon as possible.

So, this new regulatory approach to certification that ONC is proposing would allow for certification criteria to be updated more frequently under our Health IT Certification Program. This approach is designed to get public input on policy proposals as well as to enable our certification process to more quickly adapt so that we can include newer industry standards that can lead to greater interoperability rather than waiting for our three-year cycle, as it has been, as well to add more predictability for EHR technology developers to see what will be coming or what could be coming down the pike.

We have been thinking about this and I anticipate that the new approach would basically spread out over a long period, longer time period the certification requirements that technology developers have had to react so that folks can sort of get a head start on figuring out how to start incorporating some of those standards and certification criteria into products rather than having it all hit again like in a three-year timeline and all at once.

So, our first step in this new approach is to publish a proposal for 2015 edition of the certification criteria. As I mentioned, the NPRM is forthcoming, it will be a proposed rule out for public comment so as always we look forward to public input as well as Standards Committee input on this.

We intend the 2015 edition criteria to improve on the 2014 edition in several ways. First, we expect that the 2015 edition would be responsive to stakeholder feedback. So we have heard some input from stakeholders already about 2014 and we're trying to be responsive to that feedback in a more quick timeframe.

Second that it would address issues that we heard about in the 2014 edition to hopefully make it simpler for folks to comply with our requirements. And third it would reference updated standards and implementation guides that we hope will continue the momentum toward greater interoperability.

This is a really important point is the "voluntary" word on that, on this slide. We expect to propose that this 2015 edition would be voluntary. So, that means that providers participating in EHR incentive programs would not, I'm going to say it again, would not have to upgrade to 2015 edition in order to meet the requirements of the Meaningful Use Program and no EHR technology developer who has certified to the 2014 edition would need to recertify it's products.

So, this is voluntary. If it is helpful for vendors to recertify toward certain criteria that we put forward because we've improved on some of the issues in 2014 or because they are moving forward that is voluntary, it's designed to be helpful not to be a requirement for Meaningful Use.

Our intention is that the 2014 edition remains as the baseline certification criteria for meeting certified EHR technology as necessary for the Meaningful Use Program.

So, again the NPRM will be forthcoming. We do expect that the Standards Committee will be asked to respond to the NPRM when it comes out.

We of course both would welcome and expect, and hope for good feedback from you all so that we can make sure that as we're embarking on this new approach where we put out these voluntary editions in the interim between the stages that we get your feedback and that we can do it in the best way possible. So, stay tuned.

Hopefully, we'll come back at the next meeting and we can give you an update on the NPRM. And with that I think we can open it up for questions.

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

So, let us consider the floor open for questions. Great presentations Doug and Jodi. Let's open it up actually backwards. Maybe if there are first questions about Jodi's comments on the taskforce and MU feedback, the floor is open.

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

Jon?

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

This is Wes Rishel here.

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

Let's see did I hear John Halamka? I wanted to –

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

Yeah, let me just frame this a little bit because I think we'll have a rich discussion about it. The Meaningful Use Workgroup initially proposed some 18 policies, suggestions and then suggested that there were certain certification criteria not that specific, but just sort of general certification criteria around those 18 specific policy goals.

And in their first iteration they did not include any measure of standards maturity or difficulty of implementation, workflow change, impact on providers, etcetera.

So, they came back and created a beautiful grid, which I understand Michelle was the author of that framework, so thank you Michelle, which included such measures and most of them were good. I mean most of them were actually fairly accurate but there were a few that needed refinement.

And so just to clarify with Jodi, I presume what the output of this taskforce would be would be take that grid, offer the expertise of the Standards Committee both on the standards maturity side but also because we deal with the implementation, workflow redesign and such things from an IT perspective and refine that grid so that as decisions need to be made eyes are wide open as to difficulty, maturity and impact something like that.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

John, I think you said that perfectly. That's exactly the kind of feedback that we'd be looking for from this taskforce, from the full committee and then from the discussion that we have incorporating the poll and the taskforce work.

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

And just to give folks sort of a sense of the kind of granular detail we'd have to explore there's actually been really great work done by the FDA on the universal device identifier to understand, where is UDI and implementation? What would be the role of the EHR? What would be the workflow for the patient and the PHR? Where are we with UDI? Because it's really wonderful work.

And then there are some things that are, you know, slightly more aspirational. We all love clinical decision support and there are many aspects of clinical decision support you could imagine EHR consuming external rules like immunizations, Boolean logic based on age and more complexity, let's say the integration of family history into clinical decision support. Where are the standards, the rules and the workflow with regard to that?

So, I think it would be one of these discussions where it's going to be hard to achieve complete consensus, but probably we'll at least be able to come up with easy, medium and hard designations.

So, I think certainly Jodi you have my "I'm volunteering to be a member of your taskforce."

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Great John, thank you.

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

Okay and John thanks for those very helpful framing comments and Jodi for affirmation of that. I believe we have Wes's card up and we'll start there.

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

Well, thanks.

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

Jon, this is Michelle, I just want to mention there's a number of people in the queue. So, after Wes, I can go through the list.

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

That would be great.

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

Yeah, Jon, I apologize I missed the start of the call and I didn't realize the protocol, I just put my hand up and I'd be happy to wait for my turn or I can give a question and a comment now?

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

Why don't you go ahead?

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

Okay. So, I'm responding primarily to the section on certification that Jodi gave. I have a question and a comment. I will state them both and then you can move onto someone else afterwards.

My question is, do we anticipate mandatory recertification at the next Meaningful Use Stage or is this voluntary in perpetuity?

And my comment is that I think we're all aware of the importance of certification and also the limitations of certification in terms of not being a complete or even a semi-complete – there's an awful lot of noise in the background here. Can everybody hear me okay?

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

We can hear you.

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

Yes.

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

Yeah, okay.

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

If people have open lines please do mute.

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

All right, okay, so certification by being mandatory has some limits in terms of what it can expect, which leads to not – you know, the situation where two certified vendors may not interoperate.

I hope ONC will look at other voluntary means of a more comprehensive set of interoperability testing along the lines of the work that HL7 is looking into now. So, the question is about whether it becomes mandatory at Stage 3?

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

So, you know, again it's hard to say what we're going to propose for Stage 3. I think that is something we would consider doing. So, I think folks should, you know, look at the criteria and give us feedback about – I mean, some of these things are upgrades and as I mentioned, you know, upgrades in standards and implementation guides and that kind of thing.

So, we're just trying to kind of keep pace with what's been going on. So, if the standard has developed it is likely that we would, you know, require the new standard if it's something that's becoming more widespread. If it's something new then I think that, you know, that's something we would consider.

So, I think you should look at it with, you know, that as a possibility. Again, it depends on, you know, the particulars and how things go, if we, you know, it's hard to say what are policy decisions will be in the future, but yes the goal is to sort of put things forward earlier so that folks can start working on them earlier and we would consider things that we put forward and these interim editions being put forward as mandatory in the future. But again, I can't tell you what the policy is going to be.

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

Yeah, that's laudable, but, the force of mandatory certification once in a while at least helps to bring a lot of vendors into line that might have otherwise put resources elsewhere. So, thanks.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

And I just want to also remind folks our certification program is – even the one that is tied to Meaningful Use is in fact a voluntary certification program. It's of course tied to the incentive program so there is a greater market for products that have been certified.

But, there is nothing that, you know, somebody isn't violating a law if they have a product that has not been certified it is just not compliant for purposes of Meaningful Use Program. So, I just want to make sure that that's clear as well.

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

Thanks, Jodi and Michelle – and thanks Wes for your comments. Michelle you have a list of people who are trying to weigh in?

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

Yes there are four people, so Jeremy Delinsky, Eric Rose, Cris Ross and then Arien. So, we'll start with Jeremy.

**Jeremy Delinsky, MBA - Senior Vice President, Chief Technical Officer – athenahealth, Inc.**

Great, thank you, thanks for the updates Jodi and Doug. Just a quick question on certification. So, I think everyone sort of was aware of CCHIT dropping out of the certification, being a certifying body and I think that they had the largest number of vendors of any of the bodies so far. And so are you watching those cues and those transitions to see whether companies are making it through certification in a timely basis and are you at all worried about all the migration to additional testing bodies when CCHIT stops which I think is this month, I think they're effectively taking everything that was in queue and transitioning. So, I'll just take the question or the answer.

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

Well, this is John Halamka. I happen to be one of those doing CCHIT certification. So, let me just quickly speak from experience. They will continue operations until May at which point the staff currently working on certification will be reassigned to other tasks.

And they have been working unbelievably hard and diligently to get every single hospital and eligible provider's certification in their queue currently done before they transition to ICSA officially in May.

So, at least as a guy who is experiencing the process, I've both experienced goodness on the CCHIT side and very smooth transition and coordination to future maintenance by ICSA. But turn it to ONC because you may know more.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

No, we've just talked with them and we know that they're trying to provide for an orderly transition. We don't have any specific concerns at this point in time but we're paying attention to what's going on.

And I appreciate your comments, John, about what it's like from the perspective of somebody who is going through that, that's helpful.

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

Well, thanks, Michelle go back to the next two.

**Michelle Consolazio – 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**

Well, hi, I'd be happy to serve on the taskforce that you need folks for. I just wanted to make sure I understood that the document that needs Standards Committee feedback is that already – has it already been published or made available?

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

This is Michelle, so there has been work on the Meaningful Use Workgroup side, on the policy side, and they've been using their own document. I think once we identify who the taskforce is we might work on something that can specifically get to the answers that we're trying to get to you for the standards side. So, we'll work with the taskforce on that.

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

Okay.

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

It sounds like John Halamka is ready for that.

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

– wanted to make sure I hadn't missed something that had already been sent out. Thanks.

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

Great I think you're referring to the grid and –

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Yeah it is still a work in progress but we can share something that is preliminary with the taskforce.

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

Great, okay, who is next, Michelle?

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

Cris Ross.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Good morning, this is Cris, Liz Johnson and I from the Implementation Workgroup have been sharing notes here during this discussion and I appreciate the updates we've been getting. Specifically on this issue around getting feedback on Meaningful Use 2 I think we'd like to volunteer, at least ourselves, but hopefully the whole Implementation Workgroup to take a look at that feedback.

One of the issues that we've run into has been the balancing of idealism and pragmatism, readiness of the industry with ambitions to make things better. So, I think it's useful to take a look at the Meaningful Use requirements to some degree from a stand-point are they achievable regardless of whether they're good, you know, important, critical and so on. How do we balance it against the realities of the industry to actually implement? So, I think we'd like to participate in providing the feedback that Jodi requested.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

So, is that Cris and Liz both volunteering?

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

Yes.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

I think she's volunteered.

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

I am, I'm here, we've been exchanging e-mails, you know, that side-bar stuff, thank you.

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

Great and just as a note that it probably is worthwhile for anybody who has interest in the taskforce and I understand Cris and Liz your suggesting something slightly different which is the lens of the Implementation Workgroup in terms of making sure that there's a readiness for prime time.

But I would just note that anyone who doesn't get a chance to express interest in being on the taskforce please just send your expression of interest to Michelle and that would be great and we can help her find candidates from what is going to seem like a number of volunteers. With that Michelle back to you. There was one more in the queue?

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

Jon Perlin, John Halamka, just so folks know if they do want to take a look at the deliberations of Meaningful Use Workgroup if they just simply go to the ONC calendar for the Meaningful Use Workgroup and click on February 11<sup>th</sup> you will see the grids, the presentations and the discussion that we referenced.

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

Terrific John, thank you.

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

Thank you John and just adding to that there is a Meaningful Use Workgroup meeting tomorrow so that document that John just referenced will be updated. So, stay tuned. Arien Malec has a question.

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

Great, thank you. So, it occurs to me that the fixing certification criteria that may need fixing is a different concern from adding new standards or certification criteria that haven't been in previous certification criteria. So, obviously you can't comment since it's in process, but I hope there is some mechanism for allowing developers to certify or recertify on fixed criteria without needing to certify against new criteria then to be added.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Well, I can say one thing Arien which is that we do provide for modular certification and gap certification. So, I would anticipate that folks can choose to certify, again it depends on the certification bodies, but folks should be able to certify on those things that they want to certify to and not necessarily have to do the whole package.

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

All right.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

So, I think that's consistent with our current approach so I would suspect that when we get out of the – making we'd still be in that same approach.

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

Excellent. Thank you.

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

Great, Michelle, are there other people with their virtual cards up?

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

No one else is in the queue.

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

Okay, other comments either on this or switching to Doug's portion of the presentation and comments for Doug?

Okay, well thank you very much both to Doug and to Jodi for terrific presentations and also to each of you for a robust discussion. It sounds like there is a queue of activity which will go on with the Policy Committee but also a set of activities that are being referred to our Workgroups, Power Teams and to this taskforce.

Again, if anybody has interest in serving on the taskforce just get your name to Michelle and I appreciate your volunteering for extra activity. With that let us move to the last formal item on the agenda and that is the, other than the public comment which is always extraordinarily important, and that is the Consumer Technology Workgroup Patient Generated Health Data. John Halamka you were working with Leslie Kelly Hall and Russ Leftwich would you like to make some introductory comments to this section?

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

I would, thanks very much and so of course all of us think patient and family engagement is one of the most important kinds of interoperability and as folks in the committee have heard me several times describe the experience I've had with my father, my mother, my wife, etcetera it just illustrates how important it is to have bidirectional interoperability with patients and families.

What's interesting of course is to ask the Dixie Baker question of what is the state of standards maturity and applicability for a given purpose?

And so what Leslie will present is taking a look at what transactions we think we can enable today given the experience we've had with Direct, C-CDA and other standards that have been tested in the field and where are there areas where additional work is needed.

And in some ways the use cases that we should include in certification are probably those use cases which are best served by standards which are suitable for purpose and mature so you'll see some interesting tension here of what we want to do versus what we can do given the state of standards experience.

And then of course she'll also describe where we are with devices. And we all believe that in a global capitated risk world having continuous wellness as opposed to episodic sickness is going to require more telemetry from the home and therefore standards-based devices will become increasingly important. So, Leslie, please go ahead.

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

Thank you, John. I wonder if Russ Leftwich is on the call? Okay so it might – I believe it's just me. So, I'm going to take you through background slides of the team's deliberation and then we'll go to the recommendations toward the end and then take questions after that if that's all right. Next slide, please.

So, the Consumer Technology Workgroup has been meeting for over a year and from this group we discussed some of our initial findings at the Standards Committee at least twice and were given some great consideration and recommendation including taking a stop at the clinical work team to review our findings and have further discussion. Next slide.

We broke out into a smaller taskforce to look specifically at the questions that this group raised around maturity of the standards, applicability, what would be both reasonable or directional versus mandatory and so we deliberated further and presented a considerable amounts of work back to the Clinical Operations Work Team. Next slide, please.

So, our charge was to take a look at standards and interoperability related to patient generated health data. Next slide.

And there was a real emphasis on interoperability between systems. Tethered PHRs may continue to operate with proprietary approaches for internal use and that might be where the most activity is happening today. However, we feel that interoperability with non-tethered consumer applications and products and devices is really a hopeful direction. I am having a hard time hearing. Is anyone else having a lot of background?

Thank you. We also wanted to make sure that anything that we did was consistent with communication efforts that were already going on in standards but to be mindful that patients say "hey, I don't want a bunch of PHR portals to go to. I want to send the same information in the same way to all of them." Next slide, please.

If you recall, this slide represents from left to right a continuum of patient generated health data from messaging to structured questionnaires, unstructured questionnaires and narrative documents, device data, plan or plans of care and then collaborative care planning. We felt that anything we did on the left should help to inform the things as they move to the right. Next slide, please.

So, we looked at what existing standards could be used and applied to patient generated health data. And as you recall in our early discussions talked about the Consolidated CDA, Direct and also the care team roster within HL7, the Continua Alliance group of standards and then the HL7 care team roster. Next slide, please.

We looked at the Consolidated CDA as a garanimal. This approach that's been taken in HL7 of the header approach has really provided a lot of flexibility. So each template is a set of instructions of how to use the HL7 Consolidated CDA for a particular use and the templates can be combined to form two different types of documents where it's provider centric we're using a provider header. We're using the Consolidated CDA with the patient generated template for the patient generated health data. Next slide, please.

So in a header approach all benefits apply to all authors and there is no separate but equal approach for patients. We felt that it encouraged innovation and collaborative records and an EHR that was capable for any Consolidated CDA could be capable for all. Next slide, please.

We further went into some examples around how the document header for providers or patient consumers worked and discussed a good deal around the provenance that is carried with the document that was a question that this team asked over and over again. Do we have a clear direction of the document authorship, who is the guardian, the custodian and several of the other items that helped to guarantee provenance of the particular document type. Next slide, please. Next slide.

The care team roster, as you recall in the 2014 certification edition, it was mentioned that there should be the care team noted, but there was no specificity, not mentioning things like the encoding was basically text, there were no specific attributes, there was not a caregiver mentioned at all and the use case were focused on the transitions of care.

In this current effort under HL7 we really are looking at health professionals, family, community members who provide care to the patient or the patient are all involved in care planning and it's very specific within CDA entries. The contact information including the physical and electronic address, taxonomy role and unique identifier are there.

We include within the family caregiver attributes things like contact information and including an electronic address which could be a Direct address, the familial relationship as well as legal relationship and this helps to move us to a longitudinal care coordination and care plan versus a more episodic or one-time use case. Next slide, please.

We looked at four different use cases, how to share information about medical history, advance directives. We looked at forms and questionnaires things like medication information and then device data for the patient, data reporting uses using industry standards and where data provenance is also encoded. Next slide, please.

The standards that supported the use cases, we again took an emphasis on existing standards already named within Meaningful Use criteria and then expanded on those use cases to accommodate patients. In this case, we were also looking for proof points where could there be industry examples that existed today, in a very innovative way? Next slide, please.

So, this particular example is from NoMoreClipboards but there are many other organizations that also participate in this and it's using the Consolidated CDA and also the Blue Button to download information and to present that information back with an emphasis, in this case, on medication list, which was one of the use cases that this group as well as the Meaningful Use Group talked about. Next slide, please.

The advance directives use case, in this example, we used a proof point from mydirectives.com and one area of concern was that not only we were providing information or perhaps a link to the current record, but also link to the most active record, the most current version of advance directives using this same approach. Next slide, please.

We looked at the maturity and we looked at if something is mature for provider world but is new to patients, it's probably somewhere in the moderate world. Next slide, please.

So, for instance in the Consolidated CDA for questionnaires the care team roster and device use were probably somewhere in the pilot to national standards in that the Consolidated CDA has been named. We want to build on those current efforts to advance for the patient. Next slide, please.

As far as Direct, we believe that many of the issues that apply to providers will also apply to patients and family members. There is work going on in DirectTrust to help answer some of these questions. For instance, a patient might have multiple Direct addresses, wants some things public in the directories, some things private. There are privacy issues, there is level of assurance, a provider might have someone on their staff that is only retrieving information and has a lower level of assurance than perhaps that provider, acquisition information, security information and the trust structure.

More and more we are seeing that all of these issues apply to any participant and taking a look at the policies around the use of Direct for all care team members might be a good way to go forward. Next slide, please.

So, in looking at Continua I think of Continua more as an IHE than an HL7 and we asked Continua to help provide us information about how Continua works and it really constrains existing standards by creating implementation guides. It constrains underlying standards by requiring specific implementations, when things – optionality is available.

And we include things like in the Continua standards, like the personal area network, application hosting devices, wide area network information and health record network. This group, as well as the Meaningful Use Group talked about making sure that any kind of device data not only did a, perhaps a singular synchronous feed but also aggregate data could be taken and pulled up in a batch mode or even in some sort of RESTful approach. Next slide, please.

So the Continua looks at all these levels, the hub, the WAN and the health record network and allows for an existing infrastructure to be compliant over time. There are currently five versions of the implementation guide and Continua uses only existing standards with no new IP nor acts as a standards development organization it's more like an IHE. Next slide, please.

The use cases that we looked at here were the exchange of patient generated device data and active link and the exchange of patient generated device data within an e-mail. The proof points we used were the NIST Continua Conformity Tests and the e-mail exchange in the HIMSS interoperability showcase. Next slide, please.

These are some of the specifications that have been completed to date. Of interest in the Consumer Empowerment Group were things like blood pressure cuffs in the home, weighing scales in the home, glucose meters. Next slide, please.

So the Continua model of connectivity as depicted here really talks about a variety of devices using existing standards in implementation guides that can promote more interoperability. Next slide.

We also looked at patient reported outcome measures and the work in PCORI really emphasizes our need to advance this in a standards way. And we looked at questionnaires both structured and unstructured, and narrative, as was our focus given to us by the Meaningful Use Workgroup, and looked at devices integrated into this approach. Next slide, please.

So the use cases where the exchange of patient reported outcome measures and the exchange of a patient response and many of these particular standards should look familiar to the group as well. Next slide, please.

So, as we look at structured and semi-structured questionnaires, we look at templates for questions such as multiple-choice, numeric, free text, analog sliders and discrete sliders in a questionnaire form for any patient reported outcome measure. We've also seen templates for preconditions to ask a question. So, for instance if a question is yes previously then it goes to a new thread.

And important for this group were things like templates for copyright. So that if people were using existing copyrighted questionnaires and structures they could be honored within this standard. Next slide, please.

So the patient generated responses we make use of the Consolidated CDA header plus the patient generated header template and for clinician generated responses we make use of the Consolidated CDA header template. And the templates for capturing patient response to questions in the patient reported outcome measure. Next slide, please.

This is just an example of some of the XML structure that represents the templates for multiple-choice. Next slide.

And so with that background, John and I then went forward in discussing specific recommendations. Next slide, please.

It's very important that we have concern regarding certification only items as systems must be engineered to incorporate standards and processes which may not yet be mature and so this is sort of an overarching discussion and that standards applications should be constrained where they are needed and useful just like discussing something that might be an internal PHR or tethered PHR has not the same need as something that's coming in from perhaps a consumer centric system device or PHR. Next slide, please.

So, where there is a need for patient data sharing the Consolidated CDA is suitable. It's recommended as a container for certain types of templates that are well understood like problems, medications and allergies. And using the Consolidated CDA over existing exchange and other modes of transport are reasonable ways to get data in and out of EHRs, PHRs and other patient facing applications.

It should not be required as an architecture that organizations have to use because many organizations will have made a compatible system decision like in an ACO. But the outcome goal is that the entire care team is able to contribute to an integrated medical record.

If unable to integrate systems must have the functionality to receive a Consolidated CDA containing specific templates but the need to allow for innovation and flexibility in this space to not unduly constrain options for individuals to connect with their care team in ways they prefer in the future. So, we suggest using the Consolidated CDA template payloads that are sufficiently mature but not over specify how they are moved about. Next slide, please.

We want to allow for innovation as the marketplace is still rapidly evolving in the device area. We believe that the Continua standards are directionally appropriate, but we also urge ONC to help with aligning efforts with FDA guidance and other regulatory or sub-regulatory policy without constraining the marketplace.

And due to the immaturity of the market we need to allow for flexible adoption of device data and other remote data sources. We really discussed this for a long time in many of the teams and this idea that data coming out is probably – can be much more easily directed into the consumer world but data going in has to really blend the need for standards with innovation requirements. Next slide, please.

So, engaging families in our care that's what this is all about. So, for patient generated health data the recommendations for Stage 3 functionalities are that the eligible providers and hospitals receive provider requested electronically submitted patient generated health information through structure or semi-structured questionnaires or secure messaging and this helps us to meet our long-term goal of enabling patients to access and transmit their information, provide ability to contribute information to the record including patient reported outcomes and provide tools to help the patients actively participate in their care.

And this gets to that nexus point I believe we all talked about, about asking the – making sure we have standards that when the provider wants information and the patient wants to give it that nexus point is really about that patient response, provider requested electronically submitted patient responses. And I think that concludes the slide deck.

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

Well, Leslie, thanks very much and I'll be happy to facilitate discussion. Just as a quick summary, Jamie Ferguson made some really important points as we formulated these recommendations such as if his organization has a fully integrated shared record that patients, providers and families can access, maybe different user interfaces, but it's a common shared database, in a sense, you achieve the attestation criteria of wanting patients and families to be able to submit data and answer questionnaires on those sort of things without the need for mandating a C-CDA as the internal mechanism to support such functionality.

On the other hand, imagine if there is a completely decoupled PHR, an EHR were there isn't the concept of a shared medical record in an ACO that, as Leslie put it, the doctor wants information from the patient and the patient would like to contribute it then having some payload that allows the transition of data from one application to a separate application is important.

And that being said, although Direct is something we all use in multiple context as part of Meaningful Use Stage 2, when you look at the ecosystem that is evolving, of course we've got Blue Button, Blue Button Plus, but there are all kinds of very interesting Apps that are evolving and some may use a RESTful protocol or some may use a file download, all kinds of different activities exist today to get data from a provider and from patient and family to a provider and so this is our tension.

Where do we specify? Where is it useful? But how do we avoid over specification that quashes innovation?

And same challenge we face on the Continua Alliance activities. There's no question that Continua represents a great consortium of companies and the IEEE 1173 standards are regarded by almost every stakeholder as mature and appropriate for purpose, but yet we look at homecare devices and it isn't as if the bulk of devices in the US marketplace are ready to plug-and-play using this implementation guide.

So, how far do you go along in requiring that set of implementation guides versus saying, you know, we believe the market is going to evolve very, very rapidly. Directionally, we think this is exactly right. So, this is a signal to manufacturers start getting those devices into the marketplace because certification may be coming. So, Michelle, let's open it up to questions. Are there folks in the queue?

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

There are Andy Wiesenthal and then Dave McCallie.

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

Andy go ahead?

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

So, hi, good morning everybody at least it's still morning for me and maybe for you all for a couple of minutes and I've been listening avidly. I thank you very much, Leslie, for all the work. I was going to make some comments that sounded a lot like Jamie's because our experience is shared so I won't repeat those, but I'd add one other observation and it comes from my experience as a pediatrician.

And I'm very cynical and skeptical of the possibility that most people will make any serious effort to diligently maintain a freestanding PHR and so standards that we elaborate really ought to focus on them, the patients, moving information when they are asked to or when they feel the need to and responding to requests for information from various actors in the healthcare delivery system focusing attention on helping them build freestanding repositories of their own clinical data, in my view, is a fool's errand and they won't do it.

The success of what we call PHRs in the marketplace today, they really aren't PHRs, they're exactly what Kaiser Permanente has, they're a view into your own information in a shared database and they are the most successful things and it's because it doesn't require any work on the part of the patient and people really like all the transactions that they can do.

So, I support the notion of the C-CDA and mechanics for people to move information around wherever they do and I would focus our attention, for the time being, away from the notion that large masses of people will be diligently maintaining their own freestanding health information, because they just won't do it and if you think otherwise, again, remember I am a pediatrician, I've had two generations now of observing what happens to baby books for the first kid and the second kid and the third kid and look into your hearts, for those of you who have children, and think of how diligent you were with that and third child and you'll understand where I'm coming from. So, that's the end of my comment. Thank you.

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

Can I respond to that real quick? I thank you Andy and I think that when we use the term PHR it was more with the mind that having – there are many products on the market that are acting as intermediaries from several different sourced information coming from the provider on behalf of the patient.

So we weren't thinking at it as singularly as the patient maintaining your record. As a twin I share the skepticism on maintaining baby books. It just didn't happen with twins. So, but thank you for that caution.

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

And Andy as an only child I have no idea what you're talking about. Anyway, thanks so much Andy I think those are very – those comments are precisely in the spirit of what we tried to articulate which is let us absolutely assume that many vendors will produce fully integrated products and in that case, standards are neither helpful nor necessary. But as Leslie just said, in the case of middleware, creative Apps that entrepreneurs may author, there may be a need for getting data from patients to provider and back and C-CDA is probably a reasonable container in that specific circumstance. Okay, Michelle?

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

Dave McCallie.

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

Dave McCallie, please.

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

Yes, hi, I want to reiterate the cautions of John your relating of Jamie's observations and the previous observations and say that we have to really be careful not to over engineer something that needs to be really simple and flexible.

So, I was following along and comfortable with the notion of the C-CDA, well, as comfortable as I could ever be with C-CDA, which is not very comfortable, but comfortable that for the producer systems to send a copy out to the patient for local memorialization that makes sense, but when you start talking about CDA defined forms to capture data from the patient, I think you've gone too far.

I don't think we have any business trying to engineer another forms definition language. If somebody needs information from the patient send them a link that takes them to a webpage that captures that information using appropriate web-based technologies and then focus on the data not on the definition of forms definition languages.

So, I think we, you know, look at this stuff, zoom out, step back and make sure we're not over engineering and over complicating something that just, you know, will put a huge burden for relatively minimal gain.

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

And so Dave let me just respond and then Leslie I'll turn it over to you. Absolutely, it's those exact sentiments that we tried to incorporate in the documentation assuming that the vast majority of providers and hospitals will actually provide fully integrated websites for these sorts of things and the C-CDA was not meant to be used as a forms definition language or in the context of such websites. It was more in the context of there is an App, there is an application where a patient has their medication list and would like to forward that medication list to a provider for reconciliation.

And as Andy Wiesenthal said, you know, these may be much rarer than the kinds of questionnaires about medications delivered by a provider organization via a fully integrated webpage.

So, it's just really how do we capture the sentiment of all the comments here that if you had the webpage and it is integrated, no standards required, but if you don't a C-CDA is a reasonable container for the transmission of say templated information like a medication list or a problem list where C-CDA is absolutely suitable for those purposes.

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

Yeah, I – this is David again, I agree that the CDA for transport across system boundaries is a good idea. I just get really uncomfortable if you start trying to use it as a form definition language. That's just crossed over into over engineering.

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

Right, well said. Now, I would also look forward to any comments that anyone has on the Continua Alliance device work, because that's again, we struggled with that, given that this is in effect great work, accepted by many, but in terms of market adoption in the United States it's just on the cusp. So, we wanted to be careful, as David has just said, you know, where do you under specify to continue to allow the market to evolve? And Michelle any other – any people in queue?

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

Arien.

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

Arien, go ahead.

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

Thanks, John, I just wanted to respond to that last comment and just spawn some thoughts that this is a classic ecosystem problem. You're not going to get an ecosystem of devices that can upload into an EHR until you have an ecosystem of EHRs that can accept device data and vice versa.

And it may be worthwhile to consider rigorously specifying the interface into an EHR even if there aren't an ecosystems of devices that can do the upload under the assumption that intermediaries will take on some of the impedance mismatch. And, you know, there are already folks like HealthVault and others that can accept a variety of device inputs, but they don't really have any place to put the resulting data.

So, just a thought that we may be – it may be more practical for us to consider the EHR input aspect of the ecosystem. We may not need to think about or worry about the device ecosystem.

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

And I think very good point. Leslie, any comments that you would have? I guess I would just add that we would have to carefully understand the burden this would create on EHR implementers to actually look at the development necessary to receive such payloads in both transport and content standards.

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

Yeah, I agree. I think that's one of the reasons why when Continua discussed things they put so much emphasis on the Consolidated CDA, Direct for transport and using the patient reported outcome measurement structure because they wanted to align with things that were already being worked on.

So, it is – it's a good caution, though. One of the feedbacks that we received was something very narrowly specified can actually help innovation because the consumer technology vendors can focus on just that and let the market expand beyond that, which I think is very much aligned with Arien's point.

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

And so Arien one wonders if what we said was on devices, you know, there is this IEEE 1173 construct that is really more device specific but if the EHR was capable of receiving a C-CDA via Direct, I mean that may come from middleware, a hub or some other thing that would certainly not add significant additional burden because Meaningful Use Stage 2 already requires such a capability.

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

That's absolutely correct. I'd also look at the ORU specification for labs since many of the – much of the device data actually looks like lab data as well and that may be another scenario where we look for harmonization.

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

And Leslie, Liz Johnson had to drop off but she offered a comment which I think is helpful, which is our Implementation Workgroup is always exceedingly helpful in doing market surveys or talking about where is the industry headed so the comments that Andy Wiesenthal made and Dave McCallie made, you know, should we wish to get a sense of where are their products out there that might actually hit the use case of needing a C-CDA, Liz has volunteered to help us do a brief survey.

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

That's great –

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

John, this is Michelle –

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

And welcome.

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

Sorry.

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

Go ahead?

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

We have a number of other people in the queue.

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

Oh, please go ahead.

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

Wes Rishel and then Dixie.

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

So, Wes, go ahead.

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

Yes, I think there is an opportunity to synthesize some of the things that Andy and Arien said by recognizing that there are two distinct submarkets for patient devices. One is really driven by the traditional device manufacturers and focused on certification by FDA approval and things like that and the other is the things that are marketed through consumer channels directly to the consumers.

I suspect that we're going to find, we're going to continue to find that a lot of the consumers stuff follows the usage pattern that Andy described, which I've described as the New Year's Day to Super Bowl usage and when providers develop more structured ways to integrate data into actual interactions between the care team and the consumer we'll see a little more attention to rigor in data content. I just hope that we have not packaged our understanding of the data content into a set of format standards that are difficult for the innovators in the industry to deal with. Thanks.

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

And so Wes, very well said. I think two points to make is that we know that if it is in fact transport of things that have templates well-defined in C-CDA that that probably not an impediment to innovation.

If, however, we try to shoehorn in something like a completely unstructured question and response into C-CDA that's not precisely the way C-CDA was designed and so that could be an impediment to innovation.

Another thing we do need to consider is FDA guidance is both regulatory and sub-regulatory guidance and Jamie Ferguson, I know you had some thoughts and comments on some of the work the FDA had done in this regard and I wonder, is the proposal that Arien made about an EHR should be able to receive a package like a C-CDA over Direct going to be coincident aligned with the work FDA is doing on device data transmission in general?

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

Well, thanks, John, you know, I mean, I don't know all the work that's going on inside the FDA, but obviously, for devices that are intended to inform clinical decisions there are a large number of varying data requirements that have not yet been considered in the CDA or the C-CDA or the other versions of messaging that are included in the Continua specifications and others. So, you know, I'm not sure how to, how best to create that kind of coordination.

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

Well, I would say a National Coordinator would be very helpful. What do you think? Doug, anything you would add on coordination with FDA?

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

Well, yeah, there's – I can see briefly with it – there's a number of different touch points. Jodi Daniel actually is probably the best person to talk to since she's been deeply engaged in a lot of the FDASIA work.

I think what we're talking about here probably goes beyond some of those activities. We also have some connections with the FDA around the clinical research activities related to PCOR because obviously, there are some need to make sure that pharmaceutical and clinical research are both using consistent standards there as well. So, I there's some opportunities here. I don't know, Jodi, if you wanted to say something?

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Just to follow onto Doug. We do have a very close working relationship with the folks at FDA on the device side as Doug said we've been working very closely with them on the FDASIA work. And we also have talked with them about some of these other related issues on, you know, remote monitoring devices and device EHR interoperability and things like that.

So, you know, there is an opening for us to have those conversations with them and like I said we've already started, we've built some very close working relationships and they really are trying to help support the work that we're doing. So, I think we're on target. But, we're looking, you know, look forward to your insights and input on how we can – on issues that we should be working with them on.

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

Right so I think just to Jamie's point, we just have to be so careful that we don't to make recommendations like we believe that an EHR should be able to receive a C-CDA over Direct from a provider or a patient, you know, seems sort of reasonable and consistent. And then the FDA says "ah, but we're about the data integrity from a device which must now follow certain kinds of 510(k) certification guidance and a transformation into C-CDA by middleware does not align with our thinking."

And so, I guess we would offer, what you've heard on this call, is a few forward thinking suggestions, directionality, but, the request that as regulatory language is written that it is double checked with our colleagues at the FDA. So, I believe we had Dixie Baker, as well?

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

I was just getting ready to take my hand – I just would like to emphasize a lot of the other comments that have come out since I raised my hand. But, I would observe that maybe add one thing, is that the consumer health market is evolving so fast that I think it may be futile to try to anticipate where it's going.

And secondly, and this is perhaps a new point, is that we don't want to strongly constrain the types of information that we can get from consumers and I think that's particularly, you know, that the types of data they'll provide will expand as the consumers become more engaged in their health and as these new mobile Apps continue to enter the marketplace.

So, I agree with Arien that it's better to focus on being able to accept the data from the consumers and also to capture the provenance of the data in the EHR than it is to try to, you know, lasso or constrain, you know, what's happening in the consumer health marketplace because it's such a dynamic market right now.

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

So, I'm sure Doug there's probably a corollary to Postel's Law that applies here, right? That is the devices will continue to rapidly evolve and we hope that our EHRs have a little bit of flexibility in receiving the payloads they may emit.

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

We can call that Halamka's rule.

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

Oh, gee, dangerous. Michelle, are there others?

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

Becky Kush.

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

Yes, Becky?

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yes, I just wanted to comment that there is a guidance that went out late last year from FDA called eSource guidance, which does talk a little bit about EHR use in research and we have been very intimately engaged with the FDA on some of these regulations in terms of the structure data capture initiative and some of the other work we're doing with ONC.

I believe that Dr. Fitzmartin was going to attend the meeting today had we had it in DC face-to-face. So, at some point, it might be worth giving an update on those connection points with FDA because I work with them daily.

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

Right and so Jodi I would ask, I know the FDASIA work continues to evolve. Is there planned an agenda item for FDASIA FDA update in the next few months?

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

We would be happy to do that. The FDA said that – they said publicly that they were trying to get out the FDASIA report by the end of March. It is something that will go out for public comment, it will be a draft for public comment. So, there is an opportunity to weigh in. And I think it would be – you know, we can talk to our colleagues at FDA or I could do it. But we could give you an update at the Standards Committee about what's in that report and get any feedback.

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

Great.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

I'd just add, John, this is Becky again, this work that we're doing goes beyond the FDASIA report. It's a whole different congressional mandate around PDUFA. So, I think that should be considered a different initiative.

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

Sure and I was just saying an FDA update, in general, would probably be useful and so given that Jodi seems to serve as that contact point, if in the next several months, as is appropriate, Jodi, you know, we could combine an FDA update on the issues that Becky has raised, as well as FDASIA update.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

If you all could – if you all could send Michelle – if there are like some bullets of the specific issues that you'd want addressed so I could forward it onto them that would be helpful.

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

Sure and so Becky, if you draft a couple of bullets and I'll add my own. Again, I just think we want to be very careful as we offer our advice to ONC.

I think we've heard so much guidance on this call we want to capture it all which is on the one hand we want innovation to occur, on the other hand we want to provide some degree of guidance where it can be helpful and useful and our Implementation Workgroup may provide us a list of products or classes of products where it could be useful.

And on the device side focus more on receipt then send and we just want to make sure that anything we specify is aligned with FDA guidance, specifically around the integrity of the data, so that there isn't a question if a 510(k) certified device is emitting the data that it's transformed in a way that would violate their guidance. So, we will get that to you Jodi.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology**

Thanks.

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

Michelle, any other people in the queue?

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

No one else.

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

Well, I knew this would be a very interesting discussion. I do want to add just one last comment. Dixie has reminded me that the Privacy and Security Workgroup will be holding a virtual public hearing on NSTIC on March 12<sup>th</sup> and so just keep that in your calendars for those who want to learn more about NSTIC and its – as we think about identify management in the future the role of NSTIC may become increasingly important. And turn it back to you Jon Perlin.

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

Well, thank you John, and great discussion, really appreciate all the input. All right, well, the time has come for public input into the process and want to take this opportunity, Michelle, to turn it back to you and invite public comment, such an important part of the open national dialogue.

**Public Comment**

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

Thanks, Jon. Operator can you please open the lines?

**Caitlin Collins – Project Coordinator – Altarum Institute**

If you are on the phone and would like to make a public comment please press \*1 at this time. If you are listening via your computer speakers you may dial 1-877-705-6006 and press \*1 to speak.

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

Michelle, I take it there are no callers?

**Caitlin Collins – Project Coordinator – Altarum Institute**

We do have a comment from Chris.

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

Great, please proceed.

**Chris Millet, MS – Senior Project Manager - National Quality Forum**

Hi, this is Chris Millet, I had a question on some of the comments made earlier in the call. I think a few members of the committee mentioned CMS/ONC LEAN Kaizen event that happened last week and one of the major themes from that event was the need for more governance or the need for I guess more coordinated governance across a lot of different bodies and I think that leads to a key question for this group as one of the significant groups that impact the standards we use across quality measures but also other things like decision support.

So that ask would be that as this group thinks about the work plan for the Standards Committee and follow-up activity from this call to factor in touch points to some of the other groups that are also undertaking coordination efforts and I'll go through a few of them to keep in mind.

One would be the follow-up Kaizen Workgroups that are following up on the LEAN improvement events. So, a touch point to some of those groups. A touch point to HL7, which I'm sure is already there but just to kind of re-emphasize. Touch points to the S&I Framework, which I'm sure also might already be there in some capacity. And I thought there was another but I think that should at least be enough to get started.

I think having those touch points in the work plan – I guess more regular touch points would be groups that help with some of the coordination issues, as the amount of standards we are using and that get implemented, grow and there are multiple places to find them. So, the governance for how the back and forth across all these groups is critically important and this group could have a really strong role to help with that governance.

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

Thank you for your comment. We'll take that into consideration as the materials of the process come out we'll try to be more transparent in terms of touch points.

**Caitlin Collins – Project Coordinator – Altarum Institute**

We do have another comment.

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

Michelle are there other comments?

**Caitlin Collins – Project Coordinator – Altarum Institute**

We do have an additional comment. David, please proceed.

**David Tao – Technical Advisor - ICSA Labs**

Thanks, hi, this is David Tao from ICSA labs. I applaud the work of the Consumer Technology Workgroup and the PGHD recommendations and Leslie's very helpful presentation.

I agree that Consolidated CDA does have flexibility with its header and body templates to handle new use cases such as an exchange format though not a form definition language for patient questionnaire responses.

However, I do caution against saying that an EHR capable for any C-CDA is capable for all. That seems a little overstated or might be misinterpreted. I don't think it's true with all current EHRs and it also may depend on what you mean by capable. Most EHRs or hopefully all certified EHRs would be able to successfully display any C-CDA but there will be great variability of capability ranging from zero to a lot regarding EHRs importing and consuming structured data from C-CDA. Thank you.

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

Thank you very much for your comments. Michelle are there others?

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

I think that's it for public comment.

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

Okay, let me thank the two commenters very much for being part of the public dialogue. Let me thank all of the Workgroup members before we adjourn I want to get some insight and logistical information for the next meeting from Michelle. But before we go to that anything else for the good of the order from any members of the committee? John Halamka, any closing thoughts on your part?

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

Just really look forward to seeing you all in Washington and developing our work plan together and serving our National Coordinator and doing everything as we need to, to ensure that Stage 3 rolls out as smooth as is possible for all the stakeholders.

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

Very well said and I join you in looking forward to that. Michelle, what can you tell us about the next meeting?

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

As of now I can't – so originally the March meeting was planned to be virtual. We'll have to see about hotels as we get into late March we get closer to cherry blossom season so it might be harder to find a hotel.

So, we will update you as soon as possible to see if our next meeting will be in person or virtual. I know we haven't met in person yet this year, so, we will try for that, but we'll have to see how that plays out. So, stay tuned.

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

Okay, appreciate that so we'll all keep on a little bit of hold, a flexibility around that date as we can and appreciate your work on that and appreciate all of the ONC staff, appreciate all of our presenters today. And I don't know if Dr. DeSalvo is still on the line, Karen any closing thoughts on your part if you are?

Okay. Well, let me then thank each of you for the work and the thoughtful commitment of time and interest in this. Really I think it is a very important meeting today. I think an opportunity to take stock of where we've been and John Halamka, as you said, to be very optimistic about the future. So, with that, we stand adjourned. Thanks to everybody.

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

Thank you.

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

Thank you very much.

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

Thank you.

**Public Comment Received**

1. Hi, this is the public comment that I would like to say on the phone when the time comes. "This is DT from ICSA labs. I applaud the work of the Consumer Technology WG and its recommendations on PGHD. Leslie's presentation was excellent. I agree that Consolidated CDA has the flexibility with its different header templates and many Body templates to handle new use cases such as Patient Reported Outcome Measure, in addition to more established use cases like ToC, so it can be like the "garanimal" that you mentioned. However, I caution that saying that "an EHR capable for any CCDAs is capable for all" could be an overstatement or might be misinterpreted. Perhaps it SHOULD be true, but I don't think it is with current EHRs. It may also depend on what you mean by "capable." Most -- and hopefully all -- certified EHRs will be able to successfully display "any" CCDAs, but there will be variability of capability ranging from zero to a lot, regarding EHRs importing and consuming structured data from CCDAs"

2. What is the best resource to learn about the Committee's perspectives & strategies on MU 3, 4, 5, 6,... 125 ?

3. I revised my public comment: "This is David Tao from ICSA labs. I applaud the work of the Consumer Technology WG and its recommendations on PGHD. Leslie's presentation was very helpful. I agree that Consolidated CDA has the flexibility with its Header and Body templates to handle new use cases such as an Exchange Format -- not a forms definition language -- to send Patient questionnaire responses, in addition to established use cases like transitions of care. However, I caution against saying that "an EHR capable for any CCDAs is capable for all." That seems overstated or might be misinterpreted. Perhaps it SHOULD be true, but I don't think it is with current EHRs. It may also depend on what you mean by "capable." Most -- and hopefully all -- certified EHRs will be able to successfully display "any" CCDAs, but

there will be variability of capability ranging from zero to a lot, regarding EHRs importing and consuming structured data from CCDA.”