

# HIT Standards Committee Transcript December 18, 2013

## Attendance

The following members attended the meeting:

- Dixie Baker
- Steve Brown
- Anne Castro
- 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
- Eric Rose
- Sharon Terry
- Andrew Wiesenthal

The following members were absent:

- Jeremy Delinsky
- Keith Figlioli
- C. Martin Harris
- Anne LeMaistre
- Nancy Orvis
- Christopher Ross
- Charles Romine

## Presentation

### Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

This is Michelle Consolazio with the Office of the National Coordinator, and this is a public call, and there will be time for public comment at the end of today's meeting. This is the 53<sup>rd</sup> meeting of the Health IT Standards Committee and if you are tweeting, the hashtag is #HITstandards for today's meeting, and as a reminder to the workgroup members or to the committee members I should say we are going to be using the raise the hand feature today so that will be on the top left of you webinar. And 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 Act Program Lead – Office of the National Coordinator**

John Halamka?

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

Present.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Dixie Baker?

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

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Anne Castro?

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

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Jeremy Delinsky? John Derr?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Floyd Eisenberg?

**Floyd Eisenberg, MD, MPH, FACP – Independent Consultant**

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Jamie Ferguson?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Keith Figlioli? Lisa Gallagher?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Leslie Kelly Hall?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Martin Harris? Stanley Huff?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

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 Act Program Lead – Office of the National Coordinator**

Becky Kush?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Anne LeMaistre? Arien Malec?

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

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Dave McCallie? Kim Nolen?

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

Hi Michelle, I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi Kim. Wes Rishel?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Eric Rose?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Cris Ross? Sharon Terry?

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

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Andy Wiesenthal? Steve Brown?

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

Present.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Lorraine Doo?

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

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Nancy Orvis? Charles Romine? Okay, and as a reminder, if you are not the one speaking please mute your line and this call is being transcribed and recorded so please state your name before speaking. I will now turn it over to you Jon.

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

Well, thank you, good morning everybody and thank you for participating and all of your work between meetings for the Health IT Standards Committee and an agenda to really move Health IT, patient care and the health of population forward. I say that because December and this time of year, end of the year always makes one reflect on accomplishments and I know that there is a lot in play for all participants in healthcare including first and foremost patients with the changes in our country. This is a point of evolution.

I know there is a lot of work that is left to be done but I would also just want to acknowledge at the outset all the work that has been done and encourage all of us to keep spirits up and keep the progress going forward.

I know for those who are involved in organizational activities, those who have been in a number of recent conferences around the Washington area that the ecosystem of possibilities as we'd like to describe it is increasing in terms of the ability to understand health services delivery and healthcare performance, and inform policy and create discovery, but that ecosystem is incomplete and that causes challenges and interoperability remains imperfect and that's in some ways on reflection inevitable.

At a recent Institute of Medicine meeting Professor Mary Shaw from Carnegie Mellon University talked about the necessity for incrementalism and standardization.

In fact, really on reflecting on her comments since when one thinks about the alternative, the sort of Big Bang theory, the rip and replace, it's just not a tenable approach. And so by definition incrementalism means that the intersections will be perfect in areas that we deem those of highest and most immediate necessity and imperfect as one move's out from that.

And I think when we reflect on our work there is a core where standards for content, vocabulary and transport, and value sets, and security and privacy are really not leading to harmonization but sufficient harmonization and even identity that interoperability is possible. When one moves out from that court then there is messiness.

And in reflecting on Professor Shaw's comments on incrementalism it really identifies that there's more work to do but that is a challenge and it's hard to imagine that the alternative, a rip and replace, would be a tenable solution. But it does lead to an understanding that we are midcourse and at midcourse I think it is an appropriate moment to celebrate the accomplishment that has been made thus far in the journey and to acknowledge the work that lies ahead.

And really I want to really remind everyone, remind myself that this is a journey and we need to keep moving forward. I wanted to say this also in the spirit of just as much opening comments as closing comments because alas in terms of the cycle of organizations we are having our budget and strategic planning extravaganza and so I'm in a break between numerous enterprise meetings.

But I didn't want the moment to pass without acknowledging both the difficulty of the challenge, the importance of the mission, the progress in the journey and the work left ahead and by way of acknowledging all of that thank each and every one of you for your extraordinary work, your diligence, your commitment and also our colleagues in government who work really around the clock and around the calendar in the proverbial Office with no Christmas and with colleagues in other branches to help us all keep our moving forward.

So, with that I wish you all very happy holidays and health, happiness and all the very best in the year ahead and turn over either back to Michelle if Dr. Reider has joined, if not to Dr. Halamka to chair the remainder of the meeting. So, thank you very much for letting me offer those comments and again a profound thanks to each of you.

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

And Jon Perlin may your budgets be happy and bright.

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

Yes, there is a Santa Claus.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you Jon.

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

So Michelle has Jacob joined us?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

I don't think so. Jacob? No, I think he's on his way but he has not joined yet. So, John Halamka if you want to make a few remarks?

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

Right, well of course we do have that administrative duty which Jon Perlin has now passed the torch to me. So we have our minutes that I hope you have received the draft copy of the minutes and of course as is usual we ask if there are any additions, amendments to those minutes and if there are no objections then we will approve the minutes. So, I'll give folks a moment to respond.

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

John this is Wes Rishel, I just have a question?

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

Yes?

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

In the minutes it's noted that I asked a question that Jodi Daniels would answer, what would be the forum? Would I expect that in the minutes? Would I expect that at this meeting? How would that question get answered, because I haven't heard anything directly from Jodi?

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

So, Michelle, point of process, if it's recorded in the minutes that Jodi was to follow-up I presume that would be a follow-up that would happen via e-mail or some other communication?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yes and I'm sorry I thought that you actually had received the response so I will forward that to you.

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

Thanks.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

And we can include it in the minutes.

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

Thank you.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yes.

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

Hi, this is Lisa Gallagher, also I had an edit for the minutes and I didn't know how to process that?

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

And so I would –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

This is Michelle, if you could just send that to me.

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

Okay, great.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

And we will fix it.

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

Thank you.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you.

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

So, we have the Wes amendment and the Lisa amendment. Any other issues? Okay, well Michelle the minutes are therefore approved. So, let me just quickly walk us through the agenda and then we will get started with Leslie's presentation on patient generated data.

So, we have several very important topics in our 53<sup>rd</sup> meeting today. First we will hear from Leslie Kelly Hall about patient generated health data and that of course has many contexts. There is device data that might come from instrumentation in the home or from personal devices like Smart Phones but there is also that which might be provided through question-and-answer in a structured form through a PHR or standalone web application. So she'll review the kinds of standards and the kinds of use cases.

The important thing for us to evaluate is as we listen to her presentation think about the maturity, the current implementation status of some of these standards because, I mean, we know that as we've gone through our various approval cycles in the past sometimes we have to be a bit edgy and we have to skate where the puck will be and approve a standard that looks pretty good for purpose but isn't widely deployed and other times we're faced with a dilemma that there's a need out there and the standard either doesn't exist or is a draft standard for trial use, never been deployed anywhere.

So, yesterday in a conversation with Paul Tang and Jacob we just reflected as we think of Meaningful Use Stage 3 we have to be pretty careful because there is, I think everybody knows, a fair amount of agitation in the industry right now that certain aspects of Meaningful Use Stage 2 were hard to implement from a certification perspective and so what Paul and Jacob had said is it's really key that we get Meaningful Use Stage 3 right.

And just for the group I did clarify that with the recent extension of Stage 2 to a third year and that means Stage 3 doesn't begin until 2017, if you think about it on the calendar, actually Stage 3 will take effect right before the presidential election. So in some interesting ways don't think of Stage 3 as something that goes to the next president and the next administration it actually takes effect with this president and this administration. So, as Jacob said, it's just so important as we choose the standards especially for a fast evolving area that we're just very careful and we get things right. So, pay attention to that.

And then we'll talk about image sharing and Jamie Ferguson will give an important preamble about image sharing. So, our challenge is not that different from patient generated data in some respects there is a fair amount that has been done in the past for image sharing and sometimes those use cases have been institution to institution kinds of exchanges and sometimes those use cases are highly constrained and integrated and complex standard stacks.

But we know we're at a time in history where we have consumer need and professional need, and we may see some evolution of what I'll call loosely coupled models that instead of using very lengthy implementation guides you might see more use of web-based approaches and cloud-based approaches.

And so, just as with the patient generated data we have to be so careful that we choose standards that constrain optionality but we don't so tightly constrain the possibilities that we say "oh, you must use the professional very complex and lengthy implementation guide for all purposes."

We want to allow that cloud-hosted web-based consumer or different types of architectures that might evolve and so you'll see our list of standards unfortunately does have a fair number of "or"s and we've talked about the danger of the "or" in the past because it implies that for an EHR vendor they get to implement "and" every single variation. So, that I expect will be a rich discussion, what we choose, what we don't choose, what we constrain and what we don't constrain.

Then we'll hear from Lee Stevens and Doug Fridsma on patient matching a very important topic. I did ask in a planning call, so that means we're finally getting the national patient identifier and I don't want to steal the thunder but the answer is "no, no" not to be part of today's discussion. We will be talking about algorithms, data elements again sort of constraining for our industry what are the best practices around patient matching which is so important for healthcare information exchange and novel architectures for interoperability.

And then finally again, a very big day here, Doug Fridsma will talk about our work plan for 2014. And one of the things I think we've all felt is that, as Jon Perlin told us, our ecosystem is so overwhelmingly busy right now that some of us just even trying to get through each day with our operational jobs is very hard. So, how do we spread the work of the Standards Committee to workgroups and to individuals that lessens the burden?

So, what folks at ONC will talk through is, it's probably time to restructure our Workgroups a bit coming up with new ways to spread the activities across more people and more members and get folks who have an opportunity to contribute have the time, while again recognizing you guys are the brain trust, how do we leverage you and your experience and all the energy to its greatest extent? And then Doug will review what are those high, medium and low priorities that we've had from all of our planning and polling activities, and where are we in the process?

So, that is today's meeting. I think, again, very important end of year meeting because it will give us the roadmap and the guidance for how we'll all work together in 2014 and how Meaningful Use Stage 3 will get shaped. So, with that let me turn it back to you Michelle and if Jacob has joined us I'll wait his remarks and otherwise we can go to Leslie.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks John and I don't think Jacob has joined us so I think we're just going to move onto Leslie.

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

Well, Leslie, take it away.

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

All right and I hope that Russ Leftwich is also on the line, are you Russ?

**Russell Leftwich, MD – Chief Medical Informatics Officer – Tennessee Office of eHealth Initiatives**

I am here.

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

Super, so Russ is joining me as a Co-Chair of this group and just for 2 minutes or so Russ – I know that you – the group knows you pretty well, so just a brief outline of the work you've done on this.

**Russell Leftwich, MD – Chief Medical Informatics Officer – Tennessee Office of eHealth Initiatives**

Relative to this I've been involved with the S&I Framework Longitudinal Coordination of Care as one of the leads and have played the role of the liaison between the S&I LCC and the HL7 Patient Care Workgroup and the update of the Consolidated CDA standard with several of these patient generated data elements included in that work.

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

Super and I would just like to highlight and echo the comments earlier about incrementalism and a bias towards using standards that we already are here familiar with and that's kind of the undercurrent and theme today of this presentation. So, let's go ahead and get started with the slides. Next slide, please.

So, we have two groups, as you know, both on the policy side and on the standard side. This team has been meeting for over a year and working on these recommendations. You saw a glimpse of them in our last standards meeting and we'll talk today about the recommendations going forward. Next slide, please.

So, we were asked to provide feedback on two Meaningful Use Stage 3 recommendations specifically around patient generated health data to find out what's available, what's applicable, existing standards and where are there gaps specifically around the ability to have patient generated health data through structured and semi-structured questionnaires and also to take a look at criteria for devices and then to see how this can build upon care planning in the future.

So, one of the big use cases with the questionnaires is around the way to request an amendment. This has been a big deal because as we envision the Blue Button's adoption and wide use we know that one of the first things a patient wants to do is to correct or offer a correction, an amendment to the record "hey, that's not what happened. Hey, that's – I'm not a girl I'm a boy" and many other opportunities for correction. So, this was our specific look today. Next slide, please.

So, there was a combined patient generated listening session on 7/18 and if you can go ahead and do the builds, and we saw this definition as patient generated health data including health history, symptoms, biometric data, treatment history, lifestyle choices and the rest as really about patient generated data to help address a health concern.

And we wanted to make sure we could support two ways, first that this is the patient and not the provider are primarily responsible for capturing and recording the data and also that the patients can help to direct and sharing in distribution of data in the future. So, these were some of the key underlying themes and you'll see this in a document prepared by RTI. Next slide, please.

We also learned that patient generated health data is not new this is already valued and incorporated in today's records it's just not necessarily typed in or entered in by the patient. Go ahead with the builds. And today we hope to look at incorporating patient generated health data through a couple of ways surveys, messaging and perhaps device data.

And that there are four things providers need to be able to do with the data, they need to receive it, review it, respond and record it and we talked a lot about the need for computability or the need just for information.

I think Arien reminded us that the secure messaging is providing a good deal of data today that's not computable but very effective and there has to be a balance of how we take the data in. And this next evolution from secure messaging to more computable data is really the focus of our conversation today. Next slide, please.

We also learned the importance from the folks that testified specifically Dartmouth and Geisinger, and others who talked about there needed to be really good policies and procedures and clear expectations.

So, every piece of data coming in from a patient may not be relevant to the care and the provider has to use their judgment just as they would with any other incoming data, is this something to be incorporated into the record or not, what are the expectations that need to be set to help to make sure that everyone was on board with that communication.

We also heard that when it's appropriately implemented and the concerns were addressed it becomes routine very, very quickly and the patient becomes an important, a very important contributor specifically around medication history, demographics and other information that the patient is the only one that knows this information. Next slide, please.

We also talked a little bit about liability and felt that there was a really good way to reduce or eliminate the concerns when there are a mutually agreed-upon set of information. And that HIPAA is really the floor and not the ceiling. It established the rights around correction and the ability to have amendments and corrections as part of the HIPAA requirement today. Next slide or next bullet please.

So, we learned about – that providers are aligned around wanting information and they want it to be accurate and high quality, everyone wants that. We just want to make sure it's easier and ready to use. Next slide.

We talked about adoption and maturity and this was very interesting, the group took a bias towards existing named standards and looking at the lens of all patient generated data through existing standards either that were named in Meaningful Use or being adopted by the industry today.

And we felt that even if something was very low in maturity and adoptability on the patient side if it's already been adopted on the provider side then it's probably at a moderate level of maturity. So, this bias helped us to get to the incrementalism that Jon was talking about earlier, but also to skate to where the puck is going to be, because we have a new use case for an existing standard. Next slide, please.

So, we looked at all the different types of patient generated data and from messaging to structured questionnaires, unstructured questionnaires and narrative data, device data, care plans, which might be unique and episodic, all the way through to a collaborative care record or collaborative plan.

And we looked at available standards, felt that – we assumed the common Meaningful Use data set standards on vocabulary and we felt we didn't need to specify for things like mobile devices, particular design implementations, we felt that what can we use that's existing standards in the industry and we want to have a robust discussion about device data. I've asked Chuck Parker to be available to answer questions as well.

But we felt, from the left to the right the HL7 care team roster was a really great way to start. It has helped to identify the team members it's harmonized across the Consolidated CDA, the longitudinal care team at the RIM level.

We also felt that expanding Direct for use for the patient was also a really good opportunity. Marc Overhage reminded us that even with use of Direct we need to expand the trust framework associated with that with patients and also there is work to be done on things like privacy concerns around directories and so forth, that work is starting to be done or has been for about a year and a half now with DirectTrust and so we do believe there is an opportunity.

Under the structure questionnaire and unstructured questionnaire, under the Consolidated CDA there has been work being done led by Virinder Batra from Intuit, Lisa Nelson, Gordy Raup and many others to have the Consolidated CDA changed at the header level.

There was significant discussion about do we do this as a separate data type or do we want to constrain this at that header level and really look at not a separate but equal environment but truly a design for a future collaborative record.

And so the group came up with modifying this at the header level we're under ballot reconciliation as we speak. So, we're very excited about that work. That would accommodate the structured and unstructured questionnaires and give an opportunity for many, many use cases, the first one things like correct, things like pre-visit information, demographics, medication history and other templates are being worked on today.

We also felt that the care team roster helps to build across from left to right all the way through the collaborative care. First we need to identify who are the participants and we felt that was a great start.

Under the device data we felt that we could look at just naming Direct as transport and look at a Consolidated CDA attachment with a particular template but it didn't seem to cover all of the interest and all of the needs for computable data.

We thought, well there's the ultimate consumer standard, the PDF, what if we attach a PDF to a Direct message sure we can get something in there but it is not computable. And one of the things the group discussed on device standards was that on the patient generated health data side it's really the information, the provenance is absolute when we get the information from the device itself and so it can be used by many people and so felt that it was important to look at computable standards and a broad standard base. And so we'd like to talk about the Continua standard. Next slide please.

Oh, one other area, under vocabularies we felt that there was an opportunity to look at consumer vocabularies in the future, but today with the constrained use case around the questionnaires, structured and unstructured questionnaires and device data, we felt we were okay for today but we would like to continue evolving and will work with Jamie's group as we go forward. Next slide.

So, we would like ONC to consider Direct transport standard for secure messaging and for data and for devices, also the HL7 care team roster, the HL7 Consolidated CDA for questionnaires and the Continua standard for devices.

We also felt that we would encourage standards to support multiple mobile device access but we felt that that really wasn't necessary most people are working with sort of device agnostic design principles. So, we felt it was more important to focus on the interoperability and getting things in and out. Next slide, please.

We also felt that longer-term needs could help to address some of the gaps and this wasn't just for patient generated health data but overall. So, for instance once we start introducing the patient and their team member as trusted sources of information we really need to look at an overall structure for collaborative care documents and this could be a document structure, this could be a communication platform but really need to address versioning, provenance, reconciliation, data governance and curating how does that all work?

And so we would like to expand the work being done on the longitudinal care team to really address this as something for a skate to the puck moment where we define how using existing standards can be enhanced to really create a new collaborative environment and then also to consider a process to align consumer product and provider standards.

We felt that on the data coming out consumer friendly standards were probably very appropriate. Data coming in is generally provider focused data. How could we possibly align, what could we do to convene groups to see if there is an opportunity for a future collaboration.

And then to look at how does the Blue Button and the API approach, how can that accommodate patient generated data in the future? Is that worth a discussion or another type of more of a collaborative platform?

And then also looking at the trust framework for the consumer patient adoption of emerging technologies like in Direct also, to consider, to prioritize consumer vocabularies to support a wider consumer and patient family engagement.

What we heard a lot was, you know, a patient might be defining something in a very consumer friendly term, how do we get that into actionable information inside the electronic health record. So, we felt that was a longer-term need, the absence of that would not prohibit this use case of questionnaires and responses both unstructured and narrative device and the care team roster but we felt it was worth looking into. Next slide, please.

So, the Policy Committee has accepted the recommendations on the following slides and we are expecting a transmittal letter for the National Coordinator and our job is to really say do these standards match the policy needed and can we support the standards recommended from this Workgroup. Next slide. I think that's it.

No, so we are ready for patient generated data in Meaningful Use 3. The Meaningful Use Workgroup should expand the objective to also give providers additional options for incorporating PGHD through secure messaging and provider selected devices.

There was significant discussion about how do we determine which device, which standard, this plethora of devices and one way the group talked about constraining was to say, are these provider approved or provider selected devices and that way the provider could say "yes I'm ready to do this, yes these are the devices I want to communicate with." And under the criteria for patient generated health data these would all be "or"s device data or a questionnaire and response and all would meet the actual threshold.

The Meaningful Use Stage 3 requirement that addresses amendments and corrections also represents a form of patient generated health data and we want to make sure that this is accommodated, which we did and the EHR technology should have functionality to allow providers to receive, respond, acknowledge and record to PGHD.

So, basically any function within the EHR that accepts or denies, or responds to a particular – any type of result should be inherited with patient generated health data. We hope that because we're suggesting a Consolidated CDA approach that we inherit any of the functionality associated with that.

And as with any type of other incoming information there is always the ability to say no don't want that, yes I do want that, acknowledge the receipt of it and then to be able to have all the same functionality inside the EHR. Next slide.

Providers should collaborate with patients and implementation and we've talked about that. The patient generated health data should be a source of patient generated health data in addition sourcing data should follow the data if they're later shared for other purposes including treatment, payment and operations.

So, basically the patient generated health data reflects the provenance that's generated the data and it stays with the data just like any other Consolidated CDA structure, how that is handled in the EHR so it would be with the patient.

They're also suggesting that ONC should work through its own channels with federal partners to equip providers with clear guidance on how to implement PGHD similar to the notice of privacy practice which was very well done.

We're hoping that this kind of guidance could help us including tips on patient generated health data, why it's useful, establishing clear policies and workflow, how to design and communicate these policies and procedures for patients and families.

Also, this information should be disseminated through existing mechanisms such as ONC, CMS websites, RECs and the National Learning Consortium.

And guidance on how to build off this work currently be done by patient generated health data and a technical expert panel on defining processes and procedures for patient generated health data. The technical expert panel convened by ONC led under NeHC is going to be releasing the paper I believe this month. Next slide, please.

Also, accepted the policies are not needed for Meaningful Use, new policies are not needed for Meaningful Use Stage 3 because HIPAA should govern that data as it does other data in the record, but for the future ONC and the Office of Civil Rights should undertake work to address data sharing by consumer devices and Apps that providers may also use in the clinical care setting if needed.

We are also looking medium-term to examine policy and workflow liabilities issues and unsolicited PGHD and today because we're looking at the questionnaire and response we really have not tackled the unsolicited patient generated health data.

The work to provide the patients with Direct e-mail addresses should continue in order to open up more options for efficient and effective collection in the future. And additional work is needed in the short to medium-term to explore shared care plans for example issues remain around version control, reconciliation and harmonization as we noted earlier. Next slide.

That's it. So, there is an awful lot there. I think the overarching recommendations from the group are that patient generated health data is not new, providing standards that exist either in industry or that have already been named to Meaningful Use help us to an incremental approach, but also give us the opportunity to drive new adoptions. So, with that I'd like to open it up for discussion and questions, and look forward to discussing it.

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

And so Michelle of course you have suggested to folks that we use the Adobe connect hand raising feature and so of course we want to have this discussion about slide 10 especially the maturity or current adoption of the standards recommendations, but before we do, Michelle let me just turn it back to you if there are raised hands.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

There are, Wes Rishel has a question or a comment.

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

Thanks, I have a couple questions and a comment. I think we use the term fairly loosely using a standard that's been around or that we know about or things like that and I would like a fairly precise definition and I point to the experience during Meaningful Use Stage 1 with the C32 as an example of the reason why.

During Stage 1 we got a lot of exchange of C32 but any use of the C32 beyond as a text document was a very intensive bilateral effort in negotiating how to interpret the standard and we clearly, HL7 has clearly learn from that lesson and produced a C-CDA and ONC has kind of revised its approach on how to create a – how to specify certification for interoperability as a result, but it demonstrates that something that's been used a lot in monolateral situations internally, something that's been used, demonstrated across vendors in various interoperability displays hasn't been thoroughly tested.

One comment I've heard recently is that a lot of the interoperability group work that goes on only tests the happy path, only tests what, you know, how it should go if everything works and really doesn't consistently go through all of the data and tests.

So, I would like us to think about standards that are ready for being committed on the whole country at the same time as being those where – are measuring their readiness by their use in operation as opposed to the simply being a lot of vendors that have codes somewhere on a shelf that might be put into a version and might be a start on the happy path for interoperability.

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

Wes, could I ask a question?

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

Sure.

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

Do you make exception for things we are ready have like Consolidated CDA?

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

Now Consolidated CDA is a risk. I mean it is not a de novo standard it represents a massive effort by a lot of very committed vendors and users to learn the lesson of the C32. Well, I'd almost – not particularly critical of C32, everything goes through that cycle, but our judgment of when it's ready to be committed to – you know, I say committed on the country because it becomes a big deal when you have to attest to its use and you have to pass a certification test.

Although frankly, certification tests are – again they only test the happy path they don't really test what you need to know in production. So, I'm just saying that various things we point to as the value of experience, for example it having been certified by somebody or it having been included in RFPs that have not yet come to full-scale execution. That's interesting data but it's not evidence that the adoption of this standard has been successful and there is a clear understanding of what it takes in the systems to deal with the data.

So, I also wanted to make some comments on slide 13. One, is it expected that each provider that attests to use of the consumer generated data standard would have to attest that they worked with consumers in order to set up their policies or is your recommendation that the bodies that create regulations and attestation regulations and so forth do that work with consumers?

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

Which question are you asking –?

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

On – see slide 13 you have a number 5 I think, maybe Michelle can get us there.

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

Right and it was assumed the latter and not the former.

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

Okay, then I'd like to also comment that provenance which is the next item on that slide, provenance is actually a fairly difficult thing to implement at detail, this is an issue that has come up in another area and we have never decided to go forth and require full provenance at the data item level.

I think there's an alternative way to clearly identify consumer generated data that falls short of the requirements of provenance and that is that we identify data by codes whose purpose it is to say what kind of data, and those codes often already contain source information for example this was taken with a manual or an automated blood pressure cuff.

I don't see any reason why we could not pre-coordinate the codes so that a consumer stated blood pressure or a consumer stated weight, or a consumer stated, it might be assumed that all family history is consumer stated, but in general I think we can identify data consistently and keep that identity throughout without resorting to a full provenance implementation. Thanks.

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

Thanks, Wes.

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

And just one quick follow-up on Wes's comment and that is that as we in the past together have discussed maturity and adoptability of standards you recognize that we face this quandary which is, well has the standard got a good implementation guide, you know, something that people can in the industry just look at and quickly implement. Has it actually been incorporated into products and has it been incorporated into products for suitability of a particular purpose. So, for example, C-CDA is now in Meaningful Use Stage 2 products and it has a robust implementation guide.

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

Right.

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

But I am unaware of how C-CDA has been used to capture structured and unstructured questionnaires. I mean, I don't know if anyone on the call is aware of C-CDA being used in the context of a questionnaire?

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

Well, we have created it for patient generated health data based upon the suggestions from the team stating that the most meaningful data coming from patients are the things the doctor wants to know instead of the narrative or the unsolicited data and so that has been the focus is to try to make sure that we had templates available, that those were valuable under the existing named standards under the Consolidated CDA.

We have somewhat of a chicken and egg here and the – but hoping to mitigate that by using existing named standards, at least in this case, with the Consolidated CDA and also the work on the care team roster that's now done that Russ can speak to as well.

So, that's why we were constraining. We were asked to constrain. We were asked to identify a standard that could accommodate and use existing standards. So, I don't know how we could align it better. It is still new and if we wait for adoption we'll end up with having a mess where there's lots of different things going on and then trying to harmonize that mess just as we've done I think on the provider side. So, that was our approach, use existing named standards.

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

John, this is Wes again, can I –

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

Please?

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

I think there are intermediate approaches that can assess readiness particularly as we have potentially a little more time, not very much when you really think about it, but a little more time which is to say that if ONC has the ability to fund projects that go operational using the proposed standard it can make a quick three-way decision, worse case waive off, next case very minor modifications and third case this is good to go.

And but I just want to emphasize the difference between a project to demonstrate this and write a report that says “yeah, we didn’t find anything wrong” with a project that says “we used this in production with a significant number of physicians and their patients and they decided to continue to use it” or some measure like that I think we do have the bind that both you and Leslie recognize that the schedule of stages of Meaningful Use doesn’t allow a lot of time for development and testing of the standard in between.

But I think we can create a statement that describes what is the minimal level that we would think would be – create a reasonable risk profile for including something in a Meaningful Use standard, I’m sorry in a Meaningful Use stage.

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

And just as a comment, so imagine Leslie that we wanted to ask patients to self-report medications or problems, or allergies and you are quite correct a C-CDA has nice templates for such data, but if we were to ask things like “well what were your activities of daily living, functional status, what’s your pain score, how are you feeling today?”

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

Right.

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

Again, you know, these may be things that doctors would consider quite important patient generated data because they are probably in terms of overall wellness, you know, something we can’t get through our typical electronic health record data gathering processes, only the patient knows and again I ask the people on the team today, I am not sure that C-CDA has a template yet for self-reported mood, pain score or things of that nature I mean it may I just don’t know.

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

The template structure would accommodate and the questionnaires would accommodate that, the vocabulary structure for the pain scale isn’t that under SNOMED? And the observations of daily living is under LOINC I believe.

And so we felt that there wasn’t a need to name specifically on questionnaires that the existing vocabularies were probably sufficient today, because this isn’t data that’s coming in unsolicited. Its data that there is a question and you want a response. So, you have an opportunity to actually make it highly computable.

Where a patient might provide data that is more loose I think is probably going to come in through secure messaging today. It’s going to come in through a message mode than a particular document structure today.

So, that’s – you’re right John, I think there is a bit of borrowing from the existing standards and the existing named vocabularies and then saying how do we incorporate this new function of the patients being the author of the data.

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

Because this is I guess the interesting question is how specific do we want to be in our recommendations because if ADLs or pain scores, or these sorts of things functional status are our goals then actually naming “thou shalt use SNOMED for this” and “thou shalt use LOINC for that” and this template from C-CDA to record the result – I just again, toss this out as a question, is that just saying C-CDA can be used for all structured and unstructured questionnaires may not actually, as Wes has pointed out, result in –

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

Be constrained enough.

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

In an interoperable result.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

So, John, this is Michelle, there are a number of people in the queue.

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

Please, please go ahead.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

And they keep growing, so I just want to acknowledge everyone.

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

Yes, yes.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

So there is Andy, Dixie, Arien, Floyd, Steve and Eric. So, we’ll start with Andy.

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

Well, so let us release some of their energy because I think we’ve put a few issues on the table and look forward to additional discussion. So, I guess you said Andy was next?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yes.

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

Please go ahead. Andy are you muted?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

So, maybe we’ll go to Dixie if Andy is muted.

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

Yes, I'm not muted and I don't have a dog either. First I'd like to respond to that last conversation and suggest that – regarding the use of the C-CDA to capture structured questionnaire data. I think maybe that the Consumer Workgroup might want to look at the structured data capture project which uses RSD for that purpose that might be a better fit for that.

But my primary question has to do with slide 10 where it says that ONC should consider using Blue Button Plus API approach to accommodate patient generated health data. That's sort of the reverse, well, first of all, the Blue Button Plus Pull uses OAuth 2 to enable a consumer or a consumer device to pull data from an EHR and that's sort of the reverse of patient generated health data being provided to an EHR.

So, I was wondering whether you could describe a use case that you see that the Blue Button Plus API being used to enable a consumer to actually provide data to an EHR?

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

Well, the group talked about both the approach that has been used to create the actual process approach to get to it so that was part of this discussion convening a rapid cycle group to address a particular issue. And then saying, and this is more of the future, is there a way that we can look at the existing approaches or recommendations for something like API approach for patient generated health data in the future and that really addresses more of a collaborative care structure.

So the process they were talking about was both the process for a rapid cycle consideration as well as is there something in the future that needs to be defined like – the example that was used often is a HealthVault type of approach or another consideration for future states for patient generated health data. So, this is a future effort.

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

You're referring to the technical approach, you were referring to the –

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

I'm sorry, I can't hear.

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

–

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

If you aren't speaking if you could please mute your lines.

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

Thank you Michelle. So you were talking about the approach that the Blue Button Plus team used to come up to the answer rather than the answer itself.

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

Yes.

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

Oh, I see, okay, okay, thank you.

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

And so Michelle who is next in queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Arien.

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

Please Arien go ahead.

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

Hi, so just a couple of issues that I want to discuss, one is that – just related to the previous conversation I think we need to be careful when we consider using Consolidated CDA as a document type for structured data that is patient self-reported. As we discussed last time there are times when it is important to deliberately limit or restrict the structure that patients can provide.

I gave the experience and actually had a number of people come up and talk to me that shared similar experiences where if you collect highly structured data from patients, as an example medication data, they may end up putting in information that is incorrect because they feel that they have to supply that information so for example the exact dose and strength of the pill. And we found that it was better to give them some structure for the name of the medication and then to ask them to describe the strength and form of the medication in their own words and it is – so that's one basic point.

The next point is that it is often not the right process, not the right medical process to ask the patient to provide a high amount of structured information because the point of the data is to form the basis of a conversation between the patient and the provider to elicit and jog memory for example or to probe for areas where there is important follow-up and short-circuiting that cycle by collecting it in an ideally structured way incorporating it directly into the EHR misses the point that a lot of that information is therefore the workflow of questioning the patient and eliciting information. So, we need to make sure that we're considering the actual clinical practice when we're doing this.

The last question that I have is related to Continua and I'm frankly not clear on what the Continua standards are, any time I click on the Continua website to look at standards or implementation guides I get behind a password that appears to require me to be a Continua member. So, it's not clear to me what it would mean to have EHRs support Continua standards for device integration and it's not clear what the lift and ask for that actually would be.

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

Okay, so I'd like to address the first question and then I'd like Chuck to talk about the Continua and then also Russ maybe weigh in on medication too. I think your point Arien about the structured versus the questionnaire and computable versus just the standard messaging is not an either/or but a both/and.

We heard in the testimony that for instance when asking for specific list of medications "are you on this medication or what medication are taking" open-ended was very valuable but as well were the messaging that says "why aren't you taking this?" "Well I don't feel like it's doing any good."

What the testimony said is these were "ands" and for instance Dartmouth stated that they found depression six months earlier because they were asking why people were not taking their medication. But they also found that it was very important for reconciliation to get to the actual very specific data on the drug and the dosage for kinds of questionnaire types of responses and then also just open-ended questions "what are you taking over-the-counter" and so we found that each one of these areas were important and that they were – it was a matter of choice for the particular clinician workflow.

So, one of the reasons we talked about using messaging as well as the structured and unstructured questionnaire, as well as potentially coming from device data that these were "or"s and so it could be met, the objective could be met by picking any one of those. And Chuck would you like to describe and answer – respond to the Continua standard question? This is Chuck Parker from Continua he's been involved in this work team.

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Hello and thank you very much. Yes, to that question, you know, first I would like to say that we can submit to you the guidelines here to this Workgroup so that you would have those for complete reference our most current set of guidelines so that's something that we will make available to you.

As to the guidelines themselves, yes, our standard interface is to speak to the Consolidated CDA as well and we have demonstrated this at the interop showcases as well as the connect-a-thons over the last 3.5 years. So, currently to date any EHR that is capable of accepting a CDA currently has the ability to accept the output that Continua provides from a device architectural input.

Just one thing to note here is that there are not Continua standards, what Continua does is a guideline body, we're using existing standards that are in the industry today and simply applying a constraining down requirement to apply how to combine these components together.

Because there is no single standards body that allows an interoperability chain for the device architectures themselves what we have to do is we have to assemble several different standard bodies and that's what the guidelines describe is how to assemble those existing standards to get the outputs to come out on the Consolidated CDA. So, we have demonstrated the capability, we have now – you know, running for the last four years run at the interoperability showcase as well within HIMSS both here and internationally to demonstrate that capability.

So, any EHR that has the ability to accept a CDA today can accept the data output and, you know, at this point it's really a matter of the EHR beginning to actually assemble that data in a meaningful way but they can accept the output and have the input available to it.

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

So, I think, Arien in answer to your question, what would be very helpful is for Chuck to provide the committee with the list of named standards or implementation guides but it also would be helpful for me to understand the products that actually in production incorporate them because I have not – I mean Chuck and I are good friends and I have worked with Continua for years but I have yet to go to Amazon.com and see Continua inside on a product I am buying. I'm sure they are there.

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

Yes and to that point John I would say that we, you know, Continua does provide a certification process as well to ensure that the device have met a requirement and we have 95 devices and services that have met and gone through that process today. And just so you know this not only incorporates device architectures but also service architectures and cloud-based architectures. So, three of the service platforms are cloud-based today that have been through certification.

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

So, I think certainly if you have a link to the products that are certified to the question that Arien asked is what are those standards, are they in use and as we talk about mandates is it we mandate Continua or it we're mandating Consolidated CDA as a content transmission and IEEE 11073 or, you know, whatever, you know, I have no idea what transport one might use for various kinds of devices for various purposes.

**Charles Parker, MSHI – Executive Director – Continua Health Alliance**

And that is an acceptable way that we've seen it achieved in other countries where they stick up this mantra in being able to implement the technologies themselves. So, yes, we will provide those underlying standard technologies and implementation guidelines to the body here.

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

Thanks Chuck.

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

Sure and so Michelle who else do we have in our queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Floyd is next.

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

Floyd, please?

**Floyd Eisenberg, MD, MPH, FACP – Independent Consultant**

Hi, thanks for the opportunity. I've been listening to this conversation and I think it would be helpful to parse out the types of information sharing in different categories, for instance the structured sharing or the unstructured could be handled in structure data capture, but the results of a structured data entry by a patient can very easily be managed using LOINC, I shouldn't say easily, but software that manages LOINC and in CDA would be an observation as a result so results can be shared even though you may not –

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

Correct.

**Floyd Eisenberg, MD, MPH, FACP – Independent Consultant**

Share the entire document or the entire – all the answers. So, I think there are ways to manage that and it might be helpful if we could separate out the different types so that we don't get stuck with all or none. I also very much liked Wes's comment about how to handle provenance perhaps by a category of provenance and I would really like to learn more about that and see what we could do in that category.

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

Thank you.

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

Yes, thanks, Floyd. So, next Michelle?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Steve Brown.

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

Please go ahead.

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

Oh, great, well thanks for the opportunity. You know in VA we are facing these problems right now and are really spending some time and effort trying to understand how we're going to make sure that patient generated data that we get from veterans via a variety of mobile Apps and outward facing applications can integrate with the data that we're generating on the inside in a way that allows us to use it in seamless ways as you are talking. So, this is a very timely conversation from my perspective.

The problems that we're facing though I'm not hearing addressed and largely what I'm hearing addressed is sort of a lot of the conversations that we've heard year in and year out centered around various forms of information models with the assumption that the terminologies that fit into slots will be sufficient. Sometimes what we're finding is that sometimes that's true and sometimes it's not and dealing with real meaning at the leaf level is a very difficult thing to do.

The integration work that is just getting started between LOINC and SNOMED I think is a really good thing and, you know, both Regenstrief and IHTSDO are to be I think congratulated and I hope we can be as supportive as possible of that, but making sure that happens well and in ways that is scalable and reusable is going to be, I think, very important.

With regards to content coverage, I mean, you know, like real estate and I didn't make this up but content, content, content. We found to get the kinds of information we want that even with SNOMED's extensive terms that we were having to do post coordination in anywhere between 20 and frankly 100% of the elements on certain templates.

So, I think we need to be prepared for that going forward and in any ways that we can – as this group, you know, help support the library it's either whomever in making sure that we have an integrated coherent system that – where overlaps are identified and managed in the terminologies I think will be important.

It's our experience, the emerging experience that this is a particularly difficult area and just talking about various messaging standards or transport mechanisms isn't going to get us where we need to be. So, I'd like to tip my hat to the library for starting this and hope that as this group can support their work in this very difficult area.

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

Well, a very helpful comment and it gets back to the point about C-CDA template suitable for purpose joined with vocabulary, LOINC, SNOMED or something else that ensures the content is representative of a vocabulary that's interoperable.

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

And it's the coherence of them where they overlap or don't needs to be managed.

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

Yes, very good, well Michelle other folks in the queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yes, Eric Rose.

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

Eric go ahead.

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

Hi, so this is a great discussion something I personally think is something we definitely need to move forward on and at the same time there are two policy issues that I think we need to keep in mind because they may have to inform how we approach the sort of standards discussions.

Thinking of how, you know, the average doctor in the trenches, particularly a primary care doctor in private practice is going to think about this I think there are two concerns that come to immediately to mind, one is just the patient safety issue, if you have information being transmitted that indicates a serious and urgent situation that isn't acted on, you know, as expeditiously as it might if it were transmitted through more traditional modalities are patients going to be harmed and alongside that of course is going to be the liability concern you know.

The second issue is that any – you know, standards imply workflows and this for the most part – the workflows that come from the patient generated health data are going to involve work by clinicians or their staff that in most cases is unreimbursed and when you're talking about folks who are already busy and running businesses with razor thin margins that's going to generate concern.

So, I realize that we're not the Policy Committee and our job is to figure out the standards that will make the requested policies work and nonetheless I think both of those just need to be borne in mind and I don't know if it's something that's already come up in your discussion or if you would like to comment on, but –

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

Yeah, thank you for that and yes there was very robust discussion about that especially on our combined hearing where we heard providers give testimony about starting out with some of the same concerns that you had and finding that in fact they got more accurate data and actually felt that their time was being utilized better because they had more accurate data specifically around medication data was used over and over, and over again as a positive example.

There are some – there is work to be done and the committee has acknowledged that and hopes that there will be some good policy recommendations for procedures and best practices around the use of patient generated health data, but in general they found that the fear of noise, the fear of irrelevant data, the fear of a burden on staff didn't materialize.

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

Thank you.

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

Very good, Michelle other folks?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yes, so we're going to try Andy again.

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

Can you all hear me this time?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

We can.

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

We can here you now.

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

All right, good because there was terrible squealing and feedback last time. A couple of things quickly, first of all again I'm the Vice Chair of the IHTSDO Management Board and I want to assure all members of this committee that that organization takes its roll in all of this very seriously.

So, in terms of the work with LOINC and other work to make implementation with SNOMED more possible, more useful, more practical that is the complete focus of the organization, any and all suggestions would be very much entertained. We have a brand-new CEO who is an incredible practical guy from Canada named Don Sweete and he'll entertain them as well, so just one point.

The other that I would suggest is I'm feeling like the guy who wants to toss the spaghetti against the wall and see what sticks here. I believe this is a very important arena, there are clear areas where this is – whether it's reimbursed or not this is work that's already going on doctors obtain consent every day, doctors have patients fill out paper forms every day.

I would hope that we could be modestly aggressive about fielding some standard formats for the broad categories of patient generated health data and then informing the community of health practitioners that this is dynamic that we want to see what happens and at the same time, I'm also hoping that ONC could do something like challenging the specialty societies to come up with recommended approaches to the patient generated data that is of the greatest concern to them so that there is a form that comes from my specialty society about childhood immunizations and there is a form that comes from the general surgery specialty society about operative consent, a framework for operative consent that uses the standards and saw it.

We shouldn't do that, we should allow the clinician experts to do that but we should create the structure that they can hang their hats on and I hear that that's what's happening here, I hope it is, we should get this into the field, let them screw it up and fix it that's the only way – because if we try to make this into an academic exercise before it is fielded we'll never get anything done.

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

Andy, that's – I'm so glad you brought it up, because by taking the approach that we did at the header level within the CDA we really have created the opportunity to take advantage of the structures that are already there.

So, the template approach, we have things like – just anything that's there you've got advance directives, you have allergies and a chief complaint, there's all kinds of templates that are under the Consolidated CDA and many have been supported through different industry groups. So, this approach by doing it at the header level gets us to inherit all things that have been done with regard to the CDA.

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

And to the question that we were debating earlier in the conversation I wonder Leslie and Andy if would it be helpful for the Workgroup to enumerate those particular templates that they found were particularly interesting for patient generated health care data. So, as you say, advance directives, chief complaint, vital signs, problem list, medications, allergies –

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

Right.

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

And then –

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

Tobacco use, smoking status.

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

Right.

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

Quality measurement observations like experience of care, pregnancy reporting all of those things that are there, those templates are there. We could go through and highlight them based upon the technical expert panel's recommendation if you want for the constraint.

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

But I just wonder is again, useful exercise to say, we've looked at the templates and we have also validated that those templates have associated vocabularies LOINC, SNOMED or whatever because then as we get to certification criteria you could say we believe, you know, you should support patient generated data, I'm making this up, you know, that can incorporate, you know, five of these twenty that we've listed with the following vocabularies and templates or something that's testable. I mean, that's the worry I think that Wes articulated that if we just say use Consolidated CDA we could end up with mush.

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

Yes. One of the assumptions we took on was that the existing named vocabularies would be – would accommodate this particular recommendation under the questionnaires and maybe using that lens we could then test that further and make specific recommendations.

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

And so again, it's this balance that everyone has talked about Wes, Andy, etcetera of, you know, we want to constrain but we don't want to constrain innovation and there are some things that we know we can do today but there are some things we want to do tomorrow and, you know, if we try to, as a Standards Committee, figure out certain things without getting clinicians to test them in the field we may not get it right.

So, again, you know, you just toss it out that Consolidated CDA certainly seems like a rational recommendation in that the vendor community has already got familiarity and production use of it and some limited incorporation of Consolidated CDA data from a receipt of a document to the problem list or medication list and it certainly would make it more real if folks said "and, you know, what we're talking about with structured and unstructured data in the Consolidated CDA is chief complaint, functional – " you know, this sort of enumerated list of things you thought were particularly suitable for purpose and their associated vocabularies.

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

So, we did ask the policy side of the house to constrain and to say are there high value areas you would like us to look at just from the policy point-of-view. And their response was "no" one of the reasons that this is broad is to state that we consider patient generated health data as just another care team member and so if there are relevant templates available we'd like to be able to have that tested in the same way.

So, I think maybe we should come back with an overall testing example but the policy group today was not – pending our response was not yet wanting to constrain the particular areas any further.

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

Sure and very reasonable. I just would think we might be able to, what I would say, market and communicate the C-CDA as suitable for purpose if we had a couple of examples that illustrated how it isn't an artificial construct.

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

Okay.

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

So, Michelle are there other folks in the queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

There are, Stan Huff and then Wes Rishel.

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

Stan Huff, please?

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

Yeah, thank you, I appreciate the work of the committee and a couple of things come to mind, one is you know that I think I like all of the things that have been said in terms of that we need additional information in terms of templates and specifications of how – sorry.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

I'm sorry, Stan, I don't know if that's your line, but, oh, it's much better.

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

Yes, I don't think it's me. But to use it in the way we need to we need to say more about templates and terminology and even workflow and how you would recognize data that's been sent before so that you don't just get multiple copies of information that's been sent before.

So I – but what I got thinking about is this that one thing is I wonder if there is – and this is a more general question then just related to patient generated healthcare data. Is there a role for this committee to do something more strategic and what I mean by that is I get the feeling that, you know, at any point in time what we're doing is adopting the best things that we have available, which is probably what we can do right now, but it's akin to sort of saying, you know, what's the best car I can build and buy parts that I can currently buy in an auto parts store?

You know you end up with something that actually may not be – may not have, you know, everything that you want and may not be fit for purpose to the same extent that something, you know, that started out and was designed to meet that specific purpose.

And so I wonder sometimes in the committee, I mean, I think we're doing good work don't get me wrong, but, you know, if there's an opportunity for us to sort of step back and strategically say what generically are the kinds of standards that we need, what kind of information models do we need to underlie this infrastructure, are there things that we should, you know, pause it in terms of an overall architecture along the lines of PCAST that say, these are directions, you know, major directions we think we're going to go, you know, increasing utilization of the Internet of cloud-based computing, where we direct something that's maybe not going to come to fruition for 5 years, you know, if we go through a design cycle and people implementing, but we have a strategic impact on what's happening at the level of this committee as opposed to sort of reacting to, you know, the best thing we can make with the standards that exist today.

So, I don't expect a response but in some ways I think we could have – I would like to see us have more of a strategic impact on things that might – we might could bring into existence in 5 years from now as opposed to always doing the best thing we can do with sort of what exists now.

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

And this is a very fair point and Doug will discuss how we might re-organize ourselves to actually focus on the kinds of areas you've described and that is having Workgroups, four of them, that have domain assignments where it isn't just picking existent standards it may be looking for gaps and suggesting with the S&I Framework that we build something novel for the future. So, good input. And then Wes Rishel you have the final word and then I will try to summarize our discussion.

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

Thank you, John. I just wanted to pull together comments from several people to illustrate one of the main threads of this discussion which is that we have in the material that was presented a requirement for provenance which has not ever been tested at the level of detail that is called for here and unclear that the templates exist.

And alternative that is to use sophisticated vocabulary to qualify data as patient generated although in fact I think there is a level of qualification depending on what other members of the care team might be generating data and some real world experience from the VA that says the only way to put that simpler process and provenance in place is to do post coordination which really require, I mean do pre-coordination which actually requires pre-coordination it can't be done by saying "all right figure this out when you write the code."

So, all of this together implements how important it is to go through a process that completes and is used before we make the assumption that such and such a standard could be used for this purpose. Thanks.

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

All right. Well, thanks very much and let me just quickly summarize as we get to our next presentation on radiology image exchange.

What we heard from Leslie is really well summarized on slide 10 Direct as a transport mechanism and I think, you know, it will be actually interesting to test this as we look at the Continua enumerated standards because although Direct certainly is very useful for taking transfer of care summaries, C-CDA documents or other payloads of HL7 from place-to-place I don't know that devices necessarily have incorporated Direct.

You know, they may have actually used such things as HTTP or IEEE 11073 that I think Dixie had worked on in the past thinking that possibly transport from patients to providers might actually be done through a webpage and not necessarily through the transmission of a payload. So, I think there's possibly further discussion on that when we see more information from Continua.

HL7 care team roster certainly looking at the work of the S&I Framework and longitudinal care coordination group seems like a good and enumerated standard, I have actually never seen that one implemented in the field. So, I guess maybe a bit of homework we could do is to figure out in our maturity model where really is that with regard to having been incorporated in any product or production use.

For C-CDA we've had a very robust discussion and again I think just enumerating a couple of examples to communicate this would be very helpful and pay particular attention to are there needs to specify LOINC, SNOMED vocabularies in accordance with a template to make sure that the result is going to be interoperable or incorporatable in a provider system.

And in Continua we have the homework assignment of actually reviewing, from Chuck, both the products and the standards that are enumerated.

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

So, John, this is Leslie, in terms of process then this team would go back and respond to these specific questions and come back to this group now that we have a little bit more time, is that the next step?

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

All right, so Michelle, let me ask you that process question. I certainly think it would useful to have a Workgroup discussion that followed this discussion and then a report back with their final answers or commentary. I mean, we usually do our recommendations to the Policy Committee in a couple of steps, so draft recommendations followed by discussion, followed by revision, followed by final recommendations.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yeah, I think you said it exactly right John it sounds like the Workgroup will need to go back make a few adjustments and then come back to the committee for final approval.

**Russell Leftwich, MD – Chief Medical Informatics Officer – Tennessee Office of eHealth Initiatives**

This is Russ Leftwich if I could – a quick note on a couple of the earlier comments. HL7 has successfully balloted, earlier this fall, a structured questionnaire and structured response to questionnaire ballots, two separate ballots actually. They've not been published yet but CDA implementation guides for those two items.

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

Great, very good, well that's very helpful. So, Jamie, are you on the phone?

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

I am here.

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

Now, Jamie I have just been e-mailed by my CEO that he needs to talk to me for two minutes.

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

Okay.

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

So, maybe I could introduce this topic and turn it over to you to begin that presentation, make that other quick phone call and then be right back.

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

Okay, great.

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

And so, as I said earlier in the introduction, our Workgroup, Clinical Operations Workgroup, was challenged with a number of use cases, we could call them the consumer and the professional. We wanted to try to avoid the use of diagnostic and non-diagnostic because in fact a photograph taken on your iPhone 5S might be a diagnostic image and so looking at what use cases were appropriate, what standards appropriate for purpose and then we heard from Clem McDonald that it's important not only to consider various kinds of images whether those are x-rays or photographs or whatever but also the text that accompanies them.

And we also heard Farzad when he charged us with this work to also think about EKGs which are not DICOM objects but are time series sometimes represented as a PDF or some other type of media. So, when you see our recommendations you'll see this is the scope of what we had to consider. So, Jamie, let me turn it over to you and I will be rejoining you shortly.

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

Okay, great, thank you. So, what I'd like to do is I'm going to make I think 3 or 4 introductory comments leading to a conclusion that we considered carefully in developing this set of recommendations and actually if you could advance the slide I think past the Workgroup to the charge and just leave it there while I make these comments, these introductory comments, the first is actually this will end up being an addition to the glossary, but I'd like to mention a couple of different standards that we heard a lot about.

One is WADO which stands for Web Access to DICOM Objects. There are three flavors of WADO, there is a URI flavor, a web services flavor and a RESTful services flavor and so you'll see those in our recommendations.

Another thing I'll mention is STOW-RS which stands for Storage Over the Web RESTful Services and that is in essence a specification for an HTTP post of DICOM images and so these new ways of using and sharing images were developed mostly in 2012, they have been implemented. Their use is growing but it's still relatively early days.

And so I also wanted to – and if you're looking at the charge that we had I wanted to mention a couple of different dimensions of complexity that we had to consider. So, I think the first one is in essence the way we've organized our recommendations, which is the variety of content. And so in terms of content we have radiology reports and other text as essentially just text.

Then next we have non-radiology, non-cardiology images, I think John, you know, talked about this in his introductory comments. Then sort of the third level I would mention is key images that have been designated as key images by a reader or interpreter. And then finally we get to the full image sets sort of all slices of the images and so we wanted to make sure that we had appropriate standards for each of those different levels of content.

But another dimension of complexity really is the variety of participants the senders and receivers, so we have the imager, the ordering or referring clinician, we have in some cases sharing with a care team or sharing with the patient.

Then we also have the variety of systems infrastructure components so we EHRs, PHRs, PAC systems, there are vendor neutral archive systems, there are HIE archive systems and other storage infrastructure and then there are also a variety of sort of I guess maybe the last dimension of complexity is the reason for sharing which also has an impact on what is to be used which is you could be sharing for purposes of reporting or review, or audit, or diagnosis or other clinical decision requirement and so there are different reasons why these images can be shared.

We heard a variety of input and this actually took quite a bit longer I must say than we had thought initially. We heard input from quite a variety of stakeholders that the existing infrastructure is both among the most expensive as well the most extensive in healthcare. So there's a lot of existing infrastructure.

And the majority of the existing infrastructure uses DICOM images shared by XDS-based architecture but as I said earlier there is we think rapid growth of these alternative mechanisms but from a very small base of new implementations.

So, this existing infrastructure, the timeframe for changing that typically is measured in multiple years and for many healthcare organizations both the imaging and the image storage components are among the most expensive line items that they have.

We also heard from legal experts testimony that copies have to be kept, that is to say that there is a legal concern about maintenance of pointers over time leading to a risk of not being able to maintain a complete record of the information that was used to support the clinical decision and this seemed to relate to some of the existing XDS-based infrastructure which typically is a very tightly coupled implementation that does deal with these issues of maintaining the information as it was at the point of a clinical decision. So there were some questions about the maintenance of pointers, URI pointers for example, to third-party archives over time.

Despite the apparent complexity of our recommendations we really did seek to keep this as simple as possible to constrain to a minimal or as I think John would say parsimony is subset of standards while at the same time leveraging this extensive install base.

And so the existence of this existing infrastructure really led us to consider a conclusion of these different considerations is the need for us to think of a balancing test and that we really do need to balance the benefits such as lower cost, improved decisions, etcetera versus the various burdens on the potentially relegated entities such as their – of course the cost, the risks of change, resources, resource allocation and so forth.

And so this notion of considering the balancing test did lead us to the “or” statement, which we also, as I think John mentioned earlier, we did consider that carefully and, you know, it’s a question of sort of on whom, how much burden should fall over time I think is one of the things we’d like to solicit input from the committee on.

So, I think at this point in terms of the stakeholder discussions one thing I would add there is that we also of course we heard from ONC but we also heard from David Clunie, who is a radiologist, on the DICOM Standards Committee and should probably be added to the list, and so I don’t know John Halamka are you back with us yet?

No, it sounds like John is not back yet. So, then let’s go onto the recommendations themselves. So, as you can see here, we have the four different tiers of recommendations that are tiered based on the – primarily around the content, so tier 1 being text-based reports, tier 2 being the images that are non-radiology or non-cardiology images, tier 3 which is the full image sets of radiology and cardiology images and then tier 4 is those that have been designated as key images by a reader or interpreter.

So, you can see also that in terms of the modality for standardizing the content we’ve got the encoding, the vocabulary being primarily LOINC and then various mechanisms for push, pull and view. And so in terms of applying these recommendations we’d really have to go back to those different dimensions of complexity that I mentioned in the introduction to devise the appropriate use case scenarios in which these would be applied.

So, if you think back to the broad charge that we were given, which really encompassed many different stakeholder participants, varieties of content, varieties of infrastructure components, as well as varieties of purposes for image sharing we really felt that this full set of recommendations was the most appropriate way to meet the balancing test, while coming up with what we thought was the most helpful subset of standards that could leverage the existing infrastructure and still move us forward and so you’ll see that obviously we have maintained the recommendations for leveraging the XDS-based infrastructure that is prevalent today while still enabling migration to our preference for RESTful services and the use of WADO and STOW over time.

So, I think at this point I don’t think it’s necessarily useful for me to just read the slide here and I’d love to start the discussion.

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

And Jamie, I have returned, so thanks so much for that presentation.

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

Oh, okay.

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

And so as Jamie outlined, I mean, this is our challenge which is, you know, have incumbent standards that are used, emerging architectures that you want to support, consumer and professional, multiple tiers of what we need to accomplish but then the challenge of course of getting to certification criteria that wouldn’t require every vendor in America to implement every single variation of every single standard.

And so, it’s a quandary but I certainly welcome the discussion of the group and Michelle you have been the keeper of the raised hands, do we have raised hands?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Nobody is in the queue currently.

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

Well come on guys you've got to have some opinion about this? Everybody just thinks it's so perfect that there's nothing they would revise.

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

I think there's a lot of information here, a lot of really good information here and I think that's what you are hearing.

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

Right, so I would say this that I think that if I were to summarize some of the deliberations Jamie that we've had in our various meetings that there is this recognition that DICOM itself is actually a suitable content standard for encoding, just the challenge has been the transport of DICOM objects across institutional boundaries and into settings where you may not have proprietary DICOM readers so hence as you see we offered the variation of in certain circumstances the use of JPEG, PNG, PDF, H64, etcetera.

And vocabulary I don't think there was any real debate about the fact that LOINC was essentially appropriate for purpose in almost all circumstance and then where we get into these challenges is really into push and pull because we know that for text-based reporting lower level protocols like MLLP actually are used with HL7 today or HL7 over VPN, you know, but then we see the emergence of the Direct protocol and it's XDR addenda as a possible way to get text results from place to place so we think that should be listed as something desirable.

And as Jamie has already said there are a number of IHE stacks which imply a very large set of highly constrained and integrated standards working together, but then some evolution that's happening with such things as the STOW or the WADO-RS standards that seem to get to a more RESTful and decoupled architecture which we think are desirable. So, yeah, as Dixie said there is a lot on here, but if there is any philosophical comment well we welcome it.

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

John, John this is Wes.

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

Please?

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

So, I have to ask a question and I admit that it probably – people who are closer to this already know the answer, but one of the things I've seen is – I've talked to vendors who talk about their product being a vendor neutral architecture which is itself an ironic statement, but the claim is that the level of compatibility of various modality vendors is low enough that it really takes – and things like that to make them interchangeable.

This could be completely incorrect, I don't really know, but somehow these people are making money selling the products so I'm curious do we have issues at that level that would somehow impact the design of interoperable interfaces?

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

Sure, well, let me just – Jamie let me take a quick cut at that and then turn it over to you.

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

Yeah, please.

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

So, Beth Israel Deaconess several years ago built a vendor neutral archive to accept all modalities of all flavors of DICOM, JPEG, JPEG 2000, PDF, etcetera and surrounding metadata and the reason we did this is we saw proliferation of mini-PACs where suddenly you needed, you know, five different logins and three different software applications with different user interfaces to look at the various modalities when our clinicians said actually what we want is one place where we can list every imaging study that a patient has ever had over their life and click on it and read it from one archive and that turned out to also be cost-effective because we could buy storage once and do disaster recovery once and that sort of thing.

A corollary to that, which you see in a number of vendor products is to say, instead of buying the DICOM reader from GE, Siemens, AGFA, Philips, Fuji and McKesson we actually offer a DICOM reader that can be used with any of the DICOM objects from any of the modalities produced by any of those vendors now it may not include every possible bit of extended metadata that they have added that is unique to their product but it's actually pretty good for identifying, oh here's an image you can zoom, you can do grayscale and that kind of thing.

So, I think in looking at the DICOM and the IHE stack there we have not constrained the use of either vendor neutral archive or these, what I'll call, vendor neutral readers that across organization may use. So, Jamie?

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

No, I think that was probably more complete than I could have answered.

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

Well, but what I think I hear is that if we simply look at the distribution mechanisms described here and we think about our effort as trying to make implementation happened at very large scale and across organizations that there may be some work involved in somehow constraining or somehow tuning or somehow creating the right descriptions that allows one to assume that if one can get either view or retrieve an image from another organization that one will be able to work with the image? I'm just really trying to avoid the – we all interoperate and it doesn't work phenomenon.

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

Well and I think this is an extraordinary important point you make, which is our challenge is, I hate to use the term parsimony, how do we constrain to the fewest number of variations that we hope will get to near plug-and-play interoperability but deal with the fact that the industry is evolving very rapidly and there are many use cases and architectures and that's the tough issue with this particular assessment. Jamie, other things you'd add?

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

No, I think that's right, I mean, I think the experience Wes with these standards currently, I wouldn't say that it's necessarily perfect standards-based interoperability, but I would say that it does seem to be working.

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

Well, I guess that's my point, if we recognize that the limitations of, and I don't want to name a vendor, but Vendor 1's image in this modality and Vendor 2 – the limitations are simply in additional metadata that is coded with X labels, but that the fundamental usefulness of the image and ability to manipulate the image is sustained then we should set the expectations in the regulations we recommend and the certification approach that we recommend around that working minimum capability rather than leave the expectations open that if the hospital across town buys a new machine from XYZ imaging and this happens to detect the breadth of the patients aura and my equipment doesn't have aura measurements, that I should expect to get it just because the other hospital has aura measurements and I tried to pick something that was deliberately not radiologic.

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

Right, yeah, I mean, in some sense we tried to enumerate standards which set a floor and I think your observation is correct that – at least what I've seen in the industry is the image, the patient, the name of the study those are all very standardized at the moment. It's the aura that is only recorded by Vendor A that is put in some place that is not exactly going to be displayable in a vendor neutral viewer or something like that it's an extension beyond the base.

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

Right and we would hope that DICOM and others would be gradually learning by what the innovating vendors do and standardizing, because I think in general innovate and then standardize is the only way it really works. So, as long as we are managing the regulatory part to the expectation of the common subset then I think we're doing a great service.

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

Right.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

So, John, I do want to note that there are a number of people in the queue now.

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

Wonderful, please?

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

Good.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Leslie Kelly Hall?

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

Leslie, go ahead?

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

Hi, thanks, thank you very much and Jamie great work and I want to point out that this approach by having something like a very consumer friendly standard like JPEG included in the view really gives us an opportunity to incorporate this in view, download and transmit, and Blue Button in the future. So, thank you very much for including that because I think there's a huge value.

And then I have another question about the ability to have sustained URLs if the group looked at that, because that will address many other things within like advance directives and other sort of cloud-based approaches where information might be more current but that URL direction allows us to get there. Did you look at how hyperlinks –

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

So, yeah.

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

Can sustain in a record and is that something that we can be informed in other areas?

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

Yeah, so as I mentioned I think in the introductory comments, we did hear testimony from legal experts that there is a very serious concern about the maintenance of pointers to these third-party image archives over time in terms of the risk of maintaining the complete record of information that was used for diagnosis or clinical decision at the point of care.

And so I think that although obviously we're not precluding that kind of technology I think that's a serious concern for implementers and it will cause a lot of implementers to maintain extra copies of images that are shared by these mechanisms.

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

And so Jamie's comments are what I have seen, I'm an emergency physician and if I make a clinical decision based on an image in the cloud, you know, there's some part of me that says, if I'm going to be sued two years from now that I want a copy of the image I used or maybe the key image for clinical decision-making replicated in my own archives should the cloud ever disappear and I think this going to be a fascinating policy debate when is a persistent URL or a cloud-based approach, when critical to clinical decision-making is good enough? At the moment I'm hearing maybe local copies are what you need to do.

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

Or is it an artifact that just simply points you to that, that existed, but I think this is an opportunity to look at that across multiple use cases. Whatever policy happens there is relevant to many, many other things.

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

Well, but I think also it does depend on the use case and so there may be for example some reporting use cases that may potentially have a lower standard compared to treatment use cases where the image is informing a clinical decision.

So, that gets back to the variety of different purposes for image sharing but any time that you're performing an audit or a clinical decision diagnoses for example the input that we had was that in essence you have to have a – maintain a copy in order to have that record and that the pointer is not sufficient.

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

Great the next Michelle who else do we have in the queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Doug.

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

Doug, please go ahead?

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

Yeah, so thanks so much and Jamie congratulations I think you and the team have done a tremendous job of really taking a complex issue and sort of breaking it down into sort of its various pieces.

So, when I take a look at the list that you've come together there seems to be consistency with using LOINC across all of the different tiers that you've described and I also see that there is this notion of kind of the encoding based on Leslie Kelly Hall's comments, this notion of JPEG or JPEG 2000 plus some variant or some kind of core of DICOM.

And then it appears that when it comes to the transport standards, the push, the pull, the view there is a lot of options that we can consider there. It doesn't seem as if maybe things have necessarily coalesced but clearly that variation is going to be likely predicated on the use case that you have and the way in which you want to use or reuse that image information.

Are there other things that would be sort of consistent across all the tiers or that would be from your view sort of these modular substitutable pieces that are relatively stable and that would be part of that low hanging fruit?

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

Yeah, well, I mean, so thank you Doug, I think that, you know, certainly we tried to include those things that were consistent here and obviously, as you mentioned in the transport, I mean, there has been industry coalescence frankly primarily around the XDS set of standards and so in order to move away from that we thought we really had to both include the other web-based methods but also considering the balancing test to also include the ability to use the existing infrastructure. So, I don't know that there really is that kind of low hanging fruit in this area as you're asking for.

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

And I would concur. I mean, what we saw was this heterogeneity of content depending on is it consumer, is it professional, is it a key image, is it radiology, cardiology or something else and we saw heterogeneity of transport depending on architecture. So, you know, Doug we want to be modular just like you suggest and I wish we could constrain this further, but, you know, in some ways the industry continues to evolve and I guess we have to set a baseline and constrain as the industry evolves.

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

Great, thank you so much.

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

Michelle other folks?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Dixie Baker.

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

Dixie?

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

Yeah, my question actually follows nicely on the conversation we just had. I think, you know, looking at this you can't help but notice all the optionality that is here and so my question really is if we can't constrain the standards themselves will we need to constrain the certification because looking at this it seemed really very, very complex to certify products against what you're presenting here. So, how do you – do you intend to constrain the certification such that, you know, you just certify certain of these boxes on here perhaps? How do you plan to align this with certification?

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

Yeah, you know, I mean, I guess – thank you Dixie, so I guess in my mind at least that, you know, kind of gets back to the policy goal setting process and of course the charge that we had and the variety of use cases, variety of content, variety of senders and receivers, variety of infrastructure components, and varieties of purposes of sharing that we had to consider really I think is what drives us to this variety of recommended standards.

If we had a single use case scenario for a single purpose with a single image type that we were trying to make a recommendation for, you know, frankly then I think that the certification for that might be much easier and I think, you know, Doug mentioned also the need to consider the use case scenarios that this is going to be used in.

So, I think for the things that we were charged with we really had to come up with this kind of optionality and if in the future we got some policy direction that said, you know, we're really only considering full sets of radiology images in a hospital. Well that's different from the charge that we were given.

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

And in effect, so Dixie you raise this really important question which is one to I think reflect back to ONC which is the policy goal here is to ensure that images are accessible in the EHR and conceivably, as Leslie suggested, accessible to the patient and so one wonders if they word access itself is vague, I mean, right it doesn't imply that you have to download and store the image in the EHR or the PHR to access it. So certification does become kind of interesting.

I mean, if my version of access is I want a URL that points to a DICOM image and happens to display in the EHR using a HTML 5 vendor neutral reader, I mean, is that the sufficient? Well, it is access.

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

Yeah we can get that, we can carve out the subset of these recommendations for that purpose, exactly.

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

And so I guess maybe this is, you know, Doug our attempts to codify the state-of-the-art while not constraining architectural innovation which is really hard to certify because of optionality. So if the policy itself enables us more constraints we're happy to do so.

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

It may be that we have to certify to be able to view and then, you know, kind of work our way up from the bottom perhaps.

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

Right. Okay, thanks. Michelle other comments?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Andy Wiesenthal.

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

Yeah, hi, thank you Jamie, hello and how are you? I, you know, this discussion provokes in me a sense of déjà vu because it's a lot like the discussion of what constitutes the legal medical record and I think again we may need, I hesitate to say it, advice from lawyers because if we ask them they would say, well you actually have to have a copy of what you do locally in the local place and that actually governed a lot of the health information exchange that Kaiser Permanente had to do and how it was structured and Jamie could comment on that.

So, I don't know whether this same thing applies to images or not but just having a URL isn't the same thing as having the image in the local medical record where the care was delivered and the decisions were made.

So I don't think we should enter into the discussion, because the good news is I don't know that there any lawyers on the phone, but we shouldn't be making a recommendation that would then be found to be contrary to the legal notion of what a medical record is.

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

And I think that's very fair and just my Beth Israel Deaconess experience is that we have three kinds of interoperability where we pull and push C-CDA or other objects but we also do have view interoperability where an emergency physician in one click can view an Epic system at a distant provider's location and make decisions based on what they view and they may include in their note a summary of what they viewed but we don't somehow do a screen capture of what they viewed and consider that as part of the medical record.

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

Yeah.

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

So I think you're right, the legal issues of what is the medical record do somehow constrain, not so much Meaningful Use or certification, but the actual workflow within an institution.

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

Yes.

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

Michelle other comments?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

It doesn't look like there are any other comments.

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

So, Jamie I wonder if a reasonable next step – we've heard from the group and it doesn't seem like there's significant revision of anything that we proposed, but I think there is this theme that you and I feel, and Dixie articulated that if we're going to get to certification criteria we somehow need to skinny down the particular standards that would be used for any certification process and not tell every vendor in America implement every one of these optionality elements in this one.

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

Right and do everything for every purpose for every different participant in any possible exchange.

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

Right.

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

So, you know, I wonder perhaps this is a question Doug for you as to whether this is a conversation that should go back to the Policy Committee to seek more guidance on specific purposes for image sharing and specific use case scenarios that really should be considered for certification.

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

Yeah, so Jamie I think that's right. I know that both you and John did have a conversation with the HIT Policy Committee earlier this summer in an effort to sort of get some clarity around things and what I sort of remember from that discussion was what was important was to begin that incremental path, as Dixie has articulated, we should start someplace and that images are an important part of good medical care and that there really kind of two parts to this.

One is this notion of making sure it that consumers have access to that image and they can view it or if they wish to download a copy of their fracture and post it on Facebook they should be able to take a look at those kinds of images as well and what would that standard look like and would be an appropriate way to be able to have that image viewed and/or downloaded?

The second one I think was really around the lines of provider to provider which is if I have recently been diagnosed with a medical condition and I need to make sure that the physician that I'm referring to whether it's a radiation oncologist or whether it's some other sub-specialist and they need to have a copy of that image, what are the diagnostic, you know, the kind of information that can be exchanged that can come out of a radiology system and be consumed then by the other?

And I think there has been a challenge in that DICOM has often times extensions that reduce compatibility and if somebody burns a DVD that contains those extensions sometimes that can limit the ability to have that information be used in the receiving system even if there are particular viewers or other things like that that are available.

So, I think what I remember was access is important and that we need to include consumers in that and that there also needs to be a mechanism for providers to be able to sort of send and ingest the images that they may be required as well.

So, I think that the analysis that you've done here gives a tremendous number of options and it helps us recognize I think one, an image needs to also have some accompanied text and I think that's an important piece that you've got on the list.

There are a series of standards that are available within DICOM and perhaps RSNA or others can help us really figure out what that parsimonious set of standards that everybody should see as core could be and then I think when it comes to the various transport mechanisms many of those are going to be determined by the use case. So, whether it's a view use case or whether it's a download use case, or whether it's a sort of send use case I think there may be different options to consider as part of that as well.

So, I think this provides really substantive fodder to ONC to be able to sort of review and incorporate with regard to the HIT Policy Committee recommendations.

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

So, very helpful summary Doug and I will tell you just from Beth Israel Deaconess perspective we will need in the future to have both tightly coupled image exchange with owned institutions and loosely coupled image exchange with friends, family, you know, folks in the periphery. So, we wouldn't want to say you must do tightly coupled or you must do loosely coupled.

So I'm glad we provided input and I think our responsibility to the committee is once the certification rule is in process that we be very careful not to create undue burden or undue restrictions picking from this grid but not imposing this grid.

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

Very, well said.

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

Yeah, I think that's right, thank you.

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

Great, well, thanks so much Jamie and thanks everybody for your input. Now Michelle, you know, I realized I did drop off the phone for a few moments, has Jacob joined us? Where there any comments he wanted to offer before we move on to the patient matching discussion?

**Jacob Reider, MD – Acting National Coordinator – Office of the National Coordinator**

Jacob is here, John, I've been on since about 10:00, so thank you. I think you gave a good intro that I don't want to be redundant of. So, I'll just say we had a great showing for patient matching conversation here in DC with representatives from many sectors of the care delivery community, vendors, implementers, standards geeks, etcetera. And it was the start of a process it wasn't the end of the process.

This is an important topic that we've gotten a lot of feedback on. A lot of people have passionate perspectives in this domain but I think we're getting much closer to figuring out how to address this issue in a shared way across the community. So, that's all I'll say. So, thanks all for being here as usual and sorry I was late this morning.

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

Great, well, thanks so much. So, let us move on then to the patient matching discussion. Doug I believe is it Lee Stevens who is going to present that?

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

Yeah, so Lee Stevens is here with me and we're going to sort of do this jointly. What I wanted to do is just provide some introductory framing on things and then I'm going to turn it over to Lee who will step through the work that he and his group has done.

I think one of the things to recognize is that we have really since the inception of the HIT Policy Committee and the HIT Standards Committee recognized the importance of making sure that we have information for patient really matched in two ways. One is that we need to be able to make sure that over time we can follow patients and so there is this notion of longitudinal matching to make sure that historical information can be linked to the current and that we can make sure that's leveraged for the care of patients.

The second of course is that we want to be able to link across different data sources so at any given point in time to be able to link across the various data that might be collected. And so in 2011 we know that the HIT Policy Committee made a series of recommendations and there were a number of standards there were also identified by the HIT Standards Committee.

And we've been hearing a lot from the community that this is something important and that this is something that we really do need to turn attention to, because as we start looking at consumers aggregating information and making sure that it's correct as we look at what's happening regionally as people are sharing information and as we look towards things like PCOR in which the goal there is to be able to do outcomes research linking clinical data and quality to cost and other kinds of administrative data. This is an area that continues to come back and that we need to focus on.

And so as a result of that over the summer ONC contracted with an organization or one of our contractors to really help us refocus attention on this issue and to sort of start that conversation again. In large part, you know, there have been advances, there have been changes that have happened in both the standards that we've adopted as well as technology, big data all of those other sorts of things.

And so what we're going to be presenting here or what Lee is going to be presenting will kind of go through the way we've approached the problem, the scope of the work that we've taken a look at and really I think help us begin the conversation about how we can start to systematically tackle the problem of patient matching and the like.

And so with that I'd like to turn it over to Lee he is the Policy Director for the State HIE Program. He has been leading this effort and sort of has done a tremendous job of bringing together a whole host of different people into the community, getting their input and I think this is an opportunity for us to turn the attention, give you update on what we've done so far and to start the conversation I think within the HIT Standards Committee as well.

So, with that I'll turn it over to Lee and I'll make sure that we've got all of our presentations and things ready to go here. So, if we can – let's go to the next slide here. So, I sort of stepped through a lot of this stuff. We'll start here and I'll let Lee then highlight some of the work that he has been working on and we'll go from there.

**Lee Stevens – Program Manager, State Health Information Exchange Program – Office of the National Coordinator**

Sure, thanks Doug and I appreciate the opportunity to present today. This has been a very interesting and relatively fast process. What we were really looking to do was to look across all the incredibly good work that has been done over the past few years and find the common denominators and go out through an environmental scan and find out what's happening in the industry and what the health systems are doing, what the HIEs and HIOs are doing really and how patient matching is performing in these different environments.

We were very curious about explicitly what we could do to improve patient safety as we were moving forward in increasing complexity in Meaningful Use and so we really did a large scale literature review took into account much of the work as Doug mentioned and we of course worked with Audacious Inquiry to go out and perform the environmental scan and to provide that feedback to us.

I'll switch up to the guiding principles. Next slide. So, again what we were really looking at here is patient safety is the driving force for improvement in matching. We really wanted to see what the real-world impact on the workflow could be from an administrative and clinical perspective, how the improvement could really work well in the clinical environment.

Obviously, patient matching is a very complex problem. We know that there are – there's really not a final solution probably in the near term. As technology is improving and there is greater comfort with things like biometrics and that kind of technology becomes more implementable patient matching will naturally improve over the coming decade I am certain.

But for the near term we really wanted to look at what we could start doing in the very near term to improve patient safety and to ensure that patient matching helps the transitions of care and view, download, transmit perform at its really highest level so that we really start to see some of the outcomes that we're counting on.

On the next slide the goals of the project, we again, this is repetitive in some sense, it was improving patient matching based on the current outcomes from a cross section of entities we worked with the federal partners on this. We very closely with DoD, VA, SSA, with CMS. We were really trying to learn some of the key attributes that can be standardized and consistently relied on for matching patients.

And we really wanted to understand the processes and best practices that support patient matching. We wanted to pursue the improvements that would have the broadest impact across the most use cases. We did not take into account administrative or research use cases explicitly as we were sort of focused on a broad set of clinical use cases.

On the next slide there is a little bit more on the project overview. This is really what our process was. Over the summer we did a large scale literature review everyone learned a lot and found a lot of common denominators across the work that has gone on across a multitude of organizations.

The environmental scan was about 50 organizations that are doing patient matching and we tried to look from a broad cross-section and really learn what they're doing and we wanted to really take from that an initial set of findings that would allow us to do further review and feedback, just as we're on this call today it's very important to present this as transparently as we can to everyone so that we sort of maintain the integrity of this process and we really move towards some solid next steps.

On the next slide, the overview we really sought feedback before and during the process to ensure that all of the partners and participants are aware of the methodology that we were using. We really broke up into about four sets. We used standard questions for formal interviews across health systems and IDNs, HIOs, the vendor community of an HIE and master data management side, and also with EHR vendors.

We did work quite a bit with the federal partners and trade associations, consumer organizations. We really tried to engage them in a very practical way and what we found was that there was a lot of common ground in this space. We're starting to see the convergence of some of the desires of parties that have typically been very opposed to each other as we start to see consumers taking a larger role in their care and care coordination in the past of health information exchange.

On the next slide identified barriers to accurate patient matching. We found that inconsistent formatting with the data fields is pretty widespread that obviously creates a bit of a problem. Mistakes in data entry, this is really incredible and goes to the data quality issue. No matter what we standardize or how perfect we make anything with bad data it just doesn't make any difference at all and so we have to take that into account in a very large-scale to make sure that we're not producing unintended consequences by over standardizing in one particular place.

We found that smaller organizations and practices may not be able to afford the sophisticated methods and algorithms and this is why we really wanted to look from a very practical stand-point at really what we could do in the very near term.

We recognized that patient engagement efforts have not yet evolved to ensure that consumers can routinely access their demographic information to confirm and update it and this is in some places where we've talked to them, one that I know of particularly, I think that MD Anderson down in Houston has done an incredibly good job over the past decade of engaging consumers in a meaningful way and that has really made the consumer a central part of the care and improvements of all of the data.

On the next slide there is sort of the recurring theme, improving patient safety, obviously that was sort of the reason to do this work. We want to of course improve care coordination that becomes more important with transitions of care, view, download, transmit, empowering patients and their caregivers. We really, of course as everyone knows, we're pushing heavy on the consumer side which is very important for healthcare transformation broadly.

And we recognized that we were hearing standardization done incrementally really beginning with the most common demographic fields while we continue to study and do research on what's performing really well in other places. We, you know, this is sort of an area where we get into things like name, birth date, address, we have heard a lot from many people who take the approach that the more data that they capture the more they have to match on.

So, we did have some requests to go further, but again, one of the underlying concepts here is that we want to weigh quality and standardization so that we're hitting the perfect balance between those two and that really goes to the last two bullets here whether it's a technology improvement that will improve the quality of the data or if it's really a training aspect of the work that we need to do that will really get that initial input to be more accurate and to perform at a higher positive matching rate.

So with that the next slide is our initial findings. For number one we came up with, standardize patient identifying attributes in the relevant exchange transactions. Consider the certification criteria to capture the data attributes required in the standardized attributes. Study the ability of additional non-traditional data attributes to improve patient matching.

Develop or support an open-source algorithm that could be utilized by vendors to test the accuracy of their patient matching algorithms or to be utilized by vendors that currently do not have patient matching capabilities built into their systems. This is a particularly interesting finding for us and one that there has been quite a bit of feedback on.

On the next page, the second page –

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Could people please mute your lines?

**Lee Stevens – Program Manager, State Health Information Exchange Program – Office of the National Coordinator**

On the second page of our initial findings, consider certification criteria to demonstrate the ability of a system to generate and provide to end users the reports that detail potential duplicate patient records, build on the initial best practice that emerged during the environmental scan, develop best practices and policies to encourage consumers to become involved and to update their information. And finally, work with healthcare professional associations and also through the SAFER guide initiative that's coming forth to really work on some of the data quality issues here.

The next slide we start to take a bit of a deeper dive into what each finding led to and under initial finding one standardization of data attributes, it was really that standardized patient identifiers should be used that it doesn't require the standardization of the capture of the data elements but rather the exchange of the data elements which are commonly used for matching in HL7 transactions.

The data attributes and the standards are on the next slide which is really an interesting list and, you know, if you look through this slide you really see we tried to keep this at the initial simple phase of pretty common thing, we were not trying to get too exotic in our thinking here. First, given name, last name, middle initial, suffix, date of birth, current address, historical address, phone number and gender.

These were the most commonly identified attributes that were heard during the environmental scan. Of course we did get many requests for Social Security numbers to be included on this list, but it did not reach the threshold that these attributes did.

Initial finding number 2 on the next slide, capturing data attributes. This is really around certification criteria that could be introduced that would enable certified EHR technology to capture the attributes really necessary for the standardized patient identifier content.

We recognized part of the rationale here was that not all of the data attributes being recommended to be required on PID segments are currently captured by the certified EHR technology and there is variability in the ability to capture apostrophes and hyphens. This has been a problem obviously can create some false negatives from time-to-time and trying to move toward a more unified approach to this would help alleviate some of those problems.

On initial finding number three on the next slide data attributes requiring further study. Study the ability of additional nontraditional data attributes to improve patient matching. This is where we heard a lot of requests to basically capture as much data as possible, particularly numbers, people like the concept of passport number, they like the Social Security number, driver's license number and other things, of course eye color, mother's first and maiden name, father's first and last name, city of birth, e-mail address some of these different attributes.

I think that the challenge here is that we don't have good data to support how much those elements actually would improve patient matching and we would need to do a bit more analysis to prove their ability. We do know that some entities do have that and that is something that we may be looking toward in the future.

Initial finding number 4 under patient matching algorithms, this was a particularly interesting one, which was to develop or support an open source algorithm that could be utilized by vendors to test their accuracy or it could actually be implemented by vendors that don't currently have patient matching in their systems. ONC would not of course require the use of a specific algorithm that would not necessarily be our path, but this has some interesting pathways in the future. This has been of particular interest I think for Bryan Sivak and his office.

On initial finding number five identifying – so we're going up two slides now up to – back one to initial finding five, perfect. Identifying duplicates, consider adding certification criteria to demonstrate the ability of a system to generate and provide to end users reports that detail potential duplicate records.

What we learned was that many systems have this capability now, but that not many people are actually using it or are even aware that their system can do this. This has been – this would obviously be an incremental step toward improvement and this is something that we wanted to sort of call out in our list of findings as an important one that could be useful.

Initial finding number 6 on the next slide, data governance policies and best practices, clearly, you know, we want to build on the best practices that we learned about and we want to think about a more formal structure for establishing best practices. We really want to make this meaningful.

We've done a lot of work on the HIE program around best practice and it really depends on what the subject matter is for how much uptake those practices actually get and we really want to look at something here that would be a bit more formalized that could create a more unified approach nationally on patient matching. If we do more one offs it may improve in a certain areas but we would not get a marked improvement nationally.

Initial finding number 7 on the next slide is really the consumer engagement piece. We have heard very clearly from lots of folks that patients are the best people to validate that their demographic data is correct. I think that that makes perfect sense and most patients I believe appreciate the opportunity to take a look at that and to update it.

This is yet another incremental step it could have great impact depending on the level of consumer engagement but we're really looking at this as a collection of findings that all put together could sort of move the needle in the right direction.

Finally, initial finding number 8, data quality policies and best practices, this is really very, very important. The data quality issue is paramount and the way that we go about that we need to think through that and think about the ways we can be most impactful.

We need to, as I mentioned earlier, we need to strike that right balance between standardization and quality improvement to really make this matter. The issues with data quality were very evident to us across the environmental scan in some places where we found that sort of tightest, for lack of a better word, the tightest systems with the most criteria were very undermined if there was a data quality issue. So, again data quality is really at the heart here and how we address that broadly is pretty critical for our path forward.

So, with that I sort of breezed through these slides, because I wanted to leave time for questions because this has been a hot topic quite frankly and to see if there are any questions or any discussion that we'd like to have on this topic.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks.

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

Well, Lee thanks so much for that presentation and I will say that as I joked with Jacob yesterday Massachusetts solved this problem by simply buying 7 million licenses to a commercial product and in our country you'd only have to buy 323 million more and you'd solve the problem and of course this is not a scalable solution.

So, we very much appreciate the work that you're doing to delineate what data quality issues need to be remediated and what data elements would be considered a best practice with sufficient sensitivity and specificity so that as vendors implement new products, as communities implement HIEs, as registries are created that we have the guidance to know what is sufficient and aren't all forced to go out and buy a commercial product millions of times.

So, with that Michelle, do have folks in the queue who wish to make comments?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

There are a number of questions in the queue. Arien Malec.

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

Hello, this is the only meeting that I've ever been to that has been interrupted by a bomb squad evacuation so that's a first for me, but it was an excellent meeting and I'm going to be repeating myself since I already said this at the meeting, but in the Standards Committee context, one of the things that I heard loud and clear in the meeting is that number one, and that reflects my own experience, is that number one deterministic matching can only get you so far you need to move to a level of probabilistic matching.

Number two, probabilistic matching in the presence of messy data is going to have significant obstacles and number three the more data that you have that is a backup key or additional matching attributes that provide you additional levels of confidence the better off you are.

We heard some commentary on, you know, maybe it's not Social Security number but last four of social can provide a significant boost in terms of match rates and we need to be considering what are the easiest attributes that are normally collected across the health system that have the least privacy implications and the greatest improvement in match rates?

But I'd say, you know, the sense of the room was that there isn't a silver bullet when it comes to deterministic, to probabilistic matching on the usual suspects in match data or features particularly in the presence of messy data.

The second comment that I have is that with respect to EHR certification I think we maybe barking up the wrong tree in the sense of too far down the value chain or too far down the origination chain. If you follow a lean methodology you want to fix things at the source and that we may get more bang by doing things like standardizing data attributes on an 837 to ensure that they're collected appropriately upstream in the process in registration than we will in standardizing attributes downstream in an EHR system, because generally it's the registration systems that are collecting information.

And the third comment that I have is that the data normalization or best practices for data standards are not applicable just to EHR data entry or to things like an ADT transaction. I already mentioned the 837, these same attributes are included in NCPDP transactions are used for patient matching and linking. They are included – most of them are included in clear required data elements for sending a result.

There actually are some missing elements with respect to CLIA and I'd note that HHS, that while ONC has purview in a limited area, HHS has purview across a lot of the systems that play through CMS and its oversight in terms of claims transactions and eligibility transactions as well as NCPDP transactions for PDPs and CLIA clearly with regards to the lab transactions and so I'd encourage HHS to look at a wider set of policy levers that may have more impact on improving match quality than is applicable purely in the certification program.

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

Great, well thanks very much. Any – Lee or Doug any comments or response?

**Lee Stevens – Program Manager, State Health Information Exchange Program – Office of the National Coordinator**

I wanted to say that I'm glad Arien got his coat back, because we almost lost it during the evacuation.

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

Thank you Lee and my laptop too, I did appreciate that one and the iPad, yes.

**Lee Stevens – Program Manager, State Health Information Exchange Program – Office of the National Coordinator**

Oh, oh, I didn't even realize, I knew your bag was in there but I didn't realize it had that in there, in it.

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

I think the one thing that I can say is that the meeting that we had on Monday was incredibly informative and I think it really did help us understand better some of the issues and some of the things that we need to pay attention to.

In the time between the meeting ending on Monday and the bomb scare that had occurred during that meeting and this meeting today we didn't have time really I think to summarize things.

I think Arien did a nice job of really sort of summarizing some of those key features and we will I think continue to kind of collect that information and collate it together and try to understand better the results of that particular meeting.

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

Thank you. So, Michelle, are there folks in the queue?

**W**

Eric.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yes, Eric Rose.

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

Hi, yeah, this is a very interesting discussion. I had one use case to suggest to keep in mind, it may seem like an edge case, but it's going to become more and more common and that is prenatal diagnosis and treatment and the fact that there is data that applies to fetuses that is then going to need to be somehow connected up to the patient records when they're born and it's a big hole currently and of course you don't have the date of birth for instance and so I think that keeping that use case in mind as – not that everything should be held up for what's a fairly uncommon situation, but it's one to bear in mind especially to make sure what we move forward with doesn't block, you know, that particular issue.

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

Good. Other comments Michelle?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Sorry, Wes Rishel.

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

Thanks, as I understand this we started thinking about patient matching in an interoperability context and that led to discussions about patient matching in systems where information originates because of the general issue about that you can't do much better than the quality of the data.

And it strikes me that one of the biggest problems we have in this area is the lack of feedback that is to say, false negatives in terms generally creates a duplicate record and there are occasional times such as when installing a new EMPI system that people systematically go back and look for false positives.

False negatives are where one person's data gets attributed to another person. We think, but we don't know, that most times that we tend to err in the opposite direction towards a false positive because the danger of something being assumed to be correct is higher when there is a false negative, when there is a mix patients data together under one patient. It's also not easy to do some sort of computer-based study to identify these things for obvious reasons.

But I wonder if any consideration has been given to treating the discovery in care of a patient ID error that is either data that the patient disclaims or data that doesn't apply to the gender of this patient and there's no likelihood of a gender change, whether treating that as an adverse event, as a reportable adverse event, wouldn't create a feedback loop that hasn't existed. It certainly wouldn't come close to catching all the issues, but I just have known in a lot of systems when there is feedback behavior change results so just a suggestion.

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

Well, thank you for that and I certainly concur that as I look at the three FTEs that do nothing more in my organization than clean up the patient matching issues, going back to the source and saying, well it was a registration clerk at 3 a.m. that was not very good about recording some of the structured data isn't done today. So, Michelle other folks?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Leslie Kelly Hall.

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

Hi, thanks very much for this and Lee I was struck by your comment that the patient is the most reliable source for their demographics and their identity, and validation. And I wondered if we have, in this review, future opportunities for patients to self-identify the identity they would like to be used.

So, for instance if a patient goes through a process where they have their identity verified and have purchased themselves perhaps a digital trusted environment or the passport I think that was used at one time, not the US passport but some identity mechanism that the patient presents with if that's being accommodated for future use.

And then also what opportunities do we have when we think about the forward discussion about the use of OAuth where a patient is now registered to a particular system so that they can view, download and transmit, do we have opportunities to think of a future where that particular digital structure and identity around that patient can also be fed back into a registration and identity process.

So, even though it's not a government controlled opportunity, is there an opportunity for the patient to self-identify or for systems where they have had their identity registered to pass that information on in the future?

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

Any comments or reaction to that?

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

So, Leslie I think – thank you very much. I think one of the things that we mentioned at the meeting on Monday was when we think across the continuum, you know, patients, electronic health records, regional information exchanges are sort of national ways of providing for public health or for research purposes, across all of those continuums there are some unique use cases that need to be addressed in terms of challenges around patient matching.

But one of the things we also said was while we want to make sure we have solutions that can help address that whole continuum, we also have to look for solutions within those spaces and that some of the problems potentially with data quality or other things like that at the EHR or the regional level may in fact be solved by including the patient as part of the solution to making sure the data quality is good.

Now that having been said there are certainly instances where many people will reuse the Social Security number or other identifiers like that and we have to be vigilant to make sure that we do provide ways of preventing that kind of duplication, but I think you raise an interesting points which is to say we have mechanisms by which we can securely exchange information and we ensure that a person is who they say they are and there are kind of standards-based OAuth and OpenID certainly are ones that come to mind that help us with that. I think that is an area that we want to probably take a look at or explore.

How can we leverage existing mechanisms and provide some feedback? It also fits into I think some of the administrative priorities and the National Strategy for Trusted Identity in Cyberspace or NSTIC really envisions a federated way of making sure that people are who they say they are. And in any sort of federated system like that I think the patient becomes a critical component of that process.

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

Thank you.

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

This is Dixie I raised my hand but since it's on this topic maybe I should say it.

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

Sure.

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

I think there clearly is a connection between patient identity matching and identity proofing but I personally think it's more likely to go in the reverse direction where the providers perform identity proofing on the patients using their identity matching information rather than the providers relying on third-party identity proofing to certify the identity of the individual.

We talked a lot about, you know, about providers doing identity proofing for certificates and I think that that's the more likely way for it to go in my opinion.

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

Thank you. Michelle, other folks?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Lisa Gallagher.

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

Lisa?

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

Hi, thank you, Lee great job I apologize for missing the meeting on Monday so you may have answered this question there, but two questions actually. First, across your recommendations, you know, identify best practices, some convening work, development of open source code, etcetera, it might be helpful to clarify, you know, who the recommendation goes to or how we can facilitate that across the industry.

And then my second question is did you have any discussion about the suggested performance measures and key performance indicators that were submitted by HIMSS Workgroup or any other way that we could measure current performance and express that in a common way and if there are sets of, you know, measures and key performance indicators, you know, ways that we can vet that across the community and able to communicate it clearly, you know, how we're doing over time?

**Lee Stevens – Program Manager, State Health Information Exchange Program – Office of the National Coordinator**

Sure and thanks Lisa, really what we were doing is we're taking these findings and we're bringing them into ONC and really continuing this open process to see what steps and areas of work we can take forward.

Obviously, you know, we think that patient matching is something that has a long lifespan of improvement and so it is an area where we're looking to start to hone on what the key elements are and where we should focus our work and our attention internally for improvement.

On your second point you're talking about key performance indicators that would actually reflects how people across the country are doing in matching is that what you were saying?

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

Right, so we submitted a HIMSS White Paper from one of our Workgroups that identified – well they did an environmental scan of the types of measures and indicators that organizations are currently using to measure their performance and recommended a set.

So under the under the category of measures it would be total EMPI matches, total non-matches, data date duplicates, false positive match payers, true match payers, false negative non-match payers things like that and then the key performance indicators were sort of measures that could be communicated to management so duplicate creation rate, true match rate, false positive rate, indeterminate match rate things like that, there are two tables one is performance measures and the other is key performance indicators in that report.

Now what we'd like to do is to, you know, have that be considered for, you know, further vetting in the community to see if it works for everyone as a way to communicate how their improvements are being made over time.

**Lee Stevens – Program Manager, State Health Information Exchange Program – Office of the National Coordinator**

That's extremely helpful. You know one of the really interesting places where we saw in the environmental scan, and we'll have more details coming out on this particular point, at the state level some states have made it a priority to see improvement in patient matching and the reduction in creation of duplicates a priority and have put measures in place.

I know particularly the State of Maryland has done that and that's a place where looking at the states seem to be having an impact in this arena and I can't remember which other states besides Maryland are doing it but we will have that in the report that Audacious puts out early next year.

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

Well, thank you.

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

Okay, thanks.

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

So, Michelle we are at time for this discussion, anybody left in the queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

That's it.

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

Wonderful, well thanks so much for a robust discussion. We all look forward to getting a conical set of both demographic indicators and methods, as Arien described, whether that is an explicit or probabilistic approach that will give sensitivity and specificity so that all of us can be good enough.

So, with that I think we now move on to the very important discussion of our work plan for 2014 our goals and priorities and turn it back to Doug for that discussion.

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

Great, thank you so much. So, for this – this is really a continuation of the discussion that we started last month to really take a look at our standards work plan and to make sure that we're on the right track with things.

I think one of the things to realize is that, you know, from my perspective the announcement that was made on Friday about kind of where we're going in the future with some of the regulations doesn't really change the urgency that we have to really start making sure that when we're making forward progress and that we're prioritizing things effectively and the like, and so what I think would be useful for us is to sort of again go back through and I want to just remind people of the different categories that we had with regard to the work plan, sort of frame some of those activities.

We've actually, between the last meeting and this meeting, we've actually made some forward progress particularly around the image exchange activities and the report out that Jamie gave, that was one of the high priority work plan activities that we can now sort of check off the box. So, with that I'd like to just sort of dive in. Can we go to the – what I guess would be the next slide.

So, one of the things that we have to sort of think about is as we're looking ahead to the work coming up, one of the things that I think we may want to explore is do we need to take a look at the HIT Standards Committee Workgroups and make sure that we've got both the appropriate distribution of work and the appropriate kind of expertise that we've aligned for where we need to be with some of the future incentives and that we don't burn out those folks that have been really high contributing members to the organization and to the structure of the Workgroups while giving opportunities for folks who are kind of coming into the committee or that would like to make a more substantive contribution.

We also, I think, have to recognize that many of the member's terms will likely be ending in the course of the next year or so and as a result we have to make sure that we've got the appropriate load-balancing with things.

I think, you know, just for an example, Jamie has done yeoman's work within the Clinical Ops work but there is tremendous amount of activity is occurring there and that – you know, things as important as a vocabulary and terminology strategy is a task force within that larger group but we need to sort of think about how we might be able to address some of those things and make sure that we've got alignment not only as we look to Meaningful Use Stage 3 but we look beyond that to some of the other activities that might be coming down the pike and whether we need to think about what to do with our Workgroups.

So, one of the things that I think I would welcome input from this committee is are there ways in which we can begin to approach this problem and are there suggestions for how we might organize more efficiently? Let's go to the next slide.

So, you know the other thing and I sort of alluded to that, is that we are likely going to be putting out, you know, the final Meaningful Use 3 recommendations will be submitted in February from the HIT Policy Committee Letter of Transmittal, we've already received some recommendations for information exchange for privacy and security, and we are going to have to include that in our work plan as we sort of go forward and making sure that we've got the appropriate distribution of work.

One of the reasons that this is important is that we have decided not to have a meeting in January just to kind of get our Workgroup realigned and we'll meet the first part of February but that's going to happen relatively quickly and we're going to have to sort of organize to address that.

As well we're working on, you know, well, we're going to need to be thinking ahead to some of the work that's going on with the rules that we're currently looking at and trying to make sure that we've got time on the schedule to respond to NPRM and things like that and I think that needs to fit into our 2014 work plan discussions, which I think we need to kind of take a look at on February 18<sup>th</sup> based on the conversation that we have here and the input that we get from the committee. We'll go back and we'll try to come up with a strategy and a priority much like we did before to make sure that we're addressing the issues that need to be addressed. So, let's go to the next slide.

So, with that I want to just sort of review where we were last time and then make sure that if there are changes in this or the like then we can sort of put it to rest and we can make sure that we've had an appropriate conversation.

So, the first is, you know, we call it category one which is around quality and safety and we had things like standards to support flexible platforms for measuring and reporting quality that was something that was one of the high-priority activities that we had.

We had standards to try to support measurement of EHR usability. That was one of the things that was on the list although it wasn't something that we necessarily had specific activities around in terms of the high, medium priority activities, standards to address current content gaps like version 2 lab orders, formulary downloads, canceled transactions needed for hospital discharge. We've had conversations about that and we need to sort of coalesce around that.

Defect reporting to PSOs, we've got work that's ongoing within the structure data capture activities and we'll need to get some feedback on that and standards again which support redundant data, identification and reduction, we've just had a conversation around patient matching and the need to be able to sort of de-duplicate or be able to match information across different data sources.

The second category that we I think have been looking at is around health information exchange. And when we think about health information exchange we often think about that at a regional level or information exchange that happens not with a consumer or as part of a practice or within an enterprise but across those in a more regional way.

So standards which support query response of provider and patient identities and directories. We've got some work there. Standards which support record locator services that was something that was considered to be a relatively high-priority activity in terms of our assessment of that.

Standards to support consent and a query response architecture such as granular patient privacy preferences pull in a managed service or a private request where you might have a push, improvements in the Consolidated CDA, again, perhaps some of that around the patient identification areas as well as making sure that there is unambiguous parsing that we have more, less optionality and that we move towards things that will help improve longitudinal record sharing and bulk record sharing, again, some of those things fit into our data access framework and we've had an update today about standards to support image exchange, again a very important aspect of our work.

The next two categories, if we can go to the next slide, focus around consumer and we've had a really nice update from Leslie Kelly Hall about some of the activities that we can consider within the consumer space, so one of the things Leslie that I did not do prior to this presentation was to take a look at the recommendations that you had, I know those were, you know, fairly granular but to fold those into or to make sure that we've got the right categories here.

So, I'm actually going to give Leslie you a task to make sure that we've gotten the right things here and if we've missed the bullets then please let us know, but certainly standards to support representation of patient generated data including device, I think we covered some of those.

Consumer friendly terminologies, again something that we discussed. Standards to support transport of data to and from patients, we looked at Direct as well as some of the RESTful approaches.

Standards to record advance directive and care preferences and then standards to record care plans as well as to coordinate across care teams. I think we hit most of those I don't know if we've got some that are missing here, but certainly if there are some things by all means we need to make sure that that's included.

Category number four is really kind of at that larger level that includes the Accountable Care Organizations, population health and care management. These are things that I think really are very forward looking towards health care reform, the Affordable Care Act and other things like that to see how we might be able to use standards for clinical documentation to support new payment models.

Paying for quality making sure that we've got other ways that we can generate problem lists, that we can use ICD-10 and SNOMED in an intelligent way to help reduce the burden administratively for providers and allow them to document in natural ways that generate the coding and the billing based on the documentation that they do as part of delivery of care.

Standards to support registries that include, you know, the work we're doing on structure data capture and transmission to third-party repositories. Closed loop referrals was an area that we saw as a high-value activity in our priority and then standards to support data comparability across entities including this notion of detailed clinical models that allow us to get to more granular ways of representing the meaning that's present within the data that gets exchanged.

And similar to the work that we talked about over on quality and safety the other side of that same coin are standards that will support clinical decision support both in terms of disseminating that, that's one of the activities we have that's in the S&I Framework, as well as ways that we can create access to knowledge resources perhaps APIs or other things like that that will help support the ability to make good decisions as we go forward.

The last category that we looked at was around privacy and security and you can go to the next slide here, that includes standards for securing data at REST which was deemed to be something that we have existing standards out there and I'm not sure that we have to do a lot of extra work, but certainly genomic data and consumer downloads are something that might be included and it maybe that we don't need any particular work on that just because we've got those bases covered.

We've heard over and over again the need to be able to move towards more application programming interfaces or ways to have connections which I think really make some sense and so how do we do that, what's the incremental path to get to that point so we can move from giving people descriptions of how to implement the standards to giving them the instructions for how to be able to interact with a programming interface. And I think the difference between giving someone the recipe for building it themselves as opposed to the instruction manual for how to use it may be a way that we can simplify the way in which we do our work.

Standards for supporting data segmentation and privacy, we've got those things already in the pipeline and balloted through HL7. Standards in certification criteria that really are looking ahead, again, this is part of that pivot to that national, the National Strategy for Trusted Identities in Cyberspace and how we can think about more federated approaches that may leverage things like OpenID and OAuth.

And then finally standards to support digital signatures making sure that we've got the ability to understand the provenance that we have the ability to take a look at not only a collection of documents signed but also individual documents or even potentially getting to the point of having segments of a document perhaps an attending physician and a resident or a nurse and a doctor being able to sign different parts of the data that they have.

The next set of slides are really information that you've already have seen and I'm not going to go back through all of these because I've already sort of done that, but these are included just for your reference to let you know where we were at the last meeting in terms of what were the high-priority activities. We can go to the next slide.

And there were sort of two pages, there was one page of that, there were some activities that were considered medium including lab orders and some of the terminology work and then the last slide if we could go to that, a couple of other things around medium priorities and then the last slide is the notion of securing data at REST.

And so if we go to the next slide, which is really the last slide in this presentation, so the last slide here, I really would like to get a sense for what would be helpful to the committee so that as we look ahead to getting the recommendations for Meaningful Use Stage 3 from the HIT Policy Committee, as we look towards evaluating an NPRM in the next year and as we think ahead towards these high-priority items and making sure that we've got those things someplace in the pipeline so that we can be supportive.

What would be the things that, one how we should we best organize and break up some of the work so that we have a good distribution of work recognizing that there's going to be some changes in terms of the committee structures and the participants that are part of the committee as people roll off and new folks roll on?

And then how we can then use all that information between now and February to come up with a draft work plan that we can then review and vet in February leaving us ample time to be able to do some of the urgent stuff that's going to be coming down the pike with regard to the HIT Policy Committee and some of the reviews that we need for the NPRM. So, with that I'm going to turn it back over to John.

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

Great, well thanks very much, now, Doug you in slide 4 and 5 did review four categories of work and of course I just presumed in reading that that you were thinking that we would have four working groups and the work that you have categorized so well in quality, safety, health information exchange, consumer and ACO population healthcare management would become the work of assigned new Workgroups, but, just to be clear are you asking us as a group now to brainstorm if there is a different subdivision we might think is better?

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

Well, I think actually these categories make a lot of sense and certainly I think that's a strawman that we can put that out there. I think there may be other Workgroups that we need to continue. So for example, perhaps there needs to be a concerted effort to make sure that we've got our terminology work taking care of.

Certainly I think one of the areas not well covered here are things that are going to be related to the PCOR trust fund and research activities. We have engagement with our federal partners DoD, CMS and others that stuff may be crosscutting across these activities as well.

And so I think this a good place for us to start. I think we will always have activities around privacy and security. I think we do need to think about how we're going to pivot with regard to population health and care management and ICD-10 and things like that but those things may fall into another category.

I think consumer is clearly an important part, health information exchange and quality and safety. Part of it is, are these the right categories? Do we need to add some other ones in this? I'm thinking about a lot of the work that's gone in exchange right now that's been a very active Workgroup, but maybe we need to divide up the work I don't know.

I think this is kind of I think the first strawman to just sort of say, are these the right buckets? Are there buckets that we need to add? Are there ones that we need to consolidate? Is this the right kind of organizational structure as we think through the work that we have ahead of us?

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

And Dixie I didn't mean to of course leave off privacy and security as the important category on slide 6, but we all know that you rule the roost there, so there's no doubt. So, let us open it up to the larger group and Michelle do you have hands raised for folks who want to comment on this question of the work ahead and organizing ourselves to do it?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Leslie Kelly Hall.

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

Please Leslie.

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

Actually I have a question for later discussion when we talk about priorities. So, I support the definitions of the Workgroups as presented.

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

Very good. Are there other folks on our list? Michelle is the queue empty?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Dixie just raised her hand.

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

I'm sorry?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Dixie Baker.

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

Dixie Baker, please go ahead?

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

Yeah, thank you, one of the things that occurred to me is that given that our trajectory is going toward the learning health system I would have expected to see more around – in these category around clinical decision support and learning health systems and how you incorporate feedback, measurement those kinds of things that are associated with the learning health system and PCOR being one of them I guess. Where did you see that kind of thing falling?

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

Well, I think, you know, this is part of the – you know, we've gone back and forth about different ways to organize this, you know, we've always talked about the five things we standardize, vocabulary, content, transport, security and services. And in some sense we've got some of those things represented here as well but that would be another way to sort of take a look at it. I think when we looked over it though there was some clustering I think around functionality that made a little bit more sense to us as well as some of the other priorities.

And you're absolutely right this is the work that, in terms of these categories, came from a lot of the recommendations that we had from the HIT Policy Committee, we sort of coalesced that, we sent this out to the various committees to help us rank some of these things, but it's the reason that I sort of raise the issue of, you know, are we missing something and is there some work around learning health care system writ large and some of the work that PCOR and the research community are doing to sort of contribute to that learning health care system as well.

And it maybe that we need a category 6 that includes that I don't know. Is that sort of what you're thinking?

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

Well, I think it's sort of aligned – it's well aligned with quality and safety, but yet it's more – it's less static than how I consider quality and safety.

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

Well –

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

And includes more – I don't see, you know, clinical decision support anywhere here and yet we've talked about it many times or this interaction between the research community or emerging actually between research and clinical – these are important movements that I see in the industry that I think these Workgroups need to reflect.

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

So, Dixie what I'll do is perhaps put that a category six around kind of research activities and then also make a note that we need to make sure that we handle clinical decision support and where should that fit, perhaps that's something that does fit in the quality and safety. I think those are so tightly linked that maybe we need to call that out as an area of expertise within that particular group.

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

Yes.

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

A very reasonable proposal, thank you. Other folks with comments?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Wes Rishel has a comment.

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

Yes Wes?

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

Thanks John earlier today Stan made an observation about the tradeoff between developing or identifying and enumerating standards that can be applied in a single cycle of Meaningful Use and a more strategic look at standards, although he didn't mention any, I would argue that both FHIR and CIMI would fall into the strategic category.

I kind of had the impression that this was where we were going to have some discussion about that. Obviously it wasn't raised in time to prepare the slides, but there was a sense that the discussion was being deferred to later and I'm wondering if this is the place?

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

I think that this would be a perfect time for us to talk a little bit about that. I mean, I can – we are right now working on trying to not only address the needs that we have around Meaningful Use Stage 1 and Stage 2 and making sure that the communities are successful but really trying to think ahead towards, you know, what is it that we need to do for the future?

And I think one of the things that we've been sort of actively taking a look at is things like – if you think about our standards and what we do if we want to support Meaningful Use Stage 1 and Stage 2 it's really about kind of refining through experience and improving the standards that we already have out there in the community, you know, the only standards that you never have to improve are the standards you never use and so as people start to use these standards we need to make sure that we have the ability to refine and fix, and improve the standards that are out there.

I think in addition to that, as we think about Meaningful Use Stage 3 and beyond, we need to start expanding the portfolio of standards that will help us with additional use cases. So, for example discussions around vocabularies and terminologies that help us do a better job of assessing and categorizing function and maybe there's work that – you know, the VA right now is working on, in collaboration with the National Library of Medicine, to expand some of the SNOMED trees that deal with the functional assessment and certainly there's been discussion within the HIT Standards Committee around ICF or the International Classification of Function standards and we may think about how we might expand our current portfolio of standards or content specifications or transport standards.

But I think what you're talking about strategically is we'd like to be able to make sure that we provide that path for where we want to go and just as an example, you know, CIMI is really a way of creating more commutable ways of representing semantics. And it may be that we need to go from these declarative lists of standards that we use for vocabularies and value sets and get to ones that are more computable.

It maybe that we need to move from structures for content that are document centric and we need to move towards ones that are more data centric. We may need to move from ways in which we use either kind of SMTP or highly orchestrated SOAP versions to what the industry is doing which are really kind of lightweight RESTful approaches or APIs.

And when it comes to security we need to think about where we are now which is really a PKI infrastructure built around some of the Direct specifications that we've got and the web services to one that really I think aligns with the National Strategy for Trusted Identities in Cyberspace.

And so I think you're absolutely right Wes that we need to begin thinking strategically about fixing what we've got, expanding based on what the next sort of use cases might be but then beginning to kind of move towards these FHIR and CIMI, and RESTful approaches making sure that we're building on what we've got so far and supporting that expansion of the portfolio.

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

Yeah, this is Wes again, Doug I appreciate that statement. I think for it to be effective we need to sort of develop an approach to projects that are nurturing versus or incubator versus those that are on the long march to the next version of Meaningful Use and while that leads to what might be a very open list I think we can identify a few projects that seem so promising that we want to nurture them even if it's not ready for Stage 3.

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

Well, just as an example Doug, you know, we think of the phone industry and how cell phone technology said, you know 2G is really where we have to build today even though it's expensive and time consuming because 3G is not ready, oh now it's 3G and now we're going to build that out even though we know 4G is around the corner, oh and now it's 4G, and there was a thoughtful timeline of getting from 2G to 4G but recognizing that technology had to evolve in order to enable that.

And so you wonder if today is Direct and C-CDA but tomorrow is going to be FHIR, CIMI and REST with a little OAuth and OpenID, you know, are we structured with the committees you've outline to be able to make that transition and maybe it's the sixth committee that is looking at, you know, the research efforts and the future or something that is going to subsume that because you would hate to have a standardized buggy whips.

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

Yeah, John, this is Arien and I just wanted to give an Amen.

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

Very good.

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

This is Stan, yeah, I like the direction the discussion is going, what I was thinking is sort of exactly that John that, you know, an additional Workgroup would essentially be not along the same lines as the categories of the ones that are there which I think are appropriate, but we would have one that would be about future vision, you know, research, strategic, you know, things that we would like to see that might take years to accomplish but would dramatically, you know, change our ability to provide safe, effective patient care.

And so that's what I would really propose is that there be a Workgroup that was really worried about future and strategy and the research, and, yeah I don't know that I'd say more about it now, you know, we'd let that group maybe figure out how they wanted to make their charter, but that's what I would propose.

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

And I think very well stated Stan that we really do need two work streams, you know, one that works on the details of the urgent while the other looks at where the puck is going to be 2-3 years from now because we need to do both sets of work.

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

John, this is David McCallie, can you hear me?

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

Yes, I can.

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

Sorry to join the call so late today, but I'm glad I got here before we're done and I just want to second or third the votes for this notion that Stan just articulated.

I think that speaking as at least one vendor we're aggressively exploring a lot of those technologies that Doug listed but we recognize they're all quite immature and the mistake would be to prematurely standardize on stuff that's still moving but at the same time we really want to be doing experiments on that stuff because there is some real value there.

So, I support the notion that there might be a second work stream that has a different timetable to it than a particular stage of Meaningful Use.

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

Let me give you an example David, so yesterday I met with the Moore Foundation, Gordon Moore, Intel that sort of folk, and a number of people on the SMARt Project and we actually talked about Cerner for example, and we said, well can you envision where the world of Apps might go if Cerner made available a smart enabled API that two guys in a garage could now create the next great data visualization tool from.

Well, we're not quite there today. I mean, we're probably in the era where C-CDA comes out of an EHR into a registry or repository and then there is an API on that registry and repository, but the future has got to be EHR, APIs which are enabled to a platform which developers then can innovate using and you want to do both kinds of work.

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

Yes, indeed and I can assert that we are actively working on that vision, but it is very premature because the standards are quite in flux but they are the ones that you listed and I think that's absolutely the direction.

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

And this is Arien and I know or at least highly believe that David is in support of this, but that vision works best when those App developers have some confidence that they can build once and leverage across a broader ecosystem that might be Cerner and McKesson and a whole variety of EHRs and use cases and I think that's where the puck is going to.

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

And in fact David just to tell you that the very funny quote from Ken Mandel we have dozens of mid-20s developers creating cool Android Apps for health and no major incumbent vendors to connect to and that's what Arien you've just articulated.

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

Yeah, we understand that and support the SMARt work in particular have contributed heavily to it in terms of design input and look forward to finding a way to hook it up but it's premature to set it as a standard, it's certainly in the MU context.

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

Well and absolutely and that's, you know, again, I think Doug you've heard the overwhelming input that we can't lose sight of FHIR looks promising not totally ready for primetime or Meaningful Use certification requirement but we can't lose sight of where we want to get to. So, Michelle, are there other folks in the queue?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Sharon Terry.

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

Sure.

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

Yes, can you hear me?

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

We can.

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

Great. Yes, so I just want to also put in a plug for having something that's forward looking and especially in this more and more gray clinical research realm where the line is blurring and particularly because in probably the last six months working on the Steering Committees of things like the International Rare Disease Research Consortium, the Global Alliance, the IOM Data Committee Sharing Committee that's going to put out an interim report in January, and then moments ago I had to step off this call to be on the PCORI funded PPRNs and CDRN call all of them are struggling to create standards and I keep, in every situation, saying, well the standards are coming and that we are working on the standards, the standards are the ones that we should be adopting from the Office of the National Coordinator on down.

I think working synergistically with those groups, and I certainly am, but I think with a proactive forward-looking committee or Workgroup would make a really big difference for accelerating that process and skating to where the puck will be.

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

Very good. Other comments?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Leslie Kelly Hall.

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

Yes, Leslie?

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

Hi, I think this is a great way to look at both thought leadership and the work that we have to do now and perhaps this Workgroup that we're envisioning could describe "what's the evolutionary criteria" so that we always have a way to progress. So, for instance if we have a standard that is ubiquitous use but older technology we still have an opportunity to learn from that standard and apply that in a new, forward thinking environment.

So to provide the industry a roadmap that says here is an evolutionary process or here's how we think of going from this standard to this new advanced standard, it would be very important to show there's linkages so that we're not always throwing out the baby with the bathwater there's good learning.

Most people are afraid not only as Arien articulated is this going to go away, but is it replaced by something else that's even more complex. How do I apply the learning I'm doing today to something in the future because sometimes the buggy whip is being used a lot and we don't want to remove ubiquity in order to start something new and exciting.

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

Well, I think that's well said and I bet David McCallie and Arien can tell us from their work on CommonWell that they in fact had to look at the incumbent standards in order to build momentum and get people going, they might not wanted to have started with those incumbent standards but that was the practical approach and then build a path forward to what would be the next layer of standards that would be easier to implement and maybe more aligned with the Google, Facebook, Amazon standard stack, but would welcome Arien and David your comment on this challenge that Leslie has articulated.

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

This is David –

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

I – go for it.

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

Yeah, I mean the term bootstrapping comes to mind, you know, sometimes you have to start with what you've got but you have a broader vision in mind and you have to use what you've got to get to the point of where you do something that may in fact be a different approach I don't know if that fits Arien how you're thinking of it.

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

I just – that John said that so eloquently and so well, that you need to – I think also the metaphor of the mobile phone networks is right on. You need to provide people a roadmap of where you're going to so that they have less uncertainty regarding should I even learn this FHIR thing and that was actually one of the issues that we ran into in the work that we did was meeting some resistance of "yeah, FHIR looks cool, but do I really need to learn it, do I really need to go do that work" and providing that long-term roadmap actually helps get momentum towards things that have some innovation by reducing the level of risk that's required for developers to invest time, effort, energy and code to get there.

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

Great, well, thank you. Other comments on this or Doug's general thesis that we are going to have five to six Workgroups with specific domain assignments either articulated and, you know, Michelle we haven't actually talked about in any detail what it means for people to roll on, roll off, term limits or anything like that. I think, is it fair from an ONC perspective Michelle and Jacob to say that, you know, figuring out the details of how long we serve and what we do is still a work in process?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yeah, it's still a work in process. I will say I want to clarify on the first slide that the nomination process for 2014 will begin and be announced in January, so there will be a link on the healthit.gov website which we will share for people to submit themselves to be members and there are term limits for members so some members terms will be ending which is why there are numbers that are up in 2014. So, we will announce that process as we have more details.

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

Great.

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

John this is Wes?

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

Yes, please, Wes?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Sorry, Becky Kush actually had a question before Wes, sorry Wes.

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

Okay.

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

Okay well we'll go to Becky and then to Wes.

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

That's good.

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

This is Becky Kush and I just wanted to endorse the suggestion to do a group around the future that Stan had made and I think, you know, Doug will tell you that we just both have spent some time in Asia over the last few months and there our research standards that are available that are going to be adopted by the regulators and by researchers in Japan, in Europe and the US over the next couple of years.

And for PCORI especially and some of the research use cases these standard have been shown so that there are standards in the middle that connect the healthcare standards from the EHRs to these research standards and I think it's worth at least pointing in those directions and if we need to make changes or add these standards or whatever we do that, but to have people say there are no standards for research is just that I don't think we've gotten there yet and there are standards in those areas that I think people could use today.

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

Yes and of course, Becky, whenever I hear "oh, the whole problem with interoperability is the lack of standards because there are none" it makes my blood boil. So, I think we all recognize that there's been extraordinary work done to date in support of clinical trials and research and data mining and to all the rest and any time, you know, we hear something that's hyperbole what I say is, well there are gaps and here is the roadmap to filling those gaps, but in fact I think we've made more progress together as a committee in the last four years than in the previous 20.

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

Yes, so if we could paint a roadmap so that people know that there is something to skate to I think that would be really helpful.

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

Very good. Wes?

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

Okay, so I just want to recap some salient points out of the discussion we've just had and then comment on them. We started with a fair amount of group energy around the notion of the ability to have a clean break and not be driven by evolution to avoid the newer technologies and newer development methodologies and so forth that are proving to create a great deal of productivity in the tech industry in general.

Followed by a comment that said, yes, but we have to be incremental with what we already have. And I just want to point out that one of the reasons cell phones have been incremental across multiple technologies is because they contain multiple radios. And that our definition of being incremental has to somehow have the analog of multiple radios that is have the sense that we're not really going to necessarily implement the CDA as an element of FHIR or something like that and just in general I think as we, the committee, create the guidance for this Workgroup we have to make that clear.

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

Right and I think all we're suggesting is there is line of sight from what is today to what will be tomorrow, it isn't necessarily – I mean, so for example, Doug one of the things you note is that we need a standard for bulk record exchange and in your statement you say build on C-CDA well, I think Jamie has suggested C-CDA may actually be an inappropriate standard to build upon for bulk record exchange but we could have a line of sight from C-CDA to whatever the thing is that is bulk record exchange.

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

This Dixie I'm not sure we're still raising our hand or just discussing –

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

Well, hey, Michelle are there any other hand raisings, otherwise we will give the floor to Dixie?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Dixie was the only one.

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

Dixie, please go ahead.

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

I'm playing both games at once. I just want to make sure or express my opinion that I think it's important that all of the work – that we not have a separate Workgroup which looks ahead but rather that, you know, that we take more of the work stream approach and that each of the Workgroups should look both here are the standards we need today and here's where the puck is moving and here's what we need to prepare to move to including this number six that is more the learning health system and the integration of research with clinical – I think all of them need to be – that it needs to be more orthogonal that there are these work streams that cut across all the Workgroups that here's today and here's where we're going. I think that's really important.

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

So, this sounds like a very friendly amendment that what we suggest is we take the categories that Doug has presented we add to that a sixth category which focuses on the support for the research and the learning healthcare system which might subsume something like Health eDecisions or other things Doug that you have put in the S&I Framework and up to you whether you assign them to group six or put them in quality and safety.

But rather than having one group of people and one committee or one domain think of the lifecycle and connecting us from today to tomorrow that we make it a specific agenda item for each of our domain specific Workgroups what is the work of today but how do we get a roadmap for the next great thing. In fact it may very well be that it's those folks in quality and safety who know better where the quality and safety roadmap needs to go then some separate group. I mean, I think that sounds good to me.

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

John?

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

Yes?

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

It's David McCallie again, the organizational challenge when you're addressing complex problems is always, you know, is a vertical organization better than a horizontal or do you need a matrix organization or whatever.

I think in this case there is a high likelihood that the next generation of standards will require a more matrix way of thinking and they'll be less specifically focused on a single use case and more something that has core infrastructure that can be shared by many use cases and then can be constrained for specific use cases.

So, in the case of FHIR for example, FHIR by itself solves a lot of the problems at the core screen level of the kinds of things you want to move around but without profiles, what they call FHIR profiles it's not very useful and it may well be the case that in one of these Workgroups for example, you know, clinical trial reporting you have a very different profile but it runs on top of the same underlying standard with FHIR and OAuth and things like that whereas the quality group might have yet a different profile, again on the same underlying standard.

So we need to be careful not to over compartmentalize and to do a proper sort of orthogonalization of the problem space and make sure that we're using the right kind of layers in our approach and I know that's the way we've been trying to think about it but I just want to reassert the need to focus on that.

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

Sure, I mean, the challenge is always that those of us who are involved in operations have a hard time breaking out of operational mode to think about strategic planning for the future and so the question is, you know, two model or maybe three, you know, one model being future planning is assigned to a separate committee, two future planning is baked into each committee or three there's some sort of matrix approach which ensures that a future planning committee is crosscutting across every other committee keeping the ball moving.

And, you know, maybe the answer is we can do what you suggest with some project management resources from ONC that keeps the individual committees moving on future thinking and coordinates across them or something like that. Other comments? Well, so Michelle, have we exhausted them? Maybe it's they're hypoglycemic.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Yeah, people are probably hungry, yes.

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

So, if there are no further comments on Doug's presentation I think what we're left with is Doug, you know, you have given us a suggested set of Workgroups and a suggested set of high, medium and low priorities and it seems like just an edit to that and then working with ONC staff and making sure we align this with whatever timing is happening for re-nominations in January and populate the Workgroups with the people who will be anxious to serve.

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

John, I'm sorry, it's Leslie, I had one more comment on the specific work plans that Doug had, may I make?

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

Yes.

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

And that's Doug you had advance directive standards as I believe either medium or low and I would encourage that to be raised it's a very small effort with a very possible opportunity for dramatic improvement and that's to be able to record it in a standardized way so must one more plea, thanks.

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

Well, thanks very much for that Leslie and the question of course because we've had this discussion about advance directives several times in the past, do we focus on advance directives, do we focus on physician orders for life-sustaining treatment writ large and what is the nature of what we could even do as a Standards Committee given the diversity of state laws about how one has to record these things and where is it informative and where is it legally binding and such stuff, but sure, there's a whole body of work around that that is worthwhile.

So, well thanks everybody for that input. Michelle I think we're actually running a few minutes ahead of schedule and is there anything from your perspective on the agenda that remains at this point?

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

One small thing is to wish Doug a very happy birthday today. I'm sure he'll love that I told everybody that, but otherwise I think that we have exhausted the agenda.

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

Well Happy Birthday Doug he's 29 again it's remarkable and with that I guess public comment is the next order of business.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, John, operator can you please open the lines?

**Public Comment**

**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 be placed in the comment queue.

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

While we are waiting for public comment and I know Ariens made comments about having a bomb squad incident I trust that this was at his location in Georgia and not at the location of the ONC headquarters?

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

It was at Patriot Plaza which is one of the ONC offices but there were, despite the large number of police officers involved I think it was a steak, a leaking steak in somebody's trunk.

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

Ah, very good. Oh, and I forgot Ariens you are actually not at the McKesson Headquarters you in the Bay Area.

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

Correct.

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

Okay, very good, well do we have any comment?

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

We have no comment at this time.

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

Okay, well hey thanks everybody for what I knew was going to be a very rich agenda from figuring out our work plan to looking at the patient generated data to looking at the radiology and non-radiology imaging standards, but I think we certainly have gone through many of the issues that I thought would be controversial and I think we've gotten good guidance.

So, I guess I will at this point wish everybody a very Happy Holiday Season and we won't convene in January, but I am sure all of us will be communicating by e-mail. So, stay safe and I will see you in the New Year.

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

Thanks John.

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

Happy Holidays.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you John. Happy holidays, everyone.

## **Public Comment Received During the Meeting**

1. Each state has different diagnostic image retention requirements, some have none. Is there going to be a mandate to keep an image in the "cloud" under these recommendations? There is substantial cost to maintain images for extended periods of time.
2. Hello, this is Mike Schmidt / Medflow, an ophthalmology EHR vendor, we would like to suggest "other-ologies" such as ophthalmology that are also well-developed in terms of DICOM imaging standards be included in the Tier 3 / Tier 4 columns.

3. There is not a general image retention requirement, with the exception of mammography. CMS has the right, for up to 5 years, to audit billing to validate services provided. Because of this, Ascension Health has set a minimum image retention requirement at 5 years. After the minimum retention period has been met, we are deleting old images. This is similar to the purging old x-ray film and sending it to recycling. When DICOM images are deleted, the URL link in the EHR will not retrieve an image that no longer exists. Please consider this when making rules about access and/or URL link functionality.