

# HIT Standards Committee Transcript November 13, 2013

## Attendance

The following members attended the meeting:

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

The following members were absent:

- Anne Castro
- C. Martin Harris
- Nancy Orvis
- Charles Romine
- Sharon Terry

## Presentation

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

Thank you. Good morning everyone. This is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the HIT Standards Committee. This is a public call and there will be time for public comment before lunch and at the end of the meeting. As a reminder to those making a public comment, it is limited to three minutes. And also to those in the room, please state your name before speaking as the meeting is being transcribed and recorded. The hashtag for today's meeting is #HITStandards and with that, I'm going to turn it over to Jacob.

### **Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

Thanks Michelle, thank you Michelle. And thanks to the members of the Standards Committee for coming today. I thought as I did last week at the Policy Committee –

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

I have to interrupt you.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

Oh.

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

I forgot roll.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

Oh, very important.

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

It's been a little while since we were here in person so, I'm sorry. John 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**

Good morning. John Halamka?

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

Here.

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

Dixie Baker?

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

I'm here.

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

Anne Castro? Jeremy Delinsky?

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

Here.

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

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**

Here.

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

Jamie Ferguson?

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

Here.

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

Hi Jamie. Keith Figlioli?

**Keith J. Figlioli, MBA – Senior Vice President of Healthcare Informatics – Premier, Inc.**

Here.

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

Lisa Gallagher?

**Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy and 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**

Here.

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

Becky Kush?

**Rebecca Kush – Founding President and CEO – Clinical Data Interchange Standards Consortium**

Here.

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

Anne LeMaistre?

**Anne LeMaistre, MD – Senior Director, Clinical Information Systems and CMIO – Ascension Health**

Here.

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

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**

David McCallie?

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

Here.

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

Kim Nolen?

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

Here.

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

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?

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

Here.

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

Sharon Terry? Andy Wiesenthal?

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

Here.

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

Steve Brown?

**Steven H. Brown, MD, MS – Director, Compensation and 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**

Yeah, over here.

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

Nancy Orvis? Charles Romine? Okay, and now I'll turn it over to Jacob. Sorry about that.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

It's okay. Very important and it's not about me, it's about you. But I will talk about me for a second. Because many of you I know, some of you may not know me, but I thought I'd give you a little bit of an intro, as I did last week for the Policy Committee. I'm family physician, have been involved in Health IT for about 20 years, father of two married to a lawyer and I'm a marathon runner. And as I thought today on my way here this morning about what we do in this industry and this group, working on the things that we work on, I thought that running a marathon was actually a reasonably good metaphor. It's hard; you can't always see the finish line from where you start. It's painful and yet you persevere because you know you're going to get there, you know you can do it and it's an extraordinary accomplishment each step that you take on the way to the end.

And for a colleague of mine ran the New York City marathon last week and he said, that last six miles, man, that hurt every step, and I nodded knowingly. And as we were talking before the beginning of the meeting in the sidelines here, I can see some of that pain on the faces of the colleagues – our colleagues in this room. This is not an easy path that we are on, but it's so important for the health of the nation that we continue to do this work together and continue to forge ahead together. This group is so important to us because you provide us with the guidance that we use to create the certification criteria that defines how folks are going to build confidence in the products that they are purchasing. As was pointed out to me, and I nodded before the meeting today, this is not just about the Meaningful Use Incentive Program, this is about defining standards for how health information technology in the United States of America works together.

So my little homework before the meeting today was to remind myself of what this group was commissioned to do. So I looked up the section 3003 from the American Reinvestment Recovery Act and I just wanted to read that aloud, because for me it was a good anchor to remind myself of what we're doing here today. So the establishment of the Health IT Standards Committee, there is established a committee to be known as the HIT Standards Committee to recommend the National Coordinator standards, implementation specifications and certification criteria for the electronic exchange and use of the health information. It goes on, but I won't burden you with too much. The HIT Standards Committee shall recommend to the National Coordinator standards, implementation specifications, certification criteria described in subsection "A" that has been developed, harmonized or recognized by the HIT Standards Committee. The HIT Standards Committee shall serve as the forum for the participation of a broad range of stakeholders to provide input on the development, harmonization and recognition of standards, implementation specifications and certification criteria necessary for the development and adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

So it's an anchor for what we all should have stapled to each other's foreheads. This is what this group does and it's so important. So, on that note, thank you so much for coming today and continuing this great work and I look forward to a productive meeting.

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

So, good morning to everybody, it's hard to believe that this is indeed our 52nd public meeting of the Health IT Standards Committee and I know for those who've been participating through the duration, those who are participating more recently, it's been a labor of passion. Really Jacob directed so much of the ultimate goals of improving the health, the care and the performance of healthcare in the United States. I want to welcome you on behalf of the committee, really a delight to have you here and appreciate your dedication, your commitment. I know that for you, and for the ONC team, this is a labor of love, and it has to be.

Because while those in the field are implementing, those in Washington are also sharing in this marathon and when one thinks about the metaphor of the marathon today, competition level runners are effectively sprinting and so it's a hard race. It's a tough job to be a public servant, I want to thank you for taking on that responsibility. I think it's fair to say, it's definitely not a 9 to 5 job, may even not be fair to say it's a 5 to 9 job, that is 5 a to 9 p, it is really a 24/7/365 commitment. And we are so very appreciative of your taking a role as the Acting National Coordinator and for all the teams work in helping us do the work that is commissioned in the language that established the Standards Committee, the Policy Committee and indeed, accelerated electronic health information interoperable health information in our country.

With the perspective of 52 meetings, it's easy to see that both the challenges ahead, but I hope that we're taking stock as well of progress, because it's really quite extraordinary. Later this evening I'll give a plenary session at the National Academy of Sciences at ECRI and will be talking about the opportunity for discovery, for research, for new findings that are made possible by interoperable health information. Honestly, I couldn't have given this talk 52 meetings ago; in fact, I probably couldn't have given this talk last year. And really quite exciting and appreciate not only your perseverance, the perseverance of the Office, members of the Committee, but all throughout the field who are persevering as members of the community developing and implementing the products of an for meaningful use.

In our sidebar before the meeting, we discussed that this is an extraordinarily busy time. It's busy in terms of all the changes in healthcare broadly. It's busy in terms of all of the challenges developing new models of care in a world that's reforming. There are many hurdles in terms of meeting multiple requirements simultaneously such as ICD 9, and of course we look to the prospect of Stage 2 and cert 14 and the like. And I know these activities are going on in parallel. Some of the activities are decoupled. Some actually make life easier to the degree that electronic records support templating – better the ability to fulfill ICD 10. On the other hand, there are challenges, John and Jacob and others know those challenges, the lack of direct capacity to automate some of those processes, is both accurate but also a feature of a work in progress. I just encourage us to keep these goals in mind that you so eloquently recited from the establishing language.

Note that there are a lot of guardrails around what governs activity. One of the most promising part of the process is that we work under the really the Sunshine Laws, which established us as a Federal Advisory Committee, which means that this is a very public and very democratic process in which issues, challenges and opportunities are fairly discussed and broadly vetted. And done so in the full view of the full public. That's why I think today's meeting is particularly important and I want to thank John Halamka and the Office of the National Coordinator for your work specifically on the work plan because indeed, this is really where a number of these both opportunities and tensions converge. It's the role of the Standards Committee to advise on the availability of standards. Dixie Baker has given such eloquent voice to the consideration of what equals availability as a matrix, looking at adoptability and maturity. And that in turn informs our work that is the Standards Committee work, which has a relationship to the work of the Policy Committee, which does with the Office of the National Coordinator and CMS, establish cadence. So our lens on this discussion is really that through the standards, in terms of adoptability, maturity and thus availability, would encourage us to consider our conversation of the work plan and support of meaningful use and Policy Committee work through that lens.

In closing, just some introductory comments, I know that it's tempting to focus exclusively on the downside risk, but I come back to where I started which is that I hope we don't forget two things. One, patients who ultimately benefit from interoperable health information and two, the ecosystem of emerging opportunity, such that I described for discovery that's coupled with the potential for innovative technologies that can only exist, only exist with interoperable health information. And these are the systems that really allow all participants in the health system to better manage health and illness. I'm very excited about all aspects of the agenda including the work plan, the policy updates, the updates from ONC, etcetera.

But I also want to note thanks to Leslie Kelly Hall and Consumer Technology Workgroup, because that really does provide a direct convergence with the ability of patient and consumer to engage with their health information. And it allows, in the aggregate building systems that allow us to tap into the collective memory, if you will, of healthcare for improvement. So with that, I'm just extraordinarily excited about the work that we have ahead. I recognize, as does John, as does Jacob and the entire team, the complexity of the – that the challenges, the unfinished work, the incompleteness of standards, the challenge of delivering in the field, the challenge of vendors bringing product to market, but those are the downside risks. The upside opportunity is extraordinary.

Before we go to John to review the specific presentations coming up and to offer his comments, let me just perform the first ministerial action. I trust that everyone has had a moment to take a look at your minutes and I just ask if there are any amendments, changes that need to be made. Hearing none, we'll assume consensus on that and move forward. Again thank you all so very much and look forward to the day's work ahead. Dr. Halamka, I'd like to turn the microphone to you.

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

Great. Well thanks. Over the last couple weeks, many people in the press, many people in various branches of government have asked me, what makes an IT project successful? I don't know why. And I've reflected on, it's important to set the scope and scope includes priorities. It's important to look at the time required to achieve change that could be behavioral change or technological change. It's important to look at resources and it's alas, although certainly healthcare is an important sector in our economy, it's one that, at least in Boston, we're trying to shrink the costs of healthcare rather than grow the cost of healthcare, resulting in actually some more resource constraints. So if you have those three levers of scope, time and resources, it's really important you set your priorities carefully and you set your timing carefully.

To your point about running, you can't run a marathon every day and probably you don't want to sprint the entire marathon. And so today is really about taking stock of where we are, looking at our priorities ahead, and all of you have contributed to the prioritization discussion, figuring out where we focus our work over the next several months. I think we'll also have some interesting discussions on standards readiness and maturity because I think also as we discover, if you move too fast too soon, haste can make waste and hence we want to move at a deliberate and constant pace. We want to get to the end of the race. And so, as we look at the agenda, we'll hear from Jodi on the policy update and we'll hear a number of things on the SAFER Project and FDASIA, Joint Commission, where things are going on these important initiatives in ONC.

Leslie Kelly Hall will describe patient-generated healthcare data and I think there might be a robust discussion on standards readiness and where we are in that important policy goal, but is the technology mature enough. And to my point about scope, time and resources, how does it fit in the ecosystem of everything else going on? And then Doug has a series of discussions for us on S&I Framework and, reviewing our work plan as prioritized by you. And as we go forward, I think our committee is going to have a very important role of doing a reality check of where we are, where our hospitals are with regard to their readiness for the work already in progress and where they are with their capacity to actually undertake the new work ahead. And so what I hope is that as you said, the importance of this committee is, let us choose standards wisely. But let's also ensure that we work with our colleagues at ONC in our capacity as a Federal Advisory Committee, to offer feedback on scope, time and resources, so that all of us will run to the end of the race without having that last six miles be so painful, that we falter. So, look forward to the rest of the meeting.

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

Okay. Well thank you John very much for those comments. We are going to dive right into the work of the committee and appreciate Jodi Daniels giving us update from ONC Policy Committee. And creating the nexus with that committee and the work of ONC and I'm particularly appreciative that we have the opportunity to place Jodi first on the agenda, because she's often been squeezed, in terms of time at the end. I want to introduce also with Jodi Daniel is Jennifer King, so, welcome

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

Great. Thank you so much Jon and John. I wanted to start, actually we invited Jennifer King to join us as well. She had done an update at the Policy Committee meeting last week and I think it was really well received and it was some really great information and we asked her to do a repeat performance here, even if that means squeezing my time again. Because I thought it was such a valuable conversation and I wanted to make sure that the folks on this committee had the benefit of hearing her information and the status of some of the certification of our products. So, I'm going to turn it over to Jennifer King and then I will jump in after that.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Okay, great. Good morning everyone. So we have been doing some work to monitor progress towards 2014 edition certification and wanted to present some information on that here today. Basically, what we're going to show is the percent of providers that using a vendor that has a 2014 edition product certified. So important to keep in mind that we're doing this analysis at the vendor level. We haven't shown anything here today that looks at the product level, so, a provider might be using a product with a vendor that has a 2014 edition certification or product certified, but it doesn't necessarily mean that the product that the vendor – or that the provider is using has a 2014 edition product. And also wanted to point out that we don't really have any information here today that we're presenting on product roll out timelines, so just because the product is certified, doesn't necessarily mean anything in terms of timeline to implementation and roll out. But with those caveats, just launching in here.

First looking at hospitals. So this graph shows all hospitals that have attested to Stage 1 Meaningful Use by the certification status of their primary vendor. So nine vendors have an inpatient product that is certified to the 2014 edition meeting the base HER definition. And these nine vendors account for 81 percent of hospitals that have attested to Stage 1 thus far. So this is an indication that about 8 in 10 hospitals have a 2014 edition base EHR product under the vendor that they used for Stage 1 attestation.

**M**

We know that those hospitals are in fact using that edition of the product.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

No.

**M**

All right, so we don't know that.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Yes.

**M**

So the vendor produces it and they use that vendor, but they may be on an older edition of the product.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

That's exactly right. So that's sort of the caveat that we wanted to keep in mind at the beginning.

**M**

Kind of misleading graphic I would submit.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

So, I mean, I'm glad for the clarification. I just wanted to sort of illustrate here that the vendor has some product under the 2014 edition, indicating that they're moving towards 2014 certification. So again, yes, it's true that this does not necessarily indicate that that hospital is on that product. So taking a look here, at how this progress varies by hospital type. So wanted to take a look and see if certain types of hospitals are more or less likely to be using a vendor that has a 2014 edition product certified. And you can see there are some differences. So smaller hospitals and critical access hospitals, down at the bottom there, are slightly less likely to be using a vendor that has a 2014 product compared to larger and medium sized hospital.

And here is a snapshot of all of the hospitals that have attested so far. Again, it shows that 81 percent are using a vendor that has some 2014 edition products, and we called out here the vendors that have at least 1 percent of the market share in each of those categories. So, the vendors that have 2014 edition products certified that meet the base EHR definition and those that do not, thus far. And then shifting to look at this same data on the eligible professional side. We see a little bit lower levels of progress here on the EP side, so 21 vendors that have been used as a primary vendor by EPs for attestation have a 2014 edition base EHR product certified and this accounts for 58 percent of EPs that have attested so far. So, about 6 in 10 are using a vendor with a product that has – with a 2014 edition product.

And we looked at this to see if there is any variation by eligible professional characteristics. We first looked at rural urban practice location, and we don't see really any striking differences here. If anything, urban professionals are slightly less likely to be using a vendor with a 2014 edition product certified, but no big differences. So no evidence at this point of an emerging sort of digital divide in geographic location. We also took a look at this by provider specialty. So the first set of bars that are at the top show physicians by specialty area and no large differences between surgical specialists, primary care physicians or medical specialists.

The radiology, pathology, anesthesiology categories a little bit less likely to have a 2014 edition certified vendor at this point. You can see the other professionals, non-physician professionals, are less likely at this point to be using a vendor with a 2014 edition product certified. And these professionals make up I think about 10 percent at this point of all EPs who have attested so, a minority but important to keep our eye on those professionals. And this is here sort of for reference, and we broke out all of the specialties at the individual specialty level, if folks are interested in a specific specialty group there, but the previous slide showed it rolled up into overall specialty groupings. And again, here on the professional side, showing the snapshot of all EPs and where they are in terms of their vendor certification status, calling out those vendors that have at least 1 percent of the market share in each of these categories. So this last slide shows those vendors that do not yet have a 2014 edition base EHR product certified. And this last slide shows those that do have the 2014 edition base EHR product certified. So that is the end of the data slides here, I'm happy to take any questions or defer to Jodi to finish up.

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

Why don't we let – do you want to do questions on Jennifer's piece because then I'll pivot to a different –

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

Great, why don't we do that. We've got Arien Malec. Anyone on the line who wants to weigh in? And Wes Rishel. Okay, then we'll go with Arien, Wes and then we'll go to Jodi so that we –

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

When I look at that list of providers with EHRs that aren't yet certified, I see a number of organizations that I fully expect are in the pipeline. And I'm wondering whether you have visibility to the certification pipeline and can give an informed opinion about the risk of – are we talking about a timeline risk for certification or is there a significant orphan EHR risk? And whether you've been able to do that analysis.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

We're working on getting that kind of data now, can't really comment at this point, but we are working on trying to assess exactly those questions.

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

John Halamka?

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

A quick follow up to Arien's comment. As I said in my introductory remarks about time, scope and resources, one interesting issue is, that if we have this pipeline, as you describe, but because of some of the challenges around the certification of products in Stage 2, we see some of these entrants into the marketplace not having products in time for hospitals and EPs to actually get to the attestation timeframe. I think this is further data analysis that will be interesting, I mean, as you point out, there are some very hardworking companies and very large provider organizations and well-meaning people trying as hard as they might. But because of purely the artifact of time being fixed, if we suddenly see that a quarter of our professional colleagues missing their attestation timeframe, I think that would be bad, so certainly worth reflecting on our analysis on that issue.

One side effect I worry about, and that is, as you look at your slides, what you see is a lot of smaller niche and specialty vendors that may or may not be in the timeline. I actually don't know if they're in the pipeline, I'm not sure. I hear from a number of vendors who have contacted me privately that they are going to actually pull their products from the market. Or if not pull them from the market directly, that they will not be successful, they think, attesting to Stage 2 and therefore their products will ultimately die in the marketplace because it is unlikely people will buy uncertified products going forward.

And so as again we reflect as a committee, as we look at future testing and certification processes, especially around modularity and the way that we carve up the certification scripts, how do we allow innovation? How do we allow the small niche companies to succeed, even if it's not as a base EHR, even if it's a component level. Because there are aspects, that in my own certification I discovered, that are challenging for modular companies especially. So let us make sure we get innovation and the small company and the little guy can survive and thrive.

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

Okay, let's go to Wes Rishel.

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

Thank you. Thank you. I think we all have this concern and we need to, to a certain extent, balance it against the fact that the initial plan was to establish a baseline of functionality and raise the bar over time. And I am concerned very often that every small vendor who doesn't succeed is seen as having barred from innovating, when in fact, many small vendors just didn't meet the requirements. I mean, they're not necessarily innovators that failed. On the other hand, I'm concerned for the program based on this – the providers and the eligible hospitals that might suffer huge economic consequences based on the failure of a vendor. I happen to think that we always have to go to the doctor's office keeping in mind that half of the doctors were in the bottom half of their class. We also have to recognize that there's a range of capabilities of vendors, some are able to toe the line even before there's a line and others are not the number one finishers in the marathon.

We have put our providers and eligible hospitals on such a tight timeline for attestation for Stage 2 that those whose vendors are average may not support them in meeting the tight timeline. I believe – all statistics like this are a case of looking for a nickel where the light is better, you never quite get all of the data you'd like to get in order to do statistics. But I think one statistic you do have access to is how many of these providers have to do a full year certification in 2014 in order to move to Stage 2 without loss of penalty? It depends on when they certified in – 2. I think it would be very interesting to see the impact of – on providers and eligible hospitals and rural and urban and all of the different categories, with regards to vendors that will have – providers that will have failed if their vendor fails to provide them an update at the start of 2014. Thank you.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Thank you. And I will follow up on that to highlight that these data reflect all providers who have attested as of September 2013. So not all of them will be required to start in 2014.

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

That's the question that is susceptible to analysis, I believe –

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Yeah, and we have looked at it among the subset of providers who attested as of 2012 and will be required to go to Stage 2 in 2014. And the numbers are very, very similar. So the overall trends among that subset of providers is quite similar.

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

Well, I think we need to turn that into the question of, how many providers and hospitals are going to get these economic consequences because of a full one-year requirement for Stage 2 and look at it that way.

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

Let me turn to Jacob Reider –

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

Jodi, could you just give us a reminder of when they would actually need to be – in the context of the Meaningful Use Incentive Program –

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

Right.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

– when they would need to be – have the systems implemented – a 2014 certified system and for whom that would be relevant?

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

So it's – so it is for the – I think Wes raises a good point, it is for the early adopters that we're talking about that will be impacted by this year. And for Stage 2, it is a – the first year is a quarter reporting period, so we are talking about folks still have until Ju – until July to begin that – that can be the last quarter that they started, July 1, to actually be able to do their reporting period for the last quarter of the fiscal year 2014. So, there is still time, even if folks don't have a product right now, to get up and running and still meet the reporting periods, the meaningful use requirements for this year, for that subset that need to move to Stage 2.

I think you're raising a good point though. It is – it isn't everybody who has already attested, all the hospitals have already attested, that we have to be focused on, it's just those that are required to move to Stage 2. And again, it's a reminder that folks, even if they're not ready today, even though the fiscal year has started, they actually still have time to meet the requirements, because it's just a quarter reporting period.

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

Just to be clear, anybody that doesn't have a product available on November 13 of 2013 has no possibility of beginning to attest on January, there is no time left. It takes time to implement a product that's rolled out and I'm concerned about those that are under the gun. And I recognize it's a subset and so forth, I'm just trying to figure out how big the pickle is.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

Just to clarify what – the deadline, as Jodi expressed, isn't January 1, they actually have to – because the Meaningful Use Incentive Program Stage 2 expresses that it's a 90-day reporting period. So if they're going to do Stage 2, they only need to have the product up by July 1 for an EH and October 1 for an EP.

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

Okay.

W

The follow on to that point though Jacob is that it does take time and it makes a big difference whether your vendor is doing a simple upgrade versus almost a full replacement, which we are seeing in a rare instance.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

I don't think – no one is disputing that, in fact, that's part of why we're having the conversation, to express that so that you folks can say that out loud in this public forum. I just wanted to make clear exactly what the deadline is, as Jodi described it's July, not necessarily January.

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

It's July for hospitals who have – October for providers.

W

You said for those who have to, could you just clarify that, too.

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

So – if – so, for instance, it's only those that have been meaning – this is for the subset of folks that were attested to meaningful use the first year that are moving up to Stage 2. There's only a small subset of folks that started at the beginning who now have to move to Stage 2 this first year. The timetable is in the rules, but it is not – so there are folks who have attested to Meaningful Use Stage 1, hospitals that have attested to Meaningful Use Stage 1, who will stay on Stage 1 for FY14. Those that started in 2011 will have to go to Stage 2 and again, it's by July 1, because they have a 90-day reporting period, not a full year reporting period and they can – their reporting period can be from July 1 through September 30.

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

To Wes' point, the knowable piece of data has been among those that are on that timeline required to start July 1 for eligible hospitals, which among them are on systems that then don't have 2014 cert product either imminent or established?

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

And I think it's a great question. What is the actual number that we're talking about of providers that fall in the subset where there isn't a 2014 product and that would have to upgrade to Stage 2?

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

So let's get that data. I mean, if you have it at hand, great, if you don't let's get something that's knowable.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Yeah, so it's roughly about 2600 hospitals that attested to Stage 1 by the end of program year 2012, so these folks will be – have done their two years of Stage 1 by 2014 and then moving to Stage 2. And of those, about 80 percent have a vendor with a base EHR product right now. So, that's the rough number and we can provide you with the exact numbers as well.

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

Okay, thanks. And let's take one last quick comment here and then let's go to Jodi. Jeremy Delinsky?

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

Thank you, thanks for sharing the data, it's interesting. I think that there is some flexibility for the first year of Stage 2 that hopefully will allow most people to get over the line who were the early adopters. But it does bring to my memory an issue that I think has been out there that's been unresolved for a while which is, how do we address platform switching in the full year reporting periods later on? Because I think we are going to see vendors not be able to comply, decide not to comply and I worry about the full year reporting requirement, later on as a real deterrent for letting people to move when they need to or when they want to. And I don't know whether we want to think about a special program that allows platform switching that you have a shorter attestation window in the years that you do it, but I do think that – I think that many providers will feel trapped in the later years without that kind of provision.

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

That's a great point. Thank you.

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

So let's just – okay, take two short comments, I want to make sure that we don't shortchange Jodi. Let's take – Floyd Eisenberg has a card up then we'll go to Leslie.

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

Okay.

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

I'm sorry, and Dixie.

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

Just trying to do some quick math, so out of 2600, 20 percent that may not be able to is like 520 hospitals, which is not insignificant. But my other question is, for those whose vendors who have products, do we know do the vendors have on their timeline enough time to actually get those products implemented in the other 80 percent of hospitals?

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

So that's sort of some of the data we're trying to collect, in terms of getting intelligence into timelines for implementation and those kinds of things. I don't have any data on that today, I don't know if other folks have any information they'd like to add on that.

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

I'm sorry, clarify a math question for me, and this is – this goes back to trying to remember the early days of the program, because you quoted 2600 hospitals starting in 2011 or 2012. My recollection is that there were 614 or so in 2011. Did those fo – was it only folks in 2011 got three years of Stage 1 or do all hospitals have that extra implementation period? Only the first group, okay. So the number at the end is in fact, 2600 that – as of July 1 – of the eligible hospitals as of July 1, 2014, would have to have that 90-day attestation –

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

Okay.

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

– on – and the two phases of that obviously are the standards and they cert 14 technology.

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

Okay.

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

Just wanted to establish the –

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Yeah. Yup, that's right and just for additional context, that's about half of all eligible hospitals that had been in that early group of hospitals that attested to Stage 1 by the end of 2012.

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

Also on the math, regardless of your attestation timeframe, you need the 2014 certified technology installed, even if you were to attest to Stage 1 at this late state.

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

Um hmm.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Yes.

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

One of the things that might be really helpful, Jennifer, this is Liz Johnson, if you – if we can assist you in sort of laying out those timelines and attaching the numbers, because without a visual, it is confusing. I think many of us know the rules, because we deal with them every day, but I think if we could do that. And then we could look up for a percent of those who are early adopters, those who now are to go to Stage 2, those who are still remaining to go to the second year of Stage 1; I mean, there are several bodies, and John's right one the big factors everybody has to be at 2014. One of the things implementation groups are working on is that timeline, talking about how long does it take. It's not a perfect science, but I think the expression of concern about the time that's remaining is real and whatever we can do to help you, we're more than willing to do that.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Great. Thank you.

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

And my point was just to really follow up on the caveats. Part of positive, I think, consequences of meaningful use is people are looking for economies of scale. And so often times they do that by purchasing other hospitals or providers. And so just as there's an issue about timeline for platform change, there have to be considered how do organizations go through acquisition with multiple EHRs that are certified and on different timelines. They still have a very – they're very positively moving forward, they're embracing the program, but it still nine pregnant women takes nine months. And so I think it would be important to think about – ten months, there you go.

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

But there's ten – but nine babies.

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

So, just make sure that we accommodate those kinds of machinations.

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

Okay. Dixie Baker?

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Yes, thank you. Both EHR modules and complete EHRs can be certified, but this diagram doesn't mention that and yet – and each of those can meet the base EHR requirements. So you could have one module that meets the base EHR requirement. Then, of course, it's up to the adopter, the provider, to show that they are using a complete EHR tech – certified EHR technology. I think it would be useful for us to be able to see how many of these products are modules versus how many are complete EHRs, as well as, how many are base, and I don't see – we went through these pretty fast, but I didn't see that.

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

Right there. That's the light blue right there, the dark blue is the base EHR certifications, the light blue is the non-base EHR certifications and module –

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**

I realize that, but a module can have – a single module can have – can meet the base EHR definition. Or, a complete EHR can meet the base EHR definition, so we don't really know how many of these are modules and which are complete EHRs.

**Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator**

Yeah, that's right. The slide doesn't break that out, but that's something that we can look into. Thank you.

**M**

(Indiscernible)

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

Actually, let's not try to clarify, because I get that point, as a matter of fact, I'm just having – ONC is actually checking to make sure that we don't confuse the fields with numbers, so we're going to get a definitive opinion on the time. I'm not doubting Jennifer, Liz or anybody, it's arcane enough that we want to make absolutely sure that when we calc – quantify the numbers, we have –

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

– for providers and hospitals who are not going to Stage 2, to be on 2014 standards anyway.

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

Yes.

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

And I'm wondering how that requirement impacts this discussion?

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

So it sounds like – I mean, I think this is something to follow up on. I'm assuming you don't have that data –

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

I think he's asking for a clarification, I know Jon, we want to move on. I think he's simpl – the question is, that Wes, correct me – 2014 edition is required –

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

Regardless –

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

– regardless of what stage.

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

Correct.

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

Regardless.

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

And there's no equivocation on that – two questions, want to make sure that's absolutely correct in terms of a policy interpretation statement and the second is, in terms of the glide path for Stage 2 for those that started in 2012. So, just going to get an absolute opinion on that, but, that does – I mean, just to recap. That does – the fundamental point is that compresses the timeline. There are a number of questions. So this is actually a good transition to Jodi's report from the Policy Committee because there are some obvious interface issues with both the Policy Committee and ONC.

Let me just hit a recap of a few is that the data that you provided Jennifer indicates that there are some challenges among niche providers. Wes, you raised the countervailing issue is that, part of the intent of interoperability is interoperability and there needs to be a convergence. I think there's also the question about innovation, on the one hand, some niche providers are innovative and you wouldn't want to lose that. On the other hand, the broader premise is that interoperable standards allow a field in which innovation can occur because the queues, the signals for what will be a viable product, at least in terms of the standards, are known. The overwhelming sort of question here is really about the challenge of the pipeline and among those that really – and I think we may have answered that not only among the 2600 but if the requirement is indeed that regardless of stage, one needs to be on cert 2014, that presents one challenge.

What percent of institutions are either not on – or eligible providers – eligible hospitals or eligible providers are not on, not only base, but to Dixie's point, modules. Where are the challenges? Can we narrow exactly the proportion that we're speaking about? And that Arien, the point about platform switching, if there is a vendor that departs the marketplace, what is the practical way in which that will be handled? Some of these things are beyond the scope of the Standards Committee, which is – I'd encourage us again to look into – through – at this question through the lens of the availability of standards defined as adoptability and maturity. But, there are some pragmatics that we give back to you, Jodi and ONC, to interface with Policy Committee and to take also as questions to ONC and CMS, in terms of just the pragmatic challenges of these issues.

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

Okay. I will go through this quickly, and I don't think it'll be nearly as heated a discussion, although, interesting topics. And we will talk a little bit about certification and extending our certification – thoughts about extending our certification program and discussions the Policy Committee is having. So, that might lead to some continued conversations about this, but, let me start.

So I want to start with some Policy Committee updates, just to give people a heads up of some things that are coming down the pike. First, I'm actually going to start at the bottom here, is that we now have three new Health IT Policy Committee members. Folks might recall that the Policy Committee membership is prescribed in statute who gets to appoint whom. Most of the appointments are by GAO and we have three new appointments, David Kotz, Devin Mann and Troy Seagondollar. And they have – their first meeting will be in December, correct?

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

Okay, their first in-person will be in December. So we have some new faces and new perspectives that will be joining our Policy Committee meetings, so we're looking forward to their participation. Also wanted to let folks know that we do have an Accountable Care Workgroup, they are going to be holding a hearing on December 5, focusing on understanding health IT needs for ACOs and learning about some innovative uses of health IT that may be able to be shared more broadly. They are looking to receive input on whether and how modular certification of health IT that's focused on population health management and interoperability standards may help ACOs in meeting their requirements. So it should be very interesting and it may be something that some folks on this committee may be interested in listening in on. Of course, it will be webcast. But it may then come back to certification requirements or standards requirements that may be helpful for ACOs. So, we will report back on the status of that hearing, but feel free to participate as well.

Okay, Certification and Adoption Workgroup update, and I'm going to give, at the end of my talk, I'm going to let John Derr have one minute, because he has been attending these workgroup – he has been participating in the workgroup discussions. And I wanted to let folks hear his perspective and report out on some of the conversations that he has been participating in. So we had asked the Certification and Adoption Workgroup of the Policy Committee to start thinking about how we can leverage our certification program beyond meaningful use.

We've been hearing a lot from folks that are not part of the Meaningful Use Program, they're not eligible for the Meaningful Use Program, particularly long-term, post-acute care and behavioral health. Those are the two that have been – we've heard the most about, but there are others. And we asked the committee – the workgroup to recommend a process for prioritizing health IT capabilities for extending our EHR certification program beyond meaningful use and with a focus on improving interoperability across a greater number of care settings. We specifically told them that the recommendations should take into account our current certification criteria and standards, but also should look to key health IT capabilities for other care settings for the ineligible populations, for those that are not eligible for our Meaningful Use Incentive Programs.

So, two parts, one, what should we be thinking about with respect to extending our certification program beyond meaningful use and then specifically what should we be thinking about in these particular – for these particular types of providers and settings. So step one, like I said, is recommending a process. We're looking for, what if are the things that ONC should be thinking about when – if we decide to extend the program, what are the – how should we – what should the process be for us doing that, for prioritizing and identifying certification criteria? And then two, focusing on LTPAC and behavioral health, because those are the two areas where we have heard the most call from those communities as well as the greatest need for improved coordination of care, reducing readmissions to hospitals and some of the needs for focusing on patient outcomes. So that's the area that we've been thinking most about and we wanted some specific recommendations with respect to those two settings.

So the way – just to give some structure, the Certification and Adoption Workgroup will obviously make recommendations to the Policy Committee. They will coordinate with the Standards Committee and with the activities going on in the S&I Framework. We do have John Deer and Stan Huff who are participating as Standards Committee liaisons to coordinate between the activities going on in that workgroup and this committee. And we will have both LTPAC and behavioral health experts engaged in conversations with the workgroups, to give updates on the S&I activities as well as on the specific needs of those settings and those communities.

Timeline, we did start this work, a little bit delayed due to the furloughs, but we started at the end of October and we'll be looking for recommendations in March. We will have preliminary recommendations – it says February, I think we may be pushing that to January, and final recommendations to the Policy Committee will be in March, as well as we will make – provide those recommendations to you all and have John and Stan help with presenting to this committee. Okay, so that's – I will – let me finish my update and then I'll turn it over to John to give a couple of words on certification and adoption, so I can get through it this time.

Okay, so I wanted to spend a little time on safety, because there has been a lot of activity in this area and I think it's something that may be of interest to the committee, so I wanted to give a flavor of some of the activities that are going on. I know we did do an update on the Safety Surveillance and Action Plan that we put forward and I wanted to just give folks an update on some of the activities that we have in implementing that plan. So first, this is something that's new that we've just started. There's been interest in looking at how we can engage stakeholders, have public/private partnerships to do a few things to look at safety events, to prioritize safety of health IT and using health IT to improve safety. And we've engaged MITRE, which is an FFRDC, to help us assess the feasibility to establish a public private partnership. They have worked with us on safety issues before and they specifically have experience in other industries, particularly the aviation industry, so we've asked them to build on that experience and work with us on looking at options and feasibility for who we might set up a public private partnership. We're working closely with AHRQ, the Agency for Healthcare Research and Quality in thinking this through and aligning with AHRQs activities, because we know that the Patient Safety Act provides certain protections. And as we're thinking about what a Safety Center could look like and what a public private partnership can look like, we want to make sure that we're leveraging the protection for the Patient Safety Act and aligning with the work that AHRQ is doing with patient safety organizations. This work should be – this feasibility assessment should be done in the spring of this year, so we should have some early ideas about what options are available and the feasibility. Next steps are still to be determined.

FDASIA. I've talked about this as we had recommendations from our FDASIA Workgroup, FDA Safety and Innovation Act, for those who are acronym challenged. The statute required that FDA consult with ONC and FCC on identifying or drafting a framework for oversight of health IT that promotes safety and innovation of the technology. We have been working very closely with FDA and FCC continuously since we put together, actually before we put together the workgroup, but through the workgroup and continuing on. The Act asked for us to have a draft report by January of 2014. We're still assessing the feasibility of that, with the few week delay that we had, but shortly – approximately at that time, I won't make promises. And we did get input from the Health IT Policy Committee and we've been working very closely with FDA.

So, a point to make here is this will be a draft framework. It will be out for comment. I will tell you that we will be not coming up with a – in stone set of solutions, but really we see the report that we put out will be the continuation of a discussion, and we will be looking for input on refining, improving and honing our thoughts on how we can do this well. This will not, and I want to stress this, there will not be something coming out in January change in a regulatory structure will not. It will be a draft report for comment that is thinking through a framework – a risk-based framework for health IT oversight.

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

Radio emission safety?

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

It's for mobile devices and yeah, it's the radio frequencies. They honestly – the FDA and ONC are sort of kind of leading the charge and FCC is providing some contribution, because they do have some regulatory authority in this space, particularly with remote devices. But they're role is not quite as significant, I think, as FDA and ONC. I'm saying that with my ONC hat on, but they've been helpful in helping us think some of this through and being sort of an informed voice that can help us – challenge us on some of the discussions that we're having. So they've been great and helpful as well. Do you – you okay?

Okay. We also have a PSO analysis projects, PSO, Patient Safety Organization program again for the acronym challenged. In October we began two separate projects to perform aggregate analysis of health IT related adverse event data, based on PSO databases. We were told by the Institute of Medicine, when they did their report that we need to have better data to understand better about adverse events that may result from health IT. And so we are trying to leverage that data that exists with some of the larger PSOs to identify the types, frequencies and underlying causes in any health IT related events, in order to think more about public private efforts, develop evidenced-based measures and just improve our knowledge and understanding of the scope of the problem. The first results of these analyses are due in March, we have a lot coming out in March, and based on the initial results, there may be an opportunity to request additional targeted analysis – analyses that we would do later in 2014.

And finally, or not finally, this is almost finally, we do have a contract with the Joint Commission. I think I have mentioned this to this committee before. We wanted to have – the Joint Commission obviously has a relationship with most hospitals across the country, and they're going to be conducting voluntary investigations of health IT related events at hospital and provider sites. So, trying to look at what – to actually doing some investigation and understanding of how health IT may be involved in any safety events that occur. Concurrently Joint Commission is performing in-depth analysis of health IT related events based on their own database. They obviously have a wealth of information from their own work and experience, in order to increase our understanding of the role of health IT in patient safety. They will be publishing a report based on this, as well as developing educational materials that we can make widely available, and we are expecting preliminary results in January, more to come after that.

And, this is last, but not least. I wanted to let folks know some work we've been doing that I think will be really helpful and that will be practical and concrete. We've worked on SAFER guides, and I'm not going to now remember what the acronym stands for. But these are really risk assessment tools based on some of the latest evidence on health IT and patient safety to provide a way of folks understanding what the – what risks may be and prioritizing how to mitigate some of those risks. We see this as a tool to help providers in thinking about safety risks and identifying improvement strategies in their organization. And this is a Foundation for Improvement effort. Again, this is a tool that we would put out and it would help healthcare organizations to think about their own safety and safety for the EHRs in critical areas as they're implementing this technology.

We wanted to not just tell folks that there is a responsibility of all players to focus on safety as they're implementing health IT, but giving them some tools for thinking about how it's best to do that. So that's what these are and they should be coming out in the coming months. So again, soon to come, they're in the process of being reviewed by as we're hoping to get them out in the very near future. And I think, with that, I will open it up for questions. Oh, with that, I will turn it over to John Derr first, to give a little bit of feedback on the Certification and Adoption Workgroup discussions on voluntary certification – or extending our certification program.

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

Thank you Jodi. Really thanks to ONC for starting this and to Jodi and to Doug for supporting us in the longitudinal care committee and to Liz and to Leslie who have incorporated LTPAC into their workgroups. Just to remind you, this is – LTPAC is skilled nursing facilities, assisted living, home care, hospice care, independent rehab facilities and long-term care hospitals. Forty to 60 percent of the people really discharged from hospitals go to either home care or to a skilled nursing facility and that's why this is very important because we do want to be part of this whole thing, especially when the new care models and payment models come about with HIEs and ACOs and risk sharing and also bundling.

We are participating in these already, so we need guidance and at the workgroup meeting, there's been a lot of discussion so far of whether long-term post-acute care and behavioral health wants to be more controlled by government or not. Well, basically we are because we're Medicare and Medicaid, mostly and so we want to be able to play and to have you understand it when we say, we're private, we are secure, that we actually are. There are six vendors out there, which are not vendors that are listed on this board – on the slides, that are certified right now and three of them are fully certified. The stakeholders are behind us and we really do – and our vendors have robust EMRs, they just haven't, like hospitals, haven't upgraded everything. In fact, I've been giving a lot of speeches lately to the providers to ask and to get them to update themselves because the systems that we have out there, most of them, at least the ones that are certified, do a CCD and are working on the composite CDA-type of thing. So, I appreciate it. The workgroup, most of the three or four hours we've had so far, were debating this issue of whether we want more government control and why are we asking for this. And we really do want to be part of this and we do want that guidance from this workgroup, so we're very excited about it.

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

Let me thank Jodi Daniel for the overall update. John Derr, thank you very much for those eloquent comments afterwards, there are really demonstrative of faulty connections throughout the work. I believe we have a little bit of time for some comments. Arien Malec, your card is up, we'll start there.

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

Thank you. I've got one editorial comment and then one question. The editorial comment is, as Jacob started the mandate of the Policy Committee is making recommendations relative to a nationwide health information technology infrastructure and I think we're skating to – I think there's a Wayne Gretzky moment that we need to come about, too. That we're right now trying to hit the puck where it is, which is meaningful use and we keep trying to hit that meaningful use puck. If you look at where the SGR Fix is headed, and there's an uncertain timeframe there, we may be in a world in 2016, 2017 where the Meaningful Use Program is a tactical program, that providers who don't otherwise participate in value-based programs may want to participate in to avoid a penalty.

But that most providers are going to forgo those Meaningful Use Program requirements by participating in one or multiple value-based payment arrangements. And with regard to voluntary certification, I mean all the certifications are voluntary, but the eligible versus ineligible split becomes meaningless in that context. It's really is about health systems who are coordinating between hospitals, providers, long-term care professionals, pharmacies potentially. And that's really where we should be skating to. So I welcome the work the Policy Committee's been doing in looking at ACO attainment and looking at LTPAC. I would – my editorial comment would be, I'd submit that the Policy Committee should be 95 percent focused on how organizations achieve value-based care and 5 percent on the tactics of how they attest for meaningful use because I believe that by the time we get to 2016, 2017, that's where the world will be. So, that's my editorial.

The question that I have in the final FDA guidance is there's still to my mind an uncertain application of that guidance to clinical decision support, the guidance language reads, mobile apps become regulated, device by performing patient analyses or patient-specific diagnoses. There's a caveat to – similar to your performed functions relative to – that have been previously cleared or approved, and it wasn't clear from reading that language whether that was intended to say this is a 510K process or whether there was something else that was intended there. When I read the appendix, the categories all make perfect sense to me, you've got medical device-like function, but there's still for me a question that I have in, if I have a clinical decision support function that provides patient-specific treatment recommendations, that might be setting of care recommendations that might be – where does that fall relative to that guidance?

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

So one, I can't speak for FDA's guidance, because they're the only ones who can interpret that and I would be...I would probably not get it exactly right, because they – it's their authority and their guidance, although we did work very closely with them, and they were very collaborative in working with us on it. I think the basic answer to your question is that, I think clinical decision support, and where that falls in the spectrum is still – I think you're right, it's still under discussion and how that is done. And my hope is that the report we put out will provide a little bit more clarity into the thinking and will probably ask for some more feedback, because it will be draft. And part of your confusion is that there isn't necessarily bright lines at this point in that we are working on trying to figure out where – I think clinical decision support is still something that we are talking through and working on with FDA.

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

Perfect. Thank you.

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

Great. Let me thank you for a terrific presentation, very robust discussion on a number of aspects, and actually I'm sure these discussions will be a thread that follow us through the day, not only culminating in a discussion of work plan this afternoon, but actually the set of interfaces is complex and also exciting. I think Arien you gave us good aspiration vision of space, getting to where the pucks going to be. The finesse here is getting to that point effectively and efficiently as John Halamka said earlier. With that, let's segue. Thank you Jodi Daniel and Jennifer King, John Derr thank you for the work and comments that you made and we'll invite Leslie Kelly Hall to begin the discussion of the Consumer Technology Workgroup, the report there. This really is the opportunity to talk about that set of interfaces having to do with patient-generated health data, consumer devices and the like.

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

Thank you. Yes, oh, I have to go over there. Thank you. Okay.

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

And while Leslie's moving over there, I appreciate the definition of the – all of the acronyms. There is a new syndrome that's been described. It is one, in fact, that I'm suffering from. It's called PACS, progressive acronym confusion syndrome.

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

We all have it, don't we.

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

Leslie Kelly Hall, thank you very much for your presentation.

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

You bet. So, I want to start with the conundrum that we face going into this, how do you balance a new entry of a patient or a person, a participant in the health IT ecosystem? The advent of wonderful new technologies in the consumer world and the lack of standards for that consumer world inside HIT, how do you balance that with the need of providers who are entrenched in standards and HIT and entrenched in new offerings and new demands of Meaningful Use 2 and 3 and beyond? How do you balance those things with the compelling argument that the patient is the stakeholder with the most at stake and needs to be integrated and included in their own care, as a co-producer of health? So we were taken by the empowerment team to look specifically at patient-generated health data and how could that be accommodated and integrated into this ecosystem? So with that sort of conundrum and balancing act in mind, the committee went out to do its work. Next slide – oh, I do that. Next slide Leslie, okay, Leslie.

So here are the workgroup members and we had a wide variety of people participating, both from a consumer advocacy point of view and standards expertise. Our charge was to provide recommendations on standards and interoperability related to strengthening the ability for consumers, patients and lay caregivers to manage health and healthcare for themselves and others. And our scope specifically was to look at the standards and how they relate to patient access to and generation of their health data.

We...the group, it's important that we worked with the Policy Committee workgroup, the Consumer Empowerment Workgroup and also Meaningful Use. So this is really an update to tell you where we are and to get your feedback.

So our first steps were to confirm what standards were needed to support patient-generated health data, what's available now and what's missing. What are the gaps between what is needed and what exists now, and to take a look at the current maturity and adoptability of these standards, and what is the protected level of maturity and adoptability in 2014 and 2015. Some of the themes that we started with was repurpose or use existing standards where possible. This hoped to get over the chicken and egg syndrome. Don't do something new because there's no standard with – all of us face when we start to introduce new people, new things, new process. And so by using existing standards where possible, it does a couple of things, it gives us the opportunity to rebuild work already done, or reframe work already done, but it also inherits both the benefits and the problems. So something that might be mature in the provider world, is new in the patient world and vice versa and standards can constrain or encourage innovation. We'd like to be on that side of innovation versus necessarily the constraints.

We also talked a lot about that consumer friendly standards are really about where the patient is assuming a risk that data moves to the patient. There might be more opportunities for consumer-centric standards, but when data is coming into an EHR, it's really about the structure of the EHR and the existing standards in the provider world. The provider assumes the risk of accepting that data, the provider assumes the risk of entry into their system. So this is somewhat like the Blue Button Initiatives that we worked on where we consider taking information out of the EHR, we can move to new standards or more consumer friendly approaches to this. But going inbound, we look at probably a higher level of assurance of prior – a higher level and constraints on standards, and so we thought that that might also apply in this area.

Some of the high-value areas for patient-generated health data that we heard over and over again, as well as the consumer empowerment team is the safety related information like medication allergy, intolerances and barriers to care. But also there's really great care information that both the patient and the provider can use to participate with care plans in the future. Things like goals and values, shared decision-making, information that the provider requests. There's no argument there, when a provider asks for information they want it, and so they're very eager to have that available and consumed in a way that is meaningful to their workflow. There are also areas that could be – could provide very informative data is areas in advanced directives and POLSTs and MOLSTs, device data and pre-visit preparation. Of a – we had someone describe a pre-admission or pre-visit where of the data requested, almost 70 percent of it was actually generated by the patient, the patient was the author if this information and yet we retype that information over and over again. So we heard opportunities for efficiencies, opportunities for collaboration and new partnership.

Other areas of high values and benefit is a new patient concern or patient reported outcomes. And then the administrative efficiencies become very important, so profile updates, insurance updates, anything in your demographics, caregiver care team updates, communication preferences and experience of care. So the team concluded that patient-generated health data is an opportunity on the policy side, to capture needed information for use during care with the potential cost savings, improvements in quality and care coordination and patient engagement. So it's valuable for many reasons that we've talked about from safety, from data collection burden, information gaps, information repeats and reconciliation.

But we need to look at balance, both from a policy and a standards point of view. One menu item is 100 percent for the HIT vendor. When we look at the balance in episodic or collaborative care, getting information about this visit, pre-visit, post-visit, your experience of care, has an asynchrony about it, it's a dialog. When you move as a collaborative care platform, which we hope to see in the future, that's a much more complex level of patient-generated health data, where they're part of a team. And then also looking at this balance between patient standards or consumer product standards and provider standards.

We had each of our groups that did some of our testimony take a look at the maturity standards, and this again provided another conundrum because our bias was to use existing standards we said, great, let's try to use existing standards, but then, what is – that's new to the consumer. So it might be mature or highly adopted in one area, but new to the patient, how do we balance that? Everything looks like then it's in the middle, right, it's a middle level or maturity if you're use any existing standard. I don't know then if it provides us useful criteria or not, but it does – the chicken and the egg raises their head one more time here. And so we have asked each group to – in the patient-generated health data, to provide information about the readiness.

So some of the areas where we felt that there is meaningful use ready is highlighted in yellow on these slides, and you'll see that we believe that we're ready to provide the patients, the providers a record and care team information. From the left to the right, you'll see sort of the evolution of the patient-generated health data, messaging, structured data like a questionnaire, unstructured data or narrative and hybrid, device data, care planning and plans of care an individual unit, or a plan of care, and then collaborative care plans where all team members provide. So we felt that on the messaging side, we think that secure messaging tethered with attachments if they're tethered – secure non-tethered, so we're looking at standards for that, which I'll get to. And then on the structured side, a questionnaire, a patient response where something is asked of a patient and the patient has responded to, has a very high degree of opportunity of importance, relevance and good standards for interoperability.

Under the unstructured and narrative, probably a hybrid that has some sort of a structured template with unstructured narrative. And on the device side, there was an emphasis on devices that were actually provided by the provider, so prescribed, the device that goes home would be a good place to start, which those standards would be much more around provider-centric HIT than start with something like a consumer product that still has emerging standards for use and interoperability.

So we felt under the standards area, messaging, DIRECT and then using the HL7 care team roster. Under the structured and unstructured narrative, the HL7 Consolidated CDA work, and again, the HL7 care team roster. And under the device standards, we were looking at DIRECT for transport and then also things found within the Continua standard, those are the areas that we've reviewed to date. And then again, the HL7 care team roster. So we felt there were opportunities in the future to look at collaborative care document structure, overall, that includes versioning, expanded provenance, reconciliation, data governance and curation. This whole idea around collaborative care in the future, we have to address these issues. So we're not quite ready for that in prime time.

Also that in the future consumer products and provider standards forum for alignment, where can we see there's opportunity there so that we can maximize new innovation in the consumer world, and still have it relevant and participating in the provider world. Taking the Blue Button and API approach to accommodate patient-generated health data, can we build upon that? Is there opportunity for the trust framework to be expanded for consumer and patient adoption in emerging technologies? How will we use consumer vocabularies in the future? And then we think there's an opportunity for the ONC to help in patient-generated health data guidelines, similar to what they've done with the Notice of Privacy Practices, because there was a good deal of discussion about the need for setting correct expectations for patient-generated health data and policy around that for each provider.

So, with that I also have people on the line to help to answer any questions, but let me go through and introduce. I believe we have Lisa Nelson on the line, who has co-lead the HL7 effort on the patient-generated health data Consolidated CDA. That work has included modifying that at the header level so that any time we consider data to be generated and imported into a record, it is done in a consistent way and constrained so that we know that a patient or their caregiver or other participants can be included in consideration and design. This was a great approach, we felt, because it really looked at a more holistic approach to the Consolidated CDA where anyone could participate as an author or recipient of data, so, Lisa Nelson joins us. Lisa, say hi. Oh, she's not on? Okay, good, thank you. Lisa, if you're out there, please call in. And then we also have Russ Leftwich and he has been part of the team on care planning also part of our overall committee and provided testimony around care planning and the care team roster. Russ, are you there?

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

I am here. Good morning.

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

And then we also have Chuck Parker from Continua Alliance to discuss information about the device data. Of the areas that we looked at, I would say that the device data was the most controversial in the group. The other areas, especially in terms of patient response, where a provider asks a question and the patient provides a response, there was very little controversy and a high degree of agreement. So with that, I will open this up for questions and comments. Russ, or Chuck, Chuck say hi, Chuck from Continua, are you there?

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

Hello, yes I am. Thank you very much.

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

Okay, super. So, before we get to questions, I know we have enough time, I'd like Russ and Chuck perhaps you can each comment on the approach that we've taken and that would be great. So Russ, can we start with you?

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

Sure and I think the care team roster is really foundational really to the cornerstone of care coordination. And that roster includes not only the health care professionals, but the family members and the patient and an electronic representation of it that will facilitate the exchange of information among the care team as well as identify their role on the care team. The concept of a team – care team exists in the HL7 CDA standard, but it's usually applied as a team of an organization, not a team of the patient. So the concept of the person ID and their role, and that includes family members, exists in the standards. I would suggest it needs to be specified that the ID should be a unique ID, like the NPI, the National Provider Identifier that can be a pointer to the professional role of the professionals and the electronic endpoint address of those professionals. So that that information which is otherwise very hard to assemble, particularly for the family, can go with the care coordination document, those CCDs at transitions of care and in longitudinal care coordination and be available to everybody on the care team, including the family. And ultimately should include a value set that doesn't quite exist and that is, the role of each care team member with respect to this particular patient.

For the professionals is the specialist, somebody that saw the patient once three years ago and said come back if you need to, or are they, in fact, a specialist who's a de facto primary care protector because the patient has some complex or end-stage condition that falls in to the domain of that provider. With the family, is the family member the adult child of the individual who is the primary caregiver or are they a family member with an equivalent familial relationship, but are only a sort of as needed participation in care. So, but I think –

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

And Russ, oh, I'm sorry, go ahead.

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

– and I think it's also essential to patient-generated health data to identify who that information came from on the care team. Obviously from the family side, but – and then ultimately who it should go to as well on the care team.

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

So we looked at but care planning because the policy side was very eager to say, how do we move the agenda for care planning and is very be supportive of that concept. But realize, we really just didn't know who the team was and so starting with that basic premise of identifying team members and participants and the roles that they play was an important concept for us.

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

Great Leslie, I appreciate – Leslie terrific and appreciate the members of your team weighing in. We have a number of cards up here and want to reserve good time for discussion and – but let's go a little bit out of order here. David McCallie haven't – have a question, then let's go to Floyd, Wes and back to Arien.

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

Yes, David McCallie here. Leslie, I'm – it's a good overview of activities. I'm confused, are you making specific recommendations of specific standards for specific use cases, is that what these yellow boxes are or is this a survey of things you're thinking about?

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

This is what we're thinking about right now, this is really an update. We have still two touch points to do with the policy committee again, and part of this is to get the feedback from the Standards Committee, to see if this approach – to get reaction and follow up.

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

Do you have a core set of use cases to drive against? Specific, I mean everything from near field to ZIGBEE –

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

Yeah.

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

– I mean, that's a – what are we talking about?

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

Where we're talking specifically about is the Consolidated CDA questionnaire structure for patient-generated health data under the new HL7 – the HL7 patient-generated health data work that we've done at the header level for the Consolidated CDA, so, questionnaire, which is really a structured approach to patient-generated health data. We're also talking about the care team roster participate identification, and that's also being harmonized with the Consolidated CDA. And then also looking at, on the DIRECT transport, expanding on that just for transport layer. And then also looking at device data. The device data was an add, the committee said, do we have anything out there that we could consider for device data integration.

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

Okay, so with that – that's very helpful in terms of some pre-vetting of these and appreciate your expression of thinking. Let's go to Floyd Eisenberg next.

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

So first of all, thank you for a very comprehensive presentation and you've done excellent work. I have two questions, one was on your last slide of things that need to be accomplished and one was related to provenance –

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

Yeah.

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

– and especially having spoken to some folks who've implemented systems, taken data in from patients that when the physician accepts it, it goes in as entered in the EHR as the physician's data. And so the question is, it may come in the Consolidated CDA as patient generated, but I think it needs to be certified that it can be stored in the EHR, because that was a vendor issue it wasn't a local issue.

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

Okay.

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

And I think we need to address that for managing the patient and also for clinical decision support if we want to know patient data. And the other thing I think that's important and Russ addressed it is, we do need a taxonomy, value set or whatever for roles of people involved in the care. That's important clearly for coordination of care and care team, it's also extremely important on decision support and measurement to see to whom should this information go.

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

Great. Thank you.

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

Wes Rishel, you're up.

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

Thank you. This was a great job of putting that whole field into a common frame of reference and I found that very helpful. I think it's important to recognize that your group is clearly trying to – enable two kinds of patient engagement. One is engagement between the provider-based care processes and the patient and the other is just the engagement of the patient with their own health, and each provides some different set of challenges.

I sometimes wonder – I know that we are – in talking about standards now, we're a little bit ahead of ourselves in some areas because we're talking about standardizing information flows that – for practices that aren't actually happening yet. The theory being if there's a standard, the information will flow as opposed to the alternative theory, which is, if the information is flowing, then we know what we need to standardize. And I'm concerned that in some cases, if the pre-standardization approach gets rigorously bound into certification and attestation for a stage in healthcare, it will, in fact, stifle innovation. Because we simply don't understand the issues, particularly we don't have the levers over the patient and the, what you very well described as the care team, including adult children of patients and other scenarios where there's a third person taking part in their care.

So I think as you carry this effort forward to concrete recommendations, we need to look at what recommendations are effectively put out there for the industry to make use of and what recommendations become hard rock hard. You have to do this, you have to do this for 5 percent of the patients in November 2017 or whatever that appropriate – whatever the impact is of the regulation.

I recall the first year of this committee and some of the early meetings and a conflict that became clear between consumer oriented and general consumer IT vendors and EHR providers, the specific focus of it was Web services and RESTful implementations. But those were just an – those were a specific bearing point for a fundamental conflict in terms of this issue of whether creating a complete stack and a robust set of standards and putting it to industry in the terms of meaningful use requirements doesn't constrain those people on the consumer side and on the general IT site. And whether just that very – the process you go through to complete those complete stacks doesn't, by nature, fence you off from some of the more leading-edge areas of – that technology's being employed in the non-healthcare IT world.

And so I am concerned specifically in terms of what you called prescribed devices that our standards in that area have been developed and tested and there's some certification that's gone on without much uptake. And there is potentially uptake in a model of vendor based repositories that's somewhat different than the model we've worked for in the EHR in general. I'm concerned that the nature of the legislation that drives us and the natural focus on regulation – produce, makes us be too EHR centric in our thinking. And so for all these reasons, I encourage the use of specific standards at specific levels of the stack with a rollout in terms of voluntary use versus required use and avoiding sort of the – that we're going to dictate the whole stack and everybody's going to use it. I think that's an area we've found difficulty with in the past. Thank you.

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

Thanks Wes. A comment on those, because I think Wes is right on, this is a conflict we had throughout our discussions of what do you do that is actually stifling innovation or promoting innovation? Now – and I think that it can be answered in many ways. For instance, a small company who has very limited resources may want to spend those resources on their core competence and make interoperability something that, can't I just do that, can you tell me the rules and I'll do it? Because now I can spend my time doing innovation, speaking for my company that was it, we just wanted to know what is a standard that we could use, let's get on with that so I can innovate core competence.

There's the other argument that says if you make that standard so difficult or so perhaps old technology, then that small company might not innovate because they don't have any competence in that old technology. So this is very much added to the chicken and egg syndrome of how we get this new player, the patient, participating. And the discussion really landed on, when something is coming into an EHR, that we play by the rules of the EHR. When something is coming out of an EHR, that's open and it's up for grabs, somewhat because of the risk is that providers, when something comes in, do I accept that data? Do I act on the data? Am I confident in the source that data? If in accepting this data, do I further compromise my system itself? So that level of risk and the sense of making it trusted and useful has to be at a much higher degree than when the data is coming out for an individual patient to use on their own.

So that's – but it is difficult and I do think that the committee is very open to the notion of voluntary versus regulatory. Because as that first example of the innovative company, just tell me the rules and I can do my core competence, there's a rule and I can follow that. It does not, though, promote that wide adoption of that rule without saying that there's a regulatory requirement. So I welcome comments and thought on this because this is an issue that has come up over and over again, not so much that we want to stifle patient-generated health data. There's no one who's been talking about this in a way that says we don't want to do it, it's just how we do it in a useful and meaningful way

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

The discussion, I'm sure that will be a theme that will permeate the continuing discussion, and to David's question, status of these sort of pre-recommendation, but really an important sort of tenant, in terms of developing them further. We have Eric Rose on the line who would like to make a comment. Eric?

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

Hello, thank you. And Leslie, this is – I really appreciate the work of the workgroup, this is great stuff and a huge gaping hole, as you I think argued convincingly in HIT standards. So two quick thoughts, one, on your conclusion slide, slide nine, there's a list of – you say valuable for many reasons, which I happen to believe that those are true. And one thing that I think as we proceed that is going to come up and that will need to be answered is, to what degree are these substantiated by good evidence. So that's one thing that I think is worth looking into, because that really ought to help drive policy and standards.

The other thing I'm wondering about, and I wonder if this has come up in your discussions is the fact that, to Wes' point about we don't necessarily want to presume workflows that aren't currently – or use cases that aren't currently in existence. One thing that happens all the time is there are kind of self-organizing networks of care by non-healthcare professionals for vulnerable individuals, for elderly people, for people who are disabled and their friends and family and neighbors and there is a need for that kind of lay care, so to speak, to be coordinated and probably a need for standards. Who is – who knows how to change the catheter among this person's network? Who can do feeding and so on and so forth? And that is – those are things that could be represented in data and don't necessarily have to involve a system operated or owned by a healthcare professional. So I'm wondering whether it's even in scope for the Standards Committee to be thinking about standards for workflows that – or use cases where the professional is not directly involved as a generator or user of data.

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

Let me address the first question on whether anything has been substantiated or evidenced. We did have, not this committee but our combination Policy and Standards Committee on patient generated health data last year, where we heard testimony for a full day and a wide group of people. That information was made available to this group and the patient empowerment team and so largely this information is driven from that. And also we expect the ONC has created an expert panel process through the National eHealth Collaborative and they'll be publishing a document on patient generated health data. This came from some of the preliminary updates that they provided us. That, I believe is in January or February Mary Jo, is that correct? Their report is due in December, so we've been building off some of that preliminary information.

With regard to your scope question, the – when information comes back into the electronic health record, the electronic health record is the property of the provider. And therefore, that property and that access to that information needs to be...have those rules. So we've discussed this in terms of, is it the responsibility of standards to create an ecosystem for the – for others or not? Well, it's that touch point of when does the information that's done outside need to be incorporated back into the EHR, where is that touch point? And we think there's – that's a very natural and logical place for standards to be incorporated. Without them, we will continue to have people who are involved in care, like the patient, left out. And so being able to provide a touch point for integration of the data we believe is very much within the scope and that's why we were tasked to do that

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

Leslie, we just have one clarification.

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

Uh huh.

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

By provider is – the EHR is the property – we're talking about the technology, the information itself I think as a spirit, certainly some elements – Jodi you'd be able to comment better, reflected in HIPAA and elsewhere. But patient is act – we want to be sure, and I know you're a patient advocate of the highest order, patient's data, the technology and – is what we're talking about in terms of provider ownership?

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

Yeah.

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

Okay, just wanted to make that distinction.

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

Correct. The – this – I just want to further articulate that this was an ask by the policy side of the group because patient-generated health data is currently in draft proposal for Meaningful Use 3. So that's the sense of urgency we have around this and the responsibility of the group.

**Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator**

Could I make just a clarification to that, since this interest in the scope and the use case that might be applied and Michelle can certainly correct me if I'm wrong, but the Policy Committee's Consumer Empowerment Workgroup is trying to constrain the use cases. It is not, I repeat not a question of unfettered, unbridled, streams of information coming in. They are going to come up with certain constructs as did the doctor request it? Is it a structured questionnaire? So they're looking for guidance on standards for these more constrained use cases, not for the, as I say, the fire hose stream from all of the mobile apps.

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

Very much constrained around the questionnaire specifically under the Consolidated CDA. And Lisa Nelson has joined us and she was the person responsible for that, so, we have her on the phone for quest – answering questions. Thank you, Lisa.

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

Great and so, let me just acknowledge Mary Jo Deering and thank you very much for that nexus with the Policy Committee. Let's go to three last questions, comments, Keith Figlioli and then we'll go to Jeremy Delinsky and Arien Malec.

**Keith Figlioli, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

A little bit of a comment on C. Baker, on the constraint side. One way to think that this is maybe, and maybe it was where Arien, you were going earlier about value and where the puck is going. This strikes me as an area of focus that you should focus with a group that's working on value scenarios. The heightened sense of urgency to use patient engagement and outreach when you're in risk-based arrangements for patients, is 10X what it would be on a normal fee-for-service type structure. So to me, when we think about Stage 3 and wherever this goes with all this, I'm all for patient engagement, and I think our members and our hospital systems are all for it. But what we hear loud and clear is this type of discussion is relevant when they're in the risk-based arrangements.

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

And I would say that that comment was brought up a lot in the committee, that this was very much supportive of ACO and value-based payment, but we were reminded over and over again that a good med list, whether you're in value-based or whether you're fee-for-service, the patient is the only one who knows that they're actually taking. And so those safety-related patient generated health data was universal across all payment models.

**Keith Figlio, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

I agree and the only other comment I'd make, and it's just my opinion and I'm talking from 65 percent of the healthcare providers in the country that we touch is, that's where we're seeing the real need for these type of work. The other thing I would push is the comment of the rules of the EHR for inbound. I would say I'm kind of where Wes is with this, I would suspend a little bit of our belief of the EHR in this value world. And what I mean by that is when we get into patient engagement and we get into these other areas, I'm not so sure there are going to be rules for the EHR. And what I mean by that is there are going to be a lot of other players as we get into this sort of mode in 2016, 2017 to Arien's point. And I just think we need to be careful on allowing a select few vendors, if you will, to control certain attribution, albeit privacy, safety and everything else like that has to be controlled and the legal record, I get all that. But I think the inbound/outbound messaging and all that stuff really needs to fundamentally be thought through very differently, given where we're going to go.

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

Thank you.

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

Let's just interrupt the flow for a second, Jamie Ferguson's also online and apologize I didn't recognize him earlier, he's calling from London. So Jamie, go ahead please.

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

Okay. Well thank you. I very much appreciate many of the comments from the committee members, particularly want to focus in on the necessity to constrain any of these near term recommendations on specific use cases. But in order to illustrate the point, I want to go pretty, I think, pretty far afield to the Medical Informatics, the Med Info meeting this year from the International Medical Informatics Association and the 2013 proceedings on medical informatics. That journal has a whole section on the use of – the evidence around the use of consumer data in healthcare and a few things stuck out to me. There were about a dozen abstracts in there that I related to the use of what I would call nontraditional data.

And they pointed out that they did a pub med search for medical journal publications in 2012 that used – that related social media data to healthcare quality and health outcomes. And they found over 300 journal articles, I think it was 360 something journal articles, including, I believe three dozen RCTs on that subject. And so I think there is some evidence growing that the nontraditional data beyond the scope of this discussion can be highly relevant to one's personalized care, care quality and outcomes. And so – but obviously that's an evolving area. So I think that as we look at the things like some remote monitoring devices in the scope of this discussion, I think it's very important to constrain these to use cases that are real and tangible. Where creating standards in this area could have near term benefits while not constraining unduly the evolution of this whole new area of personal data that is perhaps coming into healthcare from outside.

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

Great comments. Okay let's go to Jeremy Delinsky.

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

Thanks for the great presentation. One – there are a couple of things that are in the back of my mind as concerns in implementation. And I notice – vocabularies kind of in a bar on the bottom, right –

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

Yeah, and that should have been – we would – I’m sorry, we were assuming the existing vocabularies and –

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

– so that is, I think, at the heart of my concern potentially, which is that SNOMED, LOINC, RxNorm I don’t think were intended to be patient friendly, or maybe they were, but I don’t know that they are. And I think that it’s hugely important, just in the – I’m coming from an ambulatory point of view here, we’re trying to push as much work as possible to the front end of the visit and have – hopefully having some of that work happen in the home. And what I – but the act of incorporating that data into the EHR is fundamentally more in active reconciliation, where someone is reviewing the data that the patient raises and then incorporating it into the record. And I worry about sort of a – I think a bad requirement would be that if all patient collected data would have to be expressed in a CCDA for consumption by an EHR to incorporate it into the record. I think that would be kind of a – where it would run afoul of me. But I also just wonder whether patients – whether we want them taking their medications from something that maps to SNOMED – or to RxNorm or RxNorm itself or whether there are enough vocabularies that are patient friendly for us to work from here. I think that the transport seems a little bit easier to me, but I do – could you comment on what level of conversation around vocabulary occurred.

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

We had a lot of conversation about vocabularies and agreed that there is immaturity. One of the reasons to constraining this to questionnaires with a patient response is that you are very much answering a question of a provider initiated activity.

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

Yeah, all right.

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

Of the vocabularies, actually LOINC has more things because it’s genesis was rehab, more things about how the patient feels, their readiness, things like that than others. But it’s not complete. I think it’s worth further explana – exploration of consumer vocabularies and how they’re used in the future and actually next week at AMIA there’s a whole discussion about consumer vocabularies. So by constraining this to really a questionnaire and a response, we think we can help mitigate that, start to develop a habit of accepting patient-generated health data and then see where the market takes it.

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

Okay.

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

Very tiny follow up, Andy Wiesenthal?

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

Just a brief comment in terms of patient-friendly terms. The CMT determination that we made from Kaiser Permanente to the National Library of Medicine includes about 2500 patient-friendly expressions linked to SNOMED underlying SNOMED terms. So, they’re there, they may not be perfect, but it’s a start.

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

It is a great start.

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

(Indiscernible)

**Lisa Nelson – Independent Consultant – Life Over Time Solutions**

This is Lisa. If I could say something to answer that question.

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

Sure.

**Lisa Nelson – Independent Consultant – Life Over Time Solutions**

So one of the other things to keep in mind is that one of the real strengths of CDA is the ability to record narrative text and so, as we look at making bridges to begin to enable a patient generated data to participate in this fabric of HIT landscape that's being created. Having a CDA document which is the patient generated document standard right now is expressing a header in a consistent way that vendors and in the mentors of CBA already know how to do, so it's reusing that. And then it gives us a stepping stone forward for both constrained use cases and for cases where narrative text may be the best way to pass patient information on to the care team that needs to know it. So we aren't always limited by just vocabularies like SNOMED, and I just wanted to make sure that people knew that that's a strength of the CDA standard.

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

I think – will be dominantly helpful.

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

Um hmm, okay. Thank you.

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

As some people know, we've been doing this for quite a while. I just want to pick up on a couple of comments that people have made. So first of all, again thanks for the presentation and the framework. To Floyd's point, we've got a problem right now. We can provenance tag multiple submissions from patient to multiple providers and give you an aggregated record that links to who gave the update, but there's no way that I can take that information and express it, other than as saying here's a bunch of information and it often comes in as if it came from a particular provider. So that's an issue. Focusing on provenance seems to me a good thing.

On the other hand, I want to pick up Jeremy's comment that the rubber hits the road in the reconciliation process. And I am – I think we need a cost-benefit analysis here. There's a bunch of sliders. You can do a slider all the way to – the current choice of the slider is, we don't support patient generated data or we supporting a CDA that has no provenance information or not much, so we don't know where it came from. It's probably a bad position on the slider. You put one more in and we support provenance information, and providers and EHRs can use it or not –

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

Right. Um hmm.

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

– and if it's important for value-based care, there will be pressures for them to use it and they'll incorporate it and they'll build new care models. If it's not valuable, they won't. If we put the slider over to the right, we are requiring specific workflows to be built in every single EHR. Those workflows are complicated. There are safety-related issues, we had an issue where a patient, we gave them a list of medications and a med list. They picked structured terms and an inadvertent consequence of that was they picked a specific dose form for a medication and they weren't competent to make that choice, they weren't on that dose form and there was an issue where somebody tried to renew at the wrong dose form. Fortunately the pharmacy caught that issue. I would advocate for having a summary document that supports provenance and allow EHR – allow providers the flexibility to figure out how to use that data. As opposed to a slider that forces reconciliation workflows that I think previous experience when you try to do those under tight timelines, everybody does it crappily as opposed to meet the certification requirements, as opposed to the right way, as Keith mentions, to improve outcomes.

The second point that I'd make is, we've got a really good general purpose tool that's already in certification requirement and that's called secure messaging. And there is a ton of good evidence on the appropriate use of secure messaging, even unstructured secure messaging that gets charted as an appropriate tool for doing patient-specific questionnaires, as an appropriate tool for collecting information that may be in the patient's own language, can get incorporated in the chart and then interpreted by the physicians. I'm not sure that we need to go all the way to collecting highly structured information when we've got a pretty good tool in our toolkit.

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

The providers that did testimony in the patient-generated health data day argued that point that unless it's in my workflow and can be consumed in the EHR, that I know the provenance and it's a structure that I'm familiar with, I don't want it in here.

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

That's right.

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

They don't want messaging and narrative free text. They distinguished between a message as that's a message of communication form, it's not an observation, a result or a finding, and that that needs to be treated very differently. So we heard...

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

I –

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

– both of those –

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

– so it's not in the record, but it's in the chart with a record that it occurred. We've had a lot of experience of taking that secure messaging and putting it as a task in the task list to be placed as part of the record, to be reviewed, but not actually incorporated as part of the patient snapshot.

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

And I agree, that's the norm right now, but what the committee heard from were the physicians who said, that's not good enough. We don't want to have just a message that means every single time it has to be reviewed and that there was probably a spectrum of information. So we heard both. Yup.

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

So we're not going to be able to do the work of your workgroup entirely here, but there are a number of important tensions that have been drawn out, in terms of really requirement versus optionality, both those that applies to standards, the tension with innovation as well as the workflow. And these are terrific threads throughout this really robust discussion. Let's take three sort of rapid fire last comments, we'll go to Dixie. David and Stan. And Dixie, I know you had your card up, so offer you the most latitude here.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Okay. Thank you, that was a good presentation and it's obviously an important issue. Your mention of the expanded provenance in one of your slides, it prompts this comment and a suggestion for this committee. And it also supports Jamie's comment about nontraditional data sources. In a recent meeting that Becky and I participated in, I was part of a discussion about structured vocabulary where the issue of provenance was brought up and specifically the view that provenance should reflect how the data was generated. In this case that the provenance should indicate that natural language processing was used to generate the data versus a measurement that was actually tested.

Both this example and the example of patient generated data suggests to me that provenance is interpreted in a lot of different ways by different people and that it seems to me that we may have a real need to recommend a standard for provenance. I know that the HL7 FHIR Initiative uses – has adopted sort of the W3C standard for provenance, but I don't think we have a single standard and I think a lot of people are making assumptions in different ways about what is included.

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

And part of the care team roster and the harmonization efforts that have been going on to try to say who are these people, what their roles are, we've looked at, in the team we've look at the C-DISC standard the – identifying the people and their roles. And we've looked at – I'll let – Lisa do you want to speak to that?

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

Actually, let's take – because I think this is a broader recommendation than affects just the workgroup. The issue of provenance seems so simple, until it wasn't.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

It is in everybody's mind.

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

And that's right, it really isn't because there are a number of complexities. So let's take that and parking lot it because I think it's a very important question, because of the nuances that Dixie pointed out. John, I don't know if you want to make a quick comment on that or –

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

No, I mean, I just think we've heard a number of stakeholders including CMS offer us testimony on provenance and attribution and data integrity and all the rest and there's a delicate balance here, making sure the provenance is accurate, ease of use and adoption of technologies that are mature. So I do say, I think we need further discussion.

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

So – and I think it's going to be a broader issue, so –

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

Along with versioning and reconciliation, data governance and curation, we kind of put that all as a further opportunity.

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

So David and Stan, very short or brief.

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

Yeah, just a question Leslie. We – every physician who takes care of real patients gets patient generated data every time there's an office visit and comfortably deals with that. They only get nervous when you start trying to put these formalisms around it and I'm wondering if there has been sufficient study or a thought around the implications of the formalisms with respect to liability and other things. In other words, they obviously use patient generated data every office visit without any qualms, but when you say, I want to be sent in a secure, signed, non-reputable digital message, that makes them nervous. And I'm not sure why that is the case and maybe we need some work on making sure that that's not the case, that people don't get nervous about this new way of getting the data that they've always needed to take care of the patients.

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

That's a great point. We did hear some early work, Jodi Daniel provided an overview of the risk and the legal issues with regard to patient-generated health data and the burden and so forth and seemed to address all those issues. And that is available on our – on their website, if we want to go back and look at that. But basically you're right, we've done it forever, this is just a new method and we need to know that the – who the author is clearly and it's a new data point to be included in the record. So, good point.

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

Stan, Stan Huff?

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

Oh, just a quick comment extending some of the discussion about provenance, one of the things that occurred to me as we talked about attribution and increase provenance and other things is that the primary vehicle for a lot of the other communication has been CDA. And CDA inherently and by design doesn't include provenance data, it's a document centered snapshot in time, it's not designed for somebody to basically receive different kinds of data and know where it came from and retain it. And so, there – going back to what Dixie said and others, it may be that we need to fundamentally think about FHIR or other ways that this information would be transmitted in order to actually keep sort of the audit trail attribution provenance information correct. Because CDA as its constructed today is not – it's intentionally not designed to do that, it's a snapshot in time communication around a document-centered sort of communication.

**Lisa Nelson – Independent Consultant – Life Over Time Solutions**

This is Lisa Nelson, may I address that?

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

Go ahead, please.

**Lisa Nelson – Independent Consultant – Life Over Time Solutions**

So CDA R2 as a standard has six core principles and of one of those is context. And that context is by design, built into CDA. Many implementers right now do not understand it and have not explored how to make CDA documents that leverage the full capability of having provenance expressed not only at the document level, but at the section level and down to the entry level. And those, there called participation, those participations that say the author, the informant, the subject, all that context is by design already present in CDA R2 and we merely need to tap into the use of that within the implementation guides that are using the standards. It's already there. So I have an alternate point of view from the previous speaker on whether CDA supports data provenance or not.

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

Okay.

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

That's tremendously helpful and clearly we have more work to do on this concept, and maybe coming back to the group in another format on that. Becky the last – the very last word.

**Rebecca Kush – Founding President and CEO – Clinical Data Interchange Standards Consortium**

I know you're trying to move on and we can talk about this later but I'm just wondering how this links in with the Structured Data Capture Initiative. Because when you get into that piece doing clinical research, some of the patient generated data from there could align with that work and I think we're talking about it later. But I think that's an important connection.

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

And I think it's one we need to make. At this point both have been operating somewhat in tune and harmonization efforts where we can, but it's a good opportunity. So what I've heard is to take a look at the constraints, to make sure that we're looking this in the eyes of future value-based models. Safety's a priority. Voluntary versus regulatory that what we do is evolutionary. Vocabulary should be reviewed in this context and both text and narrative is included. Provenance is a bigger picture and that both messaging has value and it also can be augmented by other types of data.

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

Well terrific, robust discussion, great summary. Obviously great presentation, great work of the group, a hugely exciting area in terms of the ecosystem, but what strikes me Leslie is that many of the issues you're dealing with recapitulate many of the issues that have been fundamental in all of our discussions all along, and just great. Obviously we're going to look forward to hearing back from the workgroup on the follow up to the points that you just mentioned. We have some homework to do as well in terms of provenance. Let me also express appreciation not only to all the members of the workgroup, but Chuck Parker, Lisa Nelson and Ross Leftwich, in addition to you for a terrific and engaging causation thank you very, very much.

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

Thank you Jonathan.

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

And with that, we'll turn to John Halamka and the next section of our agenda.

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

Very good. Well, as I said, the rest of the meeting is going to focus on our work plan and where is it that we need to go, how is it that we can serve Meaningful Use Stage 3 or provide clarifications on Stage 2. And so we should start with understanding where we have gone over the last couple months in the S&I Framework. And so recognizing that there was a period of time for which the government was not as – functioning at home, but not functioning at its 100 percent firing on all cylinders. And so we look forward to Doug telling us all the homework that you did while you were turning off your BlackBerry and I don't know, may be Excel to Gmail only.

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

For the record, I did not work while I was on the furlough. That's my story, I'm sticking to it. I'm not going to let you guys get me in trouble. Okay, so, we are – do you want me to present the – okay, hang on just a second.

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

PowerPoint standards problem?

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

Not at all. Here we go. Now I'm all about interoperability, you notice I'm not using a traditional PC here, so making sure all of this stuff works. Thank you again for having the opportunity to speak. I'm going to give you just an update on some of the work that we're doing on the S&I Framework. I have invited Mera Choi. Mera Choi is a person who's a member of my team. She is the lifeblood behind the S&I Framework in terms of coordinating and making sure that all of the various moving parts are all working together. And so I want to make sure that you have a face to put with the name, because she's the one working behind the back that's really making a lot of this stuff all work. So, I wanted to make sure that she had an opportunity to be up here and answer some your hard questions as well.

What I'd like to do is just briefly go through the S&I Framework. One of the issues that we're trying to work with as well is that as the S&I Framework activities become bigger and bigger, it's harder and harder to find information. So we're trying to develop some intermediate ways of looking at that information. We want to give you a demonstration of that that is. I think then what we'll do is we'll break for lunch and then we'll come back, after you've had a view of where we've been, we'll review all of the information that you folks sent to use about the priorities and the kinds of activities that were going on, we'll summarize those into a few slides. And then have a conversation then about how we should best proceed as we go forward. So with that, let's see. That's so weird, okay, I don't know which one is going, but I'm doing that one up there, so it's fine, whatever we're doing here.

So when it comes to the Standards and Interoperability Framework we are now about 33 months into our activities. We have and the activities that we have 2700 people that have signed up. This represents over 700 different committed members, these are folks that show up on weekly or biweekly calls, represents close to 600 individuals and now we have passed the 2000 mark, in terms of the working sessions since we've started. Our pace continues at the same rate, we're running about ev – a meeting every 3-1/2 hours. There are 2000 folks that just sort of listen in on some of the newsletter activities and I want you to take a look at the numbers of HL7 ballot comments that we've received. We're very close to 6000 ballot comments. When we did the Consolidated CDA, the second round through, we had over 1000 comments. That is a world record now with the HL7 community, it's the largest number of ballots that we've had. The reason that that's important, it means that people are paying attention and that people care and that people are commenting to try to make things better. And so that's just really, I think, a level of engagement that we're seeing in the both national and the international community in terms of what we've been working on.

If we want to kind of step through some of the things that we've got in terms of our S&I Framework activities, obviously we start with DIRECT. We continue to work on DIRECT in terms of making sure that we've got the trust and the certificate management well in hand and we've got testing environments on the – implementation and testing environment sites that people can actually bump up against DIRECT. We've had a number of people who have tested against that and we have been tracking where their issues are, where they tend to fall short. And have been using that to guide the implication advice so that we can keep track of what's working and what's not, and feed that back into our guidance for people with regard to implementation.

Transitions of care, we've talked a great deal about that. That's supported by the Consolidated CDA and those activities now have gone through second round of ballots within H7. I think all of the comments that we have, both with regard to the level, whether it's narrative, text or whether it's coded, are all important. And I think what we've tried to do in this second round is refine what we've learned within transition of care, expand some of the templates that are available for additional use cases. And right now we're in the process of revising and going through the ballots. We've got about, probably about 500 of the ballots that we've completed at this point and we anticipate that we should be done with the ballot reconciliation by the first part of January or so.

Laboratory results interface, we continue to work on that. That's really in sort of that implementation guide perspective and trying to track what's working and what's not. Query health really has been folded into the data access framework activities, and I'll do a more specific update of that because that's an important initiative that I want to make sure people understand what we're doing there. The data segmentation for privacy has continued to get some additional pilot sites that are out there. And it's going through both – we're anticipating taking the data segmentation for privacy both through HL7 but also through some of the IHE work. And we're trying to establish some working relationships with IHE, particularly when it comes to things like structured data capture and the data access framework. We're looking at IHE to help us simplify some of those activities as well.

Public health reporting obviously we had a presentation last – at the last meeting, remember, this was two months ago from esMD. They're looking at a digital signature record and we're working very closely to try to figure out how that maps into some of the other digital signatures as well. Dixie raised the question as to whether or not – how is this aligned with some of the prescribing work. And what we've found is that a lot of this has to do with people who do bulk ordering of these things, rather than the individual prescriptions, but we are trying to make sure that we have a consistent view on how we manage the digital signature in the esMD activities.

With regard to longitudinal care, again I should out to John Derr and his community. They have done a tremendous job kind of pulling all these pieces together. It's an important community for us to work with and they've been extending some of the templates and some of the data that's required. Working under the auspices of the longitudinal care activities, it's going to be important as we think about care plans as to whether we're going to have a narrative description of these, whether these are going to be structured or whether they're going to be computable. And I think what we need to do is think through those three different levels. So clearly sharing the care plan is the first thing that needs to happen. If you can structure it, then you might be able to use decision support or other ways to integrate it. Computable means you can actually integrate it into a workflow and have it execute in some fashion. We're clearly not there yet, but I think those are the kinds of conversations that we welcome the community to help us with the terms of how we decide this.

Laboratory orders interface is really quite mature at this point and we think that we can get sort of that 360 where you can actually order things with a compendium of orderables and then get it resulted back using the laboratory results interface is well. And that's going to be an important sort of 360 that we want to do. Health eDecisions, I shout out to Jacob Reider who's been really instrumental, I think, in moving a lot of these activities forward with Amy Helwig and Alicia Morton, all of whom have been really focused on doing this. I think one of the things that is so critical, and we've been working very, very closely with HL7 and they've been a supportive partner in trying to move this forward, is that when we think about e-quality measures and the measurement of quality and outcomes, it's important that it's not just about measurement but it's also about improvement.

And we've said this all along that when we talk about clinical decision support and quality measurement, it's really two sides of the same coin. And so we want to make sure that our standards that support quality assessments and clinical measures actually is harmonized in how we do clinical decision support. And so we've been working very, very closely with the HL7 community and trying to create a harmonized view of those clinical decision support and clinical quality measurement so that at the end of the day, this is all about quality improvement, not just about measurement and clinical decision support. So if I've done anything – if I've transmogrified it in some way, Jacob, let me know, but that, I think, is a really important thing, because we want measurement to be actionable. We want to be able to take that measurement and make that something a people can move something with.

Blue Button Plus, Leslie talked a bit about some of the consumer engagement, and think it's important to make a distinction between B-to-B connections, so our business to business connections between providers that are sending information to other providers or information that's being exchanged between hospitals and the like. And what I would say B-to-C which is maybe business to consumer, maybe it's P-to-P, provider to provider and P-to-C, provider to consumer. I think that's an important aspect of our Blue Button portfolio. And I think it's important, Blue Button started out as initiative that was a campaign for access to information. We have refined that by creating more structure around that so that it can be used in innovation community and reused. We've got a number of challenge grants and things that have happened as a result of that.

But I think Blue Button is going to become not just a single implementation specification, but a portfolio of standards. We're working right now on engagement with X12 and WEDI to come up with an explanation of benefit standard so that patients can download information about care that was received. And if you start to think about organizing all the people who touch a patient's care, the people that bill, there's a remarkable kind of network that comes out when you talk about the radiologist and the anesthesiologist and the other folks that are part of the care team. And so we're developing out this portfolio Blue Button, transport standards, content standards and I think the conversation about what are the right vocabularies to use becomes an important part of that portfolio as well.

So we have structured data capture, I'll talk little bit about that in just a moment and then the data access framework. Again, those are other activities that we've got. Two other things on our list, we have been working very closely with the EU and the US around internationalization. Meaningful use is actually not a bad export that could come from the United States. And one of the things that we're working with them is to try to simplify some of the optionality and complexity that we have in our existing standards. So there are 400 and some thousand SNOMED codes, can we identify the 10,000 codes that are the most important, and work with our international partners to make sure that we get that smaller subset, and to do that for SNOMED, for LOINC, for ICD-10, figure out mappings around the vocabularies. Because I think creating that smaller subset both enables innovation, it helps us focus our work, but it expands what we've done in the first world countries into emerging countries that are having trouble translating 400 thousand codes into Hungarian or into all of the dialects that might exist in Southeast Asia.

Our benefit then is that of if those people – if people do that translation now, we can help our immigrant populations, we can help urban centers that have those kinds of patients and we can begin exchanging information that has that kind of vocabularies. Doing the same around content specifications, trying to create less or – I'm sorry, more constrained versions of the Consolidated CDA, because that's what the international community uses and leveraging their experience and expertise to see if that can help us with our work as well.

The activity that's going to be launching very, very soon is called PDMP, that's the Prescription Drug Monitoring Programs. And we're trying to figure out ways that we can integrate that important safety aspect of monitoring prescription drugs into EHRs and figuring out the right standards that can map into the existing sets of mean standards that are used state to state for these monitoring programs as well. Our pilots all over the country continue and we're growing those, particularly in some of the work that's going on with the data segmentation work, and we're working as well on some of our provider directory work, to expand some of the pilots that we've got there as well.

So with regard to the structured data capture activities, we're – remember, this is something that says how can we in a generic way extend the functionality of an EHR to capture data that's not part its original charge or its original data model. So how can we do things like clinical research activities by having the ability to pull up a form, have a granular data element that might have a question or an answer, be able to populate or fill that out and then save that someplace. And we're looking at that both in terms of patient-centered outcomes research, the PCOR activities, but also the common formats with AHRQ for patient safety. And we realize, in fact, if we could have a generic way of capturing that kind of information, we might be able to extend the functionality of the EHR to do new and novel things that would then provide a migration path if we want to make that part of the core activities.

We have a leadership team that's involved with both some of our initiative coordinators, like Evelyn Gallego, Farrah Darbouze from my team is sort of the ONC lead. We've got some subject matter experts, both within our team and also in the policy groups and external SMEs both in AHRQ and National Library of Medicine and others. So right now we're working on some two implementation guides. One of them is based on REST an OAuth, the other one is based on SOAP and SAML, and we're working now to try to kick off what that granular data element might be with collaborations not only in HL7, but including CDISC and others who are participating in these activities. They reached consensus on the use cases, we're trying to work now through the detailed technical work on – to identify those granular data elements and we hope that in the course of the next couple weeks to months, we'll be able to begin migrating into pilots. Some of this has already been piloted in its original form by organization such as Greenway and others, and we hope to get other vendors that might be able to be engaged in this as well.

The second activity that we've got, and this is the most recent and it's probably the least mature is this notion of – woops, hang on, I've got two slide presentations going on at the same time, data access framework. And this is really about making sure that we have the ability for providers and patients to get their relevant data out of an electronic health record, so that if we're – if a patient is seeing a physician who uses one electronic health record, they can then extract that information and move it to the second electronic health record system. And so the ability to have access to that information in a somewhat structured way for import export, to help enable patients to move their information, is a critical part of the data access framework.

We also think it's useful that providers have the ability to ask questions, if they want to just want do a part of their board certification, want to do a small study or something like that, they may be able to do that within this data access framework. We also believe that if you add on to it an authentication framework, we can actually meet the needs of targeted query. And this is a conversation that we had had here before, which is to say, if I know there's data that exists someplace else and I'm properly authenticated, I should be able to get that then out of the EHR.

And finally for public health reporting, this is where query health begins to sort of fold in. Query health is about sending the question to the data rather than the data to the question. And so we realize that both targeted query or data access – the public health reporting in query health and this need to be able to have patients be able to move their information from one EHR to another, are all part of access. And so creating a common set of building blocks to support that is where this is headed. All of these activities were delayed about a month because we were under the furloughs, but we are working very, very closely both within HL7 and within IHE. This was one of the things that we proposed to IHE as an activity, and we may be then developing a white paper. I don't know if a white paper is going to be sufficient, whether we need to drive this more towards a profile and whether we can have time to do that. But that's one of the critical things that we're looking at with these activities.

So with that, why don't we answer – if there's anybody – any specific questions about that because now I have to go and switch things around, right.

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

MUSICO demo – I started the meeting by talking about scope and timeline and resources and so I think one of the challenges we have is as we look at Stage 2, Stage 3, we look at the ecosystem, we look at nice to haves, you have an enormous body of work on your plate. And as S&I Framework initiatives, I think we would all argue are valuable and certainly will advance the industry, but can we do all of them simultaneously. Is there a level of depth in certain of those initiatives that we should focus on rather than breadth across all of them? I only ask this to the group because we're going to be looking at our work plan after lunch. And certainly after a wonderful review that you have just done, I look forward to questions and commentary as to maybe other to focus the reference, are there items we might as a committee recommend be deferred or taken off the list? I just simply look at overflowing plates everywhere and just a concern for me. So, John Derr.

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

Thanks Doug. I just wanted to comment on the Blue Button. I've been advocating that to all of the vendors in LTPAC, mainly skilled nursing facilities and home care agencies to adopt the Blue Button. That perhaps when somebody is admitted to those facilities and agencies, they could look ahead of time by using the Blue Button and incorporating that into their longitudinal care plan so they can start out ahead of the game before a patient gets really admitted.

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

So other comments before we move on to MUSICO, as to – Stan, is that your card from a previous comment? Wow, I expected controversy, I expected emotion and passion, maybe it's hunger.

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

I do have a question.

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

Please.

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

Doug, given all this work that we're doing on the sub team on patient-generated health data, the alignment of the Blue Button and all the things we're doing on consumer and patient engagement. Is there an opportunity for us to look at that more holistically through the S&I Framework and build that into the work plan so that we are going forward with more alignment?

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

Yeah, I think that's something that we internally try our best to make sure that we make those connections that exist. We are trying to do a better job of that, to try to track those initiatives and MUSICO provides us some mechanism to sort of see some of the connections and the links that we might have. But I think it's an important point and one of things that I was talking with Mera just before we came up here is that – and we can have this conversation as to whether this would be valuable or not, but for us to just sort of give you that high-level overview. What are we trying to do with the portfolio of standards that we've got around Blue Button and how does it relate to our desire, as we heard from this committee, to move beyond kind of web services and SMTP approaches, but to think about RESTful approaches that might be supported?

Well Blue Button gives us an opportunity and a B-to-C mechanism to explore a lot and Open ID and some of the Blue Button pull, RSS and ATOM type feeds. So, we are trying to use that because if we build our building blocks correctly, even if it's used for Blue Button, it may be transport mechanism that could be used in other purposes. So there is some synergies across the things and we really need to get to a place where when we start a new initiative, part of our pre-discovery or part of our work is to say, what else is going on in the S&I Framework that we can leverage? So that we're not doing 100 percent of the work, we're taking 60 percent that we get from other activities and embellishing or adding that additional 40 percent. That's how we're going to get to the economies of scale and the acceleration. And I think we are at a point now, having enough in our portfolio, that we should be able to begin to have those kinds of connections. And FHIR would be another one somebody raised as well, how do we fold that in.

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

Um hmm.

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

Jeremy.

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

Yeah, just a clarifying question on data access framework, could you give a little bit more detail on the user story? So what is the fundamental use case that we're going after here?

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

So Mera tells me – I had a quick consultation here, she tells me they're still working on a lot of the use cases.

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

Okay.

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

I will tell you what in large part motivated this. There are a couple of things. One is my sister, but she motivates a lot of what I do, you just need to know that. Thanksgiving is coming and I'm going to see her again, so – I think one was that patients need to be able to move their information from one place to another. And oftentimes right now, you might have complex decision-support and the ability to graph your information and the links between all of those records, but if you move from one system to another because your insurance has changed and your provider has changed, there's no good way to oftentimes move that in a computable way.

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

Um hmm.

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

So we can leverage our existing standards, maybe with a lightweight wrapper around that, that would allow a patient to be able to be portable with their information. Second thing that we heard is that we have oftentimes made it easier for others to get access to the physician's information in their EHR than we have to make it easy for a physician to get access to their own information. So we have these query response and targeted query and all those other sorts of things, and I knew David's card was going to go up as soon as I said that, because his solution, he's got the solution, but not everybody else does and so that's an issue.

And I think the third is that we've heard from the innovation community to say gee, we have trouble, we have this great, like really good way of doing workflow improvement or do quality assessment or provide analytics. And unless you live in – unless you work in a big major institution where you've got a big data warehouse that you can do this, you don't – the smaller providers don't necessarily have the ability to understand how they're doing with diabetics and whether they're on time with their patients and who's missing their appointments. And so there's an innovation community that says, if we had a simple way of interfacing the EHR, we might be able to provide value-added services that would help improve patient care.

So we're trying to take a look at all of those things. Within the community they're still trying to figure out what the use case is, but those are some of the things that sort of drove the motivation behind this. And David –

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

David.

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

I don't know where to start. No, I mean, I think my main concern I guess is there's such a – even in data access framework alone, there's such a broad portfolio of potential there that the focus and prioritization work needs to happen quickly enough for the relevant provider – or vendors and others to engage to make sure that they understand what's going on. These are very open-ended, potentially huge or potentially tiny, depending upon where they go. So part of this is just again a plea for clarification as to which ones of these will go forward and in what priority and connected to what obligations vis-à-vis certification and Meaningful Use Stage 3.

So for example, the portability model is obviously important but it's a broad subject all in its own. Are you talking about porting one patient at a time? Are you talking about a legally binding port of the patient? Is it ad hoc, subsets of the record? I mean, there's a lot there if somebody wants to move their record. The notion of a provider being unable to get data out of their own EHR seems like an EHR vendor problem with that provider, not a regulatory standards problem, I'm not su –

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

If you think about the innovation community who says 1600 innovations are hard, but maybe if there was something – maybe not with full functionality but something that would make it easier, that could provide benefit to the patient.

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

Yeah, that's different than providers who can't manage their diabetic pool of patients, which was the example that you used. I mean, you need to be able to manage your patient populations, but people are doing that through complicated population health management approaches that do far more than just open a channel into the EHR. So opening a channel into the EHR that's standardized for external purposes for consumers to query, say through Blue Button pull that's a use case that I think you've already got and should be refined and continued. But it seems like it overlaps a lot with a vague notion here that it's hard for vendors to know what to pay attention to.

I mean, you know I like FHIR as a general model for these things and I think I'm all in favor of pushing that further forward so it can be a common infrastructure for a number of these use cases. But I just asked for, again for clarity, on which ones are priority and why are we pushing on them, so we know which ones to engage with.

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

So that will be our conversation after lunch. There is nothing that we are working on here that didn't come from inspiration from this committee. So perhaps it's an embarrassment of riches with this, I agree.

But, you just added FHIR to my plate saying that would be a good thing for us to work on, we're tracking FHIR. I'm trying to figure out the best way to engage, and that's the conversation I think we should have this afternoon.

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

Well Doug, we don't want to expand your plate, honestly. But what we do want to do is to, I'll use the word parsimonate –

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

Parsimony.

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

Yeah, and that is, if we look at the S&I Framework and we see oh, here are 12 disparate initiatives. Um, if we just said REST, OAuth, Open ID and FHIR, we could actually meet seven of those initiatives without creating such burden for either our public-sector friends or our provider – communities and patient communities that need to implement them.

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

Which is I think exactly what John said to HL7 last September.

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

That would be –

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

I heard, we heard.

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

Well good. Let us move on to the MUSICO presentation so we can get people some calories and recharge their energy.

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

So hang on just a second. I may have to move this over. So I am going to do my best to do this on my second screen here. So can people see that okay right now?

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

It's not projecting.

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

Oh, it's off the web, oh God.

**W**

Yeah, it's off the –

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

Okay, hang on just a minute – one moment please. Where's my mouse? I took it off it off this thing and then it, of course, we lost it. So, here – you want me to fix this? I can – hang on, hang on just a sec – okay? Does that work for you? Good. Okay, now can people see it?

So MUSICO is really Meaningful Use S&I Framework coordination, I didn't come up with the name, somebody else did, but I like it. Because much of what we do with orchestrations, and this whole musical theme kind of made sense to me. So one of the things that we were trying to do is understand when we think about informa – interoperability, remember interoperability has a definition of two parts. The first part is ability of two or more parties to exchange information, so there's a sender and a receiver. And then there's the ability to use the information that's been exchanged. And so one of the things that we've been experimenting with is, how do we visualize the parties that are exchanging information and then what is being supported when we're exchanging that information?

So what we have here is on this side we have a series of different participants, all of whom have come from use cases that have come out of some of the standards activities that we've got. But if what we were to do is say, take a look at the primary care provider, we can center the primary care provider in the middle of this network and in doing so, it changes the way that the network is. Green lines indicate that there is an existing activity or use case about how those people exchange information. A red line says that we're working on developing some of those connections. And if there isn't a line there, we don't have any sort of exchange that might occur.

If you were to go then and take a look at say the relationship between the primary care provider and the patient and click on the patient, it'll show you the S&I Framework Initiatives that are being used to support the kind of exchange. And then what you can do is you can sort of go through the standards that are in play, the meaningful use alignment in terms of what the policy recommendations are and then a very high-level description of the initiative and kind of what's going on. We're trying to create a way so that if we want people to understand the work that's going on within the Standards and Interoperability Framework, they don't have to dive deep into the wiki, but have a graphical interface that we can take a look at.

Similarly if we were to take a look at say, the interface between the primary care physician and a secondary hospital or the like, there's a number of things, transitions of care, the longitudinal care coordination and data segmentation. And again, shows you the meaningful use alignment, the standards that are in use with that. So all you have to do is just sort of click on one of the activities, recenter and you can begin exploring how this all might work. And so it tells us where there are holes in our specifications, it shows where we're working on things. So right now HIE and lab is an area that we don't have an activity, but it's something that we may want to take a look at or we might want to explore.

So, I would welcome people, and I don't want to spend a lot of time on this, but just welcome people to take a look at this. It's onc-musico.org and give us some feedback about whether this is a useful way to view the information and how we might be able to make better. We're trying to find a way to sort of interface between kind of here's our regulatory framework, here's our deep dive for the working group within the S&I Framework. And is there an interface that will allow us to explore the various connections and standards in way that is pleasing to the user and makes it easy for people to sort of understand the various relationships that are there. So with that, I', going to just sort of stop and see if there are questions.

**M**

Could you give us that URL again.

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

It's onc-musico.org.

**M**

Dash, okay, sorry.

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

And just in case anyone tries “dot,” what you end up with is a domain for sale.

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

Somebody must have already gotten that one.

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

Yeah, but it looks like country music, so, it’s not pornography, don’t worry.

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

So the issue, I think though, is that we’re still working the bugs out with this, it doesn’t work in every browser. All of the features aren’t available in everything, but we would like to find out more from folks about what’s working and what’s not working, how we can make it better and more approachable. But we’re really trying sort of trying to struggle with that visualization, because a lot of what we do is we talk about the things we build as opposed to the exchange we enable. And this gives us a way of looking at what kinds of exchanges are being enabled, in terms of our interfaces.

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

Actually, just one quick comment. Of course the entire user interface says left click and right click, I have no idea what a two-button mouse is.

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

I can talk with you John about how to do that. It’s in your environ – your set up and you change it to a two-finger click, but that’s –

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

– you know what I was –

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

There are ways to do that. I know –

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

I know.

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

I know. But that may be useful feedback, if there’s a way that we can make this easier, please let us know.

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

Very good. Okay any comments, other than my of course, jestful comment.

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

I just want to also thank the team and Mera and the work that S&I Framework folks have been doing just to coordinate all of this and trying to make this a bit more accessible as well. So thank you.

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

Very good. Well, let me turn it back to Jon Perlin and we want public comment and then we will break for lunch and talk about our work plan.

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

Let me just turn to Michelle Consolazio immediately for public comment.

**Public Comment**

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

If there's anyone in the room that would like to make a comment, if you could please come up, Doug and Mera, I'm going to have to ask you to move, I think there is a comment in the room. And while we wait for anyone to come up to the table, we will open it up through the operator.

**Alan Merritt – Altarum Institute**

Also if you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press \*1. Or if you're listening via your telephone, you may press \*1 at this time to be entered into the queue.

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

We have a public comment in the room.

**Asif A. Syed, MD – Director, Medical Informatics & Healthcare Strategy – American Medical Association**

My name is Asif Syed. I work for the American Medical Association and my responsibilities include informatics and strategy for CPT as a main role and then other products we manage. My comments are related to the consumer sort of representation of data standards. And just as an information item, at AMA we do provide the whole set of consumer friendly description related to CPT procedures and the way we created, I mean it's exactly to support meaningful use regulation. And these are all available along with regular CPT files to all of our licensees. Do you have a comment John?

(Indiscernible)

**Asif A. Syed, MD – Director, Medical Informatics & Healthcare Strategy – American Medical Association**

Yeah, so just as information, like we've been working on these things to support meaningful use and we are continuing to enhance those in order to support whatever is coming out from the committee and the recommendations. Thank you.

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

Thank you very much. Michelle, any comments online?

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

I think they are checking, yeah. Oh, and there are any –

**Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute**

We have no comment at this time.

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

Okay John, the committee – I think we were scheduled lunch until one o'clock, is that correct?

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

To 1:15.

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

So, 1:15 it is. Thank you very much. We're actually pretty much on schedule and I appreciate that, very robust discussions. I think Doug – I want to add my thanks, MUSICO is really very helpful in terms of understanding the relationships between different participants in the ecosystem of information initiatives in progress. So with that, let's reconvene at 1:15. Thanks.

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

If everyone could get ready, we're going to get started in a minute. Jacob told me –

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

Yeah, wait for me.

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

All right, now we're really going to get started again. So I believe the lines are now open, so I'm going to turn it to you John.

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

Great. Well, as I said, we're going to spend the remainder of the meeting talking about our work plan, looking at the priorities you submitted and make sure that they dovetail with the requirements the Policy Committee has for us to clarify Meaningful Use Stage 3 issues. But before we begin, Jodi has dutifully looked at all of the regulations and has a quick summary for us, I think validating what Liz Johnson has told us.

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

Yes. So, I just wanted to clarify any misunderstandings and validate, based on the conversation we had this morning, some of the questions that were asked about Stage 2 and timing. So first off, it is 2012 – 2011 and folks who started Stage 1 in 2011 and 2012 have to go to Stage 2 in 2014, so it's both cohorts, it's the 2011 and the 2012 folks. So that is the larger number of hospitals, the 2000+ that Jennifer mentioned. And two, it is in fact true that everybody in 2014 will have to use 2014 edition products, whether they're at Stage 1 or Stage 2, but for everyone there is a 90-day reporting period. So that means that they have to be using the product for the 90-day reporting period. So anybody, whether they're at Stage 1 or Stage 2 can begin July 1 and have 90 days in using their 2014 edition and still comply with the requirements for 2014, regardless of what stage you're at. I think that clarifies the two questions.

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

Very helpful. Yes, Wes.

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

Is there any chance that the people who begin in July 2014 will be subject to a penalty? There are penalties –

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

Yeah.

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

– I've heard that it's possible you can get both an incentive and a penalty if you start your 90-day period July 1, is that –

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

I am – I have not heard that, I am not aware of that, I mean, we will confer with our CMS colleagues, but I am not aware of that.

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

Thanks.

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

Okay, any other comments? Well – let's move directly to the FY13 work plan, starting with image exchange.

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

Great. Well listen, thanks again. I just want to thank everybody on the committee who took a look at the spreadsheet that we had distributed, all four tabs and all the activities that were going on in those and took the time to really go through and give us some feedback about what's a high priority, a medium priority and a low priority. And so, I just want to thank you because obviously that came due while we were all out on furlough and so we were hoping to have a conversation last month, but we'll have the conversation this month as well. So, with that, let me just dive right in.

We have a number of things that were uniformly ranked as high priority items for us to work on with regard to meaningful use. And I think one of the things that's important, and this I think goes to comments that Arien said earlier today is that we're going to focus in large part around some of the meaningful use activities, but in fact, there is going to be this need, I think, to support things broader than meaningful use. And we didn't ask that question specifically, but this is a place where I think we can have some of those conversations. So, if there's something that's high priority both for meaningful use and for our path forward, that may mean something different than if it's a low priority for meaningful use but a high priority for the path forward. And I sort of rely on you to help get us some of that feedback and see how best to balance it. There may be some things that over time aren't even on this list that we need to add, and I think that's also something that I'd be happy to talk about.

So, with that, high priority items many of these things focused on transport and on content specifications. I think one thing that we didn't ask a lot about were where we were with some of the vocabulary work that's going on. So, at the end I think that's one of the things I'm going to tee up as well, for us to make sure that is there something in the vocabulary space that we need to consider as well. So with that, there were approximately six different work plan activities, and remember, these were things that we had talked about earlier in the year about things we wanted to try to accomplish as a team, as a committee.

The first is image exchange and standards to support image exchange. That's work that's gone on with the Clinical Operations Workgroup, in fact, they've had a number of different hearings and meetings related to that. I think they are beginning to sort of converge on a particular approach and recommendation, but that was something that we have ongoing work that was considered high priority. What I'd like to do is just step through these and then I can flip back and forth between the slides as people have discussion.

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

Jamie has confirmed from London that we will be presenting our recommendations to this committee next month, for your feedback. I mean, they may not be in a final form, because we want your feedback, but I think we'll be ready after one last bit of testimony from Scotland.

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

Yup. So, things are moving very, very well along that and I think, as John has said, and Jamie has said, we'll hear more about that next month. Data transport. The – this was additional standards to support transport of data to and from the patients. You'll notice there's a D. Baker that kind of shows up every now and then in this, this goes to Dixie. She was very, for her size, more robust than any of you, in terms of her comments and feedback. So we've called out some of those things because we thought they were good. So this task, Dixie tells us, is completed, no further action is required therefore a "1" priority. And in some sense, we've got a portfolio of standards. I think part of what we may want to think about is what is beyond Meaningful Use Stage 3, are there other things that we need to think about, and that may be a conversation to have.

Quality reporting and measurement, again, very high, standards to support flexible platforms for measuring and reporting quality and so we've been working very, very hard with HL7 to make sure that quality reporting, quality measurement and clinical decision support and improvement activities are harmonized and aligned. Standards to support closed loop referral, this was a pilot that was done within the HIE community that allowed people to both send the consult and get back the results; again, very high priority. Record locator services, standards that support record locator services, a high priority there and care plans to record care plans and care team activities.

Now when it came to the next set, we have a number of things that are sort of in that middle range. We have sort of a bell distribution, I suppose, some things high, some things low but a lot of things in the middle. One was laboratory orders, gap an – kind of content gaps in laboratory orders and the Clinical Operations Workgroup reported out in June and we've been working on an LOI specification, that's gone through ballot and has been accepted through an HL7 as an HL7 V2 message. Digital signatures, standards to support digital signatures, CMS presented the HIT Standards Committee over the summer. And there have been subsequent meetings of CMS that met with privacy and security officers. We're not, at this point, exactly sure what we need to do and I'm going to be coordinating with Joy Pritts, to make sure we've got the digital signature stuff taken care of as well. But that was one of the things that was in the medium range.

Terminologies, this is an area in which, I think, we may need to have some conversations about. One of the recommendations, and I went back to the 2012 recommendation that we got from this committee, and one of the areas that they looked at was, what are we going to do with things like ICF, the International Classification of Function? I will tell you that among our federal agencies, the VA and the DoD in particular, this is a high priority thing for returning servicemen and women who then need to be able to determine disability status and then be able to follow them over time. It's also something important for CMS because they'd like to see, are there ways that we can use functional assessment sort of pre-op postop kinds of things, to see what a person's functional status was before their hip replacement and what it was afterwards. And so there are some instruments, there are classifications and there are descriptors, terminologies that we need to address.

Another medium activity is parsing and record sharing, so improved standards to facilitate unambiguous parsing, longitudinal record sharing and bulk record sharing. So, this is a pretty big and broad activity. We have some activities in this space, we probably aren't covering everything across the range there. Advanced directives, standards to record advance directives and care preferences. APIs, standards for application programming interfaces to support modular application integration, a medium priority. And clinical decision support, standards to support clinical decision support both knowledge, representation and application interfaces for query response to knowledge resources. Those two things really define the two use cases that the Health eDecisions, or the HeD activities are working on right now.

A couple of other medium priority, defect reporting, standards to support defect reports to patient safety organizations. Registry support and SDC, so standards needed for registry support including structured data capture and transmission to third-party repositories. And then some activities around query response of provider and patient identities within directories, so provider iden – directories and patient identity. Standards to report those query response. Again, here's another Dixie Baker comment here, standards here will be dependent about how providers and patient directories are implemented. For example, you could use RESTful FHIR based queries for resource, which is sort of what Blue Button pull uses, DNS query which Direct uses, or LDAP, which is sort of a Direct alternative and something that also fits into some of the HPD plus specifications that are out there being piloted right now. Do we want multiple specific – specific alternatives? And how best to approach sort of that query response to provider directories?

The last page of medium priority is query response consent management, so standards to support consent – I'm sorry, I've got two presentations, I apologize, but thank you for keeping up with me. Umm, there we go, got it – standards which support consent in a query response architecture such as granular patient privacy preferences hosted in a managed service like “pull,” or sent as a request as in a “push.” Data segmentation for privacy. Clinical documentation for new payment models, so, supporting these new payment models, how can we support additional ways to do clinical documentation? It may look different than the way we do it now. And local and targeted queries, standards which support query of data within organizations and targeted query across enterprises for particular patient data.

The one thing I have on a low priority is securing data at rest, standards for securing data at rest, especially genomic data and consumer downloads. Dixie Baker said, given the factors I have entered in the status field priority is rated 1. But I think this is one of the things that we have to sort of decide how far down the road we want to look with genomic data, for example, and where the boundaries exist between consumer downloads for encryption and decryption, securing that information as well. And if we need to, we can talk a little bit about HIPAA and the responsibilities we have for providing access and not providing – not putting other barriers in place. If patients want to send their data through my hellokitty.com address, we shouldn't put in barriers if that is, indeed a legitimate address and that's where they want to have their information sent.

So with that, that sort of is a summary of Dixie Baker –

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**

Yeah.

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

I tried to include all the comments, but –

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

But this topic was not a broad securing data at rest, that's –

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

Right.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

– the topic originally was securing data at rest on a consumer's computer –

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

Right.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

– which is why I made the comment that the Omnibus Bill clearly said that's out of scope.

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

Exactly. Exactly.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

So are you changing the topic to securing data at rest – ?

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

No, that's the high level just kind of summary topic, it's –

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

You're still –

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

– for consumer downloads is the piece that you're talking about.

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**

Yeah –

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

So this –

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

– for consumer downloads, yeah.

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

Okay, so that was the feedback that we got and things kind of filtered out. I mean, there's a big chunk of stuff that's in the medium category that we probably want to have additional conversations about. And there may be some things not on this list that people feel strongly about. But with that, I'll go back up to the high –

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

I'd like to open it up for the conversation to say that just because they were listed in a survey doesn't mean that they all should be done. And beginning of the meeting, time, scope, resources, what is it as you look at this that we should focus on? And recognize that one of the challenges, I feel, it's palpable in my work with the Clinical Operations Workgroup is everyone is so busy trying to meet the demands of Meaningful Use Stage 2, ICHN, HIPAA, Omnibus Rule, and ACA operationally, that their time to be spent on standards making and harmonization is itself compromised at this particular moment in history. So, we have to look at what is it we want to do? Who we're going to assign it to? What is the scope of that? So certainly while beginning with that slide. But Andy, you put up your card and Wes you put your card.

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

So, two things, one, a small editorial comment on one of the specific sections, when I became a Permanent doctor in 1983, we didn't have a billing and claims system at all at Kaiser because we didn't need one. So I'm amused by the fact that if we're moving toward a system of pre-payment, that we need some more advance way of collecting all this information. That's just funny to me, anyway, because we find a way to make it more complicated when it ought to be much less complicated.

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

Andy, can I push back just a little bit?

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

Sure.

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

So if what we're going to do is actually pay for quality and pay for performance –

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

That's where I was going here –

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

Okay.

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

– was the second part of the comment that wasn't funny. So I agree with you. If you want to pay for quality and if you want – then there are things within this first list that are foundational, rather than non-found – so they're all important and we listed them as high priority. But if the point is not we're just doing – paying "X" number of dollars per member per month period, without any adjustment for good or bad outcomes, if you want to know that, then we've got to do the quality reporting and measurement piece. That's what is really, I think, you're really – what it's really about, not –

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

What I was trying – what I was saying about documentation is, currently doctors create a subjective, objective assessment and plan, but nobody ever records outcomes. Outcomes is sort of in an emergent property that we try to decipher from the care that was delivered.

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

Right.

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

So when we talk about, and when we talk about things like – where is it here, the clinical documentation for new payment models, do we need something in the Consolidated CDA that includes something about outcomes, for example. That's kind of where I was going with it.

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

Okay, so if that's incorporated in quality reporting and measurement, then I'm with you, because I think that's where we all want to go.

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

Okay. Great.

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

I might say as a quick editorial follow on to that is, given that we're migrating from fee for service to goal per capitated risk from episodic sickness to wellness, we don't need ICD-10 at all, what we need is good quality and outcomes measure. What do you think? I can dream can't I.

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

The pathologists still need it to classify dead people, so –

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

– there you go. Okay, so Wes and then Jeremy.

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

Yeah, I'm just taking advantage of a chance to make a comment that got skipped earlier, but, at one point I thought the Data Access Initiative was related to helping with the high cost of switching from one EMR to another. And I think in light of the discussions we had this morning about the possibility that there will be consolidation and change in the EMR market, that's an important thing to consider. As the discussions went on about DAF, I was less concerned that that was a specific use case that was focused on, but I did want to get an opportunity to put that in.

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

Sure. I think that's an important point. I think part of within the Data Access Framework, trying to figure out what the use cases are that need to be prioritized and to work on, clearly if you can export a patient's information for a patient to move, you might be able to loop over all patients and get most of the information out. Usually when it comes to migration too, there's often administrative and insurance information as well. Whether that's in scope or out of scope, I think that's a conversation that's going on right now within the Data Access Framework. But trying to figure out what's the first step in that –

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

I'd just like to add that anyone who has seen an organization go through a change in EMR recognizes that good is better than perfect in the sense that they're less likely to get anything if they shoot for too high a goal, in terms of the transferability.

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

So we can distinguish that by saying there's patient data portability and then there's practice data portability. That would be kind of what you're describing –

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

No, I was actually describing the degree of semantic interoperability between the old EHR and the new EHR with regards to patient data. In the sense that certainly particularly in practices when they go through an upgrade in EHR, they ex – they are – it's not a decision that's made lightly, it's a decision that's made understanding that part of the consequence will be a loss of some fidelity of information. What we need to avoid are situations such as one that came up with a vendor that for good business reasons discontinued a product line, but essentially had a lock or a high economic cost to them going to anything else except another product from that same vendor. And I don't think that was deliberately malicious on the vendor's part, I think it's just a case of if we can get a lot of information transported from one vendor to the – and we make it clear it's an obligation to sell into the market to be able to support exporting out, then I think we help to let economics take their course in choosing the viable vendors.

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

Probably have a friendly comment, he is part of this thread.

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

Well, just to reiterate Doug, the distinction that you made there, I think is really important, the distinction between a patient migrating their record to a different provider versus a provider migrating his entire population to a different vendor. They sound similar and they are similar, but I think they're very different use cases and the complexity of one is much higher than the other. There's a lot of non-patient state that would need to be preserved and migrated if it's a vendor switch, that I think makes those two cases separate. There may be overlap, hopefully there's overlap in the services that you have to build, but they're different use cases.

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

So Jeremy.

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

So a couple of lenses that I'm look at this list through, one is sort of where – questioning where providers are having difficulties today meeting performance standards. And the other is, where is there real world demand for transactions to occur? So where's the paper still in healthcare? And so about 50 percent of the documents in our system are through EDI, and that's – 80 percent of our lab results are EDI, about 2/3 of prescription renewals are EDI. But imaging studies, referral, consult notes, very, very low rates of electronic exchange. So it would be a plug for both of those remaining high priorities because I think there are millions of transactions to automate in the world, and paper to take out, if we focus on those. Whereas some of the other things I think in the medium and in the lower categories, to me, we'd almost be creating markets, I think, for some of the – for the underlying use cases.

And the other thing I'd say is, it's really a question on quality reporting and measurement. In my mind, the reporting element is a significant gap. I don't know that measurement is, so how are you drawing the line in the work there between the sort of – the measurements I think is something that sort of happens in the platforms and then maybe other people take feeds of data and comb through them. But the reporting of everything that providers are doing through manual attestation today, I think, is one of the things that we really have to get through. So, can you talk about the split between those two?

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

Sure, there are actually two separate suites of standards, one which supports an electronic description of what the quality measure looks like and then the second is a series of quality reporting standards that allow you to do individual level, sort of a spreadsheet view or aggregate quality reporting standard. So, there – within HL7 there are these standards called QRDA –

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

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

– those are the quality reporting standards and there's a category 1, 2 and 3, depending on what level of aggregation occurs. And then for quality measurement there's something called HQMF, which is a different standard that is an electronic version of how you would specify that quality measurement.

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

So I guess if all the platforms are certifying on their ability to meet the CQMs, is – I don't know that it's a high priority to focus on measurement. But I think getting – the attestation workflows are pretty laborious today, I think, for a lot of providers and I think figuring out we get the paper out – the manual effort involved in that reduced I think would be really important. So I guess it's a vote for those three to kind of remain high.

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

Okay.

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

So Floyd and then Arien.

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

Thank you. So, I wanted to touch on the quality reporting measurement and I know our focus that I heard earlier was its quality improvement. So what's interesting to me is, decision support is medium and quality measurement and reporting is high and I think it's maybe more of a marketing approach. But I think we are talking about quality improvement, because your stan – if your standardizing the way you express both measures and decision support, to me that fits into what you have as quality reporting, regardless of who named HQMF and who named QRDA. There was a context to that, HQMF was named by Jacob Reider and he bought the first domain, internet domain for it. I didn't know if he wanted me to say that. But the harmonization, I think, is important as standardization so, that can happen, whether the actual constructs are the same.

But one thing bothering me a little bit about the outcomes. I think outcomes are important and I think you see outcomes as part of care plans and the plans of care that compromise – that comprise, sorry, the larger care plan. So I think outcomes needs to be embedded in more than just – it shouldn't be a separate effort for – it's in CDA because I have the outcome of what my plan was. But then I have a care plan that has a different outcome. It's the same thing and we shouldn't create silos when what we're really trying to do is get to as we document, we document what's out expected outcome and maybe the CDA can say, how far am – what percent of my expected is present today. Because that's a snapshot, but we should think about outcomes throughout the same way.

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

Okay, Arien.

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

So, just on this thread and to play off of Jeremy's comment, I look at this very – this particular quality reporting and measurement category very differently if we're talking about measuring an individual provider at a single setting care of care in the EHR they support versus measuring at a population base or a system base where you may have a – in a patient-centered way with patients who see multiple providers. And I...there's a lot of innovation in this space, there's a lot of potential innovation in this space and I think we would be poorly – I think we'd poorly serve the community if we looked at EHR-centric quality measurement approaches as opposed to system-centric quality measure approaches that have the reality that you've got multiple EHRs.

We also have the shift from claims-centric decision support and quality measures to clinically-centered decision support and quality measures and need to make sure that we're managing that translation well. And that we're doing the mirroring and mapping if CMS is judging the system on the basis of claims submission, that clinical improvement happens on the basis of clinical data, making sure that we've got line of sight. And just to underscore John's comments, maybe we should just move to SNOMED for everything.

So, and so if you just pull that thread apart and you pull the thread of quality reporting, you need to get at data access as well. Because if you want an ecosystem of high-end population management, quality reporting, quality measurement, decision support tools, they should operating at a patient-centered approach, with the ability to combine and manage data from multiple settings of care. And that ends up looking like a cluster where if you look at it alone, you might say data access is a low priority. If you look at quality measuring and reporting at a system level, you might conclude that data access is a high priority.

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

And this is a quick comment on what you said about quality reporting. I report quality from multiple EHRs, multiple inpatient and outpatient systems, normalize them in a repository and then use that repository to submit to CMS and other government entities in a standards-based way. So as you said, we need to think about this more globally and Jon Perlin and I often discuss the burden of quality reporting. And of course Floyd always chimes in, it is challenging for any of us to hard code quality numerators and denominators in source systems when, in fact, the landscape of quality measure definitions can be – is changing quite rapidly, as to Jacob's vision. The notion that somehow we can actually collect data, normalize it, whether it's an EHR or a registry or a repository or whatever, we can simply run a definition against it ad hoc, we can extract a quality measure is certainly a very good and generalized vision. So David.

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

David McCallie. On the quality measures and the CDS being sort of thought as part and parcel of the two sides of the same coin, I think that makes some sense. But I'll just reiterate maybe a common drumbeat from me that the focus be on unambiguous definition of the measures and of the CDS, rather than on the notion that you could specify an executable format that is suitable for automatic incorporation into the EHR. The former is achievable, the latter I suspect is not, and would be inhibitory to different approaches to making decision support more workflow friendly and the like. So, you've – Jacob's heard me say this before, I'll say it again in public.

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

So if we take a look at this slide overall – you described that slide.

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

Okay.

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

So image exchange recommendations, initial recommendations coming next month. Data transport, Dixie's already done foundational work there. Quality reporting and measurement, there's a very significant body of work, which we've just articulated, has many moving parts and components and probably needs to be broken up into a couple of segments. As you point out, referral workflow is largely – well there's administrative and peripheral workflow, but clinical referral workflow is either done in a proprietary ad hoc way across private and public HIE. There isn't sort of a simple, universal way we can do this, so we get structured data into our EHR systems, so certainly that seems valid.

Record locator services, well I imagine that our CommonWell colleagues can comment on the need for standards there, but in Massachusetts we're going live next month with a record locator service and we do invent all the standards. And it wasn't that IHE and others have looked at this, it's just the nature of our use cases and the existent EHR technology and our requirements, were just simply different than had been universally completed in the past. So, you hate to have to invent any ad hoc standard, there should be some universal way to do it. We, by the way, have called it a relationship locator service rather than a record locator service. And then care plan, certainly as we've heard from Leslie, I mean there's a desire to, whether that's a provider or patient generated care plan or both, to represent that in a structured way. So we look at all this, certainly it all sounds like goodness, there is further detail. Wes, you have a comment on this slide?

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

Yeah, I'd like to follow-up on your comments, John. I have to at least facetiously say, oh my God, another one thing they've done in Massachusetts they can't do anywhere else. But, I believe that we can cut through a lot of the issues about the ultimate economic benefit of the work case by looking at what people are doing the hard way, such as making up their own standards and addressing those. So at least we know that there has been sufficient investment in that, justified by some sense of economic benefit, to be sure that if we invest a lot of time and begin to force these down vendors throats, to use a metaphor that might be used across the bar more, but that we know the payout is there. We understand that only workflows that are running using these data flows and things like that. So, I just would like to see us, as we look at this list of things, look at those things that are actually working the hard way somewhere and focusing on making those easier as opposed to creating workflows that we would like to see exist, but we have no idea whether the underlying economics are event here for them.

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

Okay, good comment. Other – Eric?

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

Question for Dr. McCallie. If there were to be a method of expressing a clinical quality measure and/or a clinical decision support intervention, such that it was explicitly unambiguous as you described/request, and some were to choose to consume that in some way, in a computable form, would that be a bad thing?.

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

No, voluntary consumption of something like that, if it's useful, would be encouraged, but turning it into a certification requirement that says you can't qualify unless you can consume it and demonstrate a non-workflow friendly embodiment of it would be counterproductive.

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

Understood. Thank you.

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

Any other comments on this first slide. Since these are all high, there's not a lot of controversy. The mediums, that's hard.

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

Got a ton of mediums.

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

Yeah, and the lows we can just say no, the highs we can just say yes, but the mediums, ooh, I don't know what to do with. So, comments here, I mean, lab orders, S&I Framework already in progress.

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

Let me say, I think there's been progress made on the lab orders interface in terms of low-hanging fruit, there's an existing standard that's out there. I think the question is whether it solves what is now a paper-based system in which there's lots of transactions and we want to be able to support that. It kind of goes to, I think, the comment that Jeremy made around can we do these things electronically in a consistent way? Is there some value in that? Is this a high volume activity? And I think we've got some standards that are out there that may be helpful.

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

Digital signature, we have heard from CMS about that effort, but as we talked about today, digital secure provenance, there's a variety of efforts there. No question that there are certainly terminologies like ICF, as you highlighted, that do need some harmonization and you did cover the parsing, the advanced directives and API CDS use cases. But, I see some cards coming up, so look forward to comments on some of these items. Andy.

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

The one distinguishing one that I would like to call out is APIs, realizing that this is going to be a real challenge for the vendor community. If there were standard APIs and we're worried about innovation, that would be the one thing we could do to amp up the possibility of innovation. Because it would mean people could understand what their targets were if they were trying to create something new that would attach to existing large footprint EHR backbones. And I know that again, it's a challenge, but it would be great. It's like saying that these guys have a standard, a little jack and it's called a mini-USB and you can buy one of those anywhere and you can hook it up to this fellow here and synchronize it.

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

And to your point – oh please, go ahead.

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

Can I have a follow up question?

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

Please.

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

And this is general Andy, you don't have to necessarily answer this, although I'm sure that you have some suggestions, is APIs is a huge thing. So if you say, I only want – I only wanted to have four APIs or five or whatever it was, what would those be? So when we say we'd love to have APIs to support modular integration, do we need a presentation layer? Do we need a data layer? Do we need a middle layer? I mean, help me understand, if we were going to do an API, and we couldn't do them all, what would be the one that would provide the greatest value?

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

My own opinion, again you didn't say it was for me, but I think the presentation layer.

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

Okay.

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

But I know people will argue with that, but I think – but to me, on the user side, the end user side, getting something that works well for my poster child for this, the image acquisition guys like gastroenterologists and the cardiologists and something that works well for procedure guys who are doing stuff to patients. And something that works well for the primary care docs. The underlying data and data model should basically all be the same, but how you interact with the system can make you work efficiently can be very different.

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

Okay.

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

I was at a conference yesterday run by the Economist magazine and was asked the question, well, can you imagine a world in which, well look at this device, only products made by the manufacturer ran on it? Well welcome to the world of EHRs, that is – it isn't as if there are APIs that allow two guys in a garage to come up with whatever it is, unique visualizations for patients, unique interoperability. I mean sure you can cobble together a few things with the standards, but that's a little bit imperfect and APIs might offer a, if you will, "app store for modules." Certainly a desirable thing but as Doug points out, what is the finite number of APIs one would offer, given the complexity of the healthcare record. Well, we've seen the SMART platform start with meds. I mean, there may be some low-hanging fruit.

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

Yeah, I mean, if I could jump on the – carry that one forward, because I blurted out no to Andy in a way probably that wasn't a respectful one and clear, too. I certainly think we need a way to embed a user experience into an EHR context. I don't think that's an API in the level of – that maybe Doug is asking about it. So something like the SMART platform, which is a simple way to embed an HTML to find user experience into an EHR, I think is absolutely one of the core components that we should focus a standards effort on in the future, because it opens the door to an immense number of problems to be solved.

But in addition to the user experience embedding, you need a way to move data back and forth between the service that's being embedded and the local EHR. And the only candidate for that frankly, in the standards world today is FHIR, and it's not finished and it's far from finished. But it's very promising and I think what will – I'll predict that where we end up is, we settle on FHIR the core capabilities and then start defining specific profiles for specific use cases. So a vendor could say, we support FHIR profiles 17, 24 and 93 and there'd be a bunch of use cases that are dependent on those profiles and then things would work from there. So that the nice thing about what they're doing with that is that they've cleanly separated the core model, which is just straightforward RESTful use of HTTP style services that we all know how to use now, from the profiles to specific use cases. So it opens the door for much more rapid evolution than what we've done in the past, which is we start from scratch every time, at the bottom. So I think you do need an embeddable user experience and you need a standard data pipe and those two together spans an awful lot of space. And we've got two good candidates out there.

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

Well we have many cards that have gone up, so I – Floyd and then I think coming after that Keith, and then Jeremy and then Arien, then Leslie and then Wes and so forth.

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

At the risk of going to the parking lot that we created this morning, I see individual items along here that we all voted on, but one issue seems to come up across many of them and that is provenance. So, is there a way we can deal with it to identify what is it we're dealing with, the three blind men and the elephant came to mind this morning. But I think all were true and so if we can define that and come up with something standard across – I don't know where it fits, but it just struck me that this is going to continue to happen and I don't think ignoring it will help us.

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

Very good. Thank you. Keith ?

**Keith Figlioi, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

Which one of these works – I just wanted to come back to the API discussion, and Doug specifically to your point about how broad it is. I mean is there something that we could look at this as a foundational thing of what we do as a group and what we recommend? If you look at Dr. Farzad's comments this past week, he said the number one thing he regrets is he didn't push the API movement stronger, and it was in – I read about it, I read it this week. So it strikes me as if – it's kind of like an apple, an orange and a peach sometimes, when you look at these different things on the list here. And it strikes me as this is one of those things because what is interesting is for those of us who are in it or have been in it, pretty much every vendor has APIs, they're just not published. And so the SIs know it very well, the people that implement these systems, configure these systems know it very well.

I'll just give you one aside story where in my old life we were thinking through our HIE strategy and we had three or four different developers come up to us and go, why do you need an HIE? I basically have built a handful of APIs, they give you every single thing you need to do for CCD or CCR. So I just think we need to think about this as a foundational piece of the work that this committee does. That's actually why I'm here, because I firmly believe in this. And it's one of the things that I know, again using our membership base just because of who we are, it's a big part why they want us here. And so I just think we need to think, not on the list, but as a core pillar of this group. And then bifurcate it and get into the discussion about okay, so what are we attacking, knowing that downstream what you really want, is you want all of this stuff published and you want anybody to be able to take advantage of it.

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

So when we talk about the things that we standardize, sort of our portfolio, remember, you guys should be able to recite this because – I should actually just go around and make a – because if you're on the HIT Standards Committee, you've got to know this. So there are five things that we standardize, right, we standardize meaning, structure, transport, security and services. So we have vocabularies, controlled vocabularies. We have structures that we put those in to, a way of moving things around, a way of securing it and then we have services. So when I think about services, one could think about them not just like what a provider directory might be as a service, but really an API.

**Keith Figlioi, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

That's right.

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

So I think of a service as taking the first four of our building blocks, collecting them together to serve a function. Because even the most ubiquitous API that all of you guys use, it's called GET, it uses HTTPS. It's a web service out there like an API. It has a controlled vocabulary of what you can say, it has a structure about how that information is organized. It has a transport mechanism, probably GET things back and forth, both the sending and receiving of things and then there's a security layer, TLS or whatever, that helps you. So, I think you're right on. When you think about API, API is one of the five fundamental building blocks and we have not done a lot in APIs, in terms of what we're trying to do. But we could solve problems around say, advanced directives, we could say, there's an API.

But I think part of what we may get from this group is that this is something that we should add to our portfolio and put some more time into to solve some of those bigger functional problems that we're trying to do. You could do 360 referrals as an API. We have to make sure that we've got the vocabularies and the content and its transport, but you package it together as an API and say this is a function that's available. So when I think about the five fundamental things that we do, if you take the first four of those and you package them together to solve a problem. That really kind of defines what API is, it tells you you've got to have certain controlled words that you're going to use, in a structure that gets transported and is secured in some fashion.

**Keith Figlio, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

And I agree, but the only last comment and then I'll get off it is, what's happening in other industries is there are API platforms being created. And so – I mean, I think we have to be kidding ourselves thinking that's not going to happen here. And secondarily, I know a number of our members that are actually going out and contracting with some of these entities today to open up Cerner, to open up different pieces, whether by right or by wrong of some of their contracts. So I just think we really, really need to think about this long and hard and figure out how it intersects with all the different subgroups and workgroups and this list and that list. And really to your point, I agree, it's four of the five things that we need to focus on, but we need to structure it in a way so people can consume it.

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

So Keith would put a vote to make that a high rather than a medium?

**Keith Figlio, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

I would. And I do apologize, I actually shouldn't vote, because I didn't get my list in, so I do apologize.

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

There you go.

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

It could have been high had Keith voted, that's right.

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

Jeremy?

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

So, a comment on digital signature, I think it is something that needs standards work, but I was concerned by the underlying use case that we talked about over the summer because it seemed as if it was fundamentally damaging to the provider experience in an EMR. And it was largely to accomplish an administrative aim of CMS rather than something else as part of the Meaningful Use Program. And so I'm worried about enabling that without a lot more discussion about how it's to be used and how it could be particularly used to make provider's jobs easier and more secure. And so that – it's more – we need it, but not being concerned about how it would – how the hammer would be wielded.

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

So, let me just paraphrase that, digital signatures are important, but we need work on how we approach the problem, feeling uncomfortable about what was presented over the summer. So it's not that we should proceed with what was presented over the summer, but this is an important area but maybe we need to change tact or have a little bit more discussion about that. Okay.

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

Yeah.

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

Very helpful. Arien?

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

Just a quick tag on that, if you don't solve for – on behalf of rules in healthcare, you're going to mess things up terribly. One quick comment on orders and then I'm going to go straight to APIs. On orders, the work that's been done so far on AOE's and orderable catalogs is great stuff. Our experience, we do a lot of digital ordering, our experience is actually the tricky parts are insurance related and registration related, and I don't believe there's been any work there, so just to play this out. If you sent a lab order to a reference lab, they want enough insurance information so they can get paid. But there's no universal list of insurers, so you end up having to do proprietary mapping there. And if you sent it to a hospital lab, they often need the patient to be registered or preregistered in an A-14, for example. And if you don't standardize those areas, you're going to end up with an order transaction that's perfectly standardized but the surrounding transactions aren't, and so nobody's going to be able to accept your order.

On the topic of APIs, this is a really complicated topic. You don't want to over-constrain or overburden innovation. On the other hand I'll tell you an experience of having modular secure messaging in 2003, where we built to Epic at UC Davis and had single sign in to a patient context and all the things you needed to get the information charted back out. We worked with John at Beth Israel Deaconess to extend that at Care Group, to do things like message history and flow, great. And then you go EHR by EHR and everybody has a product that they want to sell or they have a set of APIs they require their providers to go. And so our ability, even one that customer wanted it, our ability to integrate that secure messaging was inhibited by the lack of some of the basics. And I just want to also – this kind of lack of innovation is pervasive in this industry because of the difficulty in getting those workflows opened up. You often get into weird situations where somebody support-fit an organization, but the general manager of the person who's got the product blocks it because – and just all these kinds of economic issues come out.

I want to double down on David's comment that FHIR is an excellent platform, at least directionally, to do this in. And if all you had was single sign in with patient context to foo and then FHIR-based workflows that may be modular, may be profiled, to get some data back, you may discover that you're opening up a generalized toolkit that gets used in ways that you didn't expect, which I think is part of the hallmark of innovation. And just lastly, Josh Mandel I think would be a good person to talk to related to this in the work that he's been doing in the SMART platform and exposing the SMART platform on FHIR.

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

So one of the things, and Arien and David, this is an assignment, you've got to get back to me with this, just make that part of the minutes Michelle. We've been tracking FHIR. There are two people in the world who knew about how to do this a year ago, and it's rapidly growing. Problem is, of course, they were separated by 16 hour differences, one in Australia and one in England. And there is tremendous interest in this, but I need advice about how to accelerate this process because I think there is a lack of pilots, I think there's a lack of resources, in terms of trying to get this stabilized. Because they're going to kind of swing back and forth between sort of two RIM-like kinds of things, the things that are going to be more the 80/20 rule and I see a lot of that happening.

I would love to figure out a way to accelerate this process. And so I am interested to see what people can do, because there are a lot of little one-offs that I've approached the FHIR team and said, we'd love to do "X," "Y" and "Z." And I've gotten pushback to say, well, we don't have the time, we don't have the resources, we don't have the way to be able to be responsive. So, and David, you don't have to respond right now, okay. This is a homework assignment.

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

I've done my homework.

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

Is it helpful that we would get vendors engaged in this in a substantive way to kind of make this happen around a specific use case? I don't know how to – I can certainly help to facilitate that, but, if what we're hearing, and John has said this and Arien has said this and David has said this and I've heard lots of other people say, FHIR is the thing to happen. But when I ask people, when is this going to be ready for us to be able to start pushing this as a national strategy or the like, people are saying, it's going to take us some time, and we're not talking weeks to months, we're talking more like months to years. Not ten years, but there's a fundamental shift that's happening.

So I need to understand, around this group, how can we accelerate this, because we can only do so much, I think, from a government perspective. And if what you're saying is that we should drive what we do because there's exchange happening, that people are demanding this because it solves a use case, and we don't have people at the table saying, this is the thing that will solve my problem. And we need to drive it forward, I'm left in a quandary because we need to get there, but I'm not sure that all the folks there are necessarily pushing it forward in the organizations in which it needs to occur. So help me understand how best to do that, because I think that's an important thing that I'd love to accelerate, but we have to get alignment that says, if this is about exchange that's already happening that's going to drive the adoption of standards. And we're not going to work on stuff that hasn't been implemented, then we need the folks that are interested in implementing this driving the bus, if you will, to make sure that it happens.

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

Just to clarify, I think you meant Ken Mandel?

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

No, Josh, Josh.

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

Josh is SMART.

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

Because Ken and Zack –

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

(Indiscernible)

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

So there's a Josh Mandel, but I don't know him.

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

He's umm –

**M**

They must be brothers.

**M**

John, that's Mandel –

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

– with an “E,” Ken has no “E” between the “D” and “L.”

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

Okay.

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

And he is phenomenal.

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

He's a superstar. Yup.

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

Leslie?

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

So there's this little thing on there called advance directives and perhaps that could be a use case that we've adopted for some of this newer technology, especially around either APIs or services. Because this is a problem that folks are trying to figure out how to solve and we're talking about having, as you know, right now the menu item is you have an advanced directive, yes or no. But going forward, how do we find the most current advanced directive? Who has it? It's not – it's a conundrum, one that's worth solving. So I would just offer that up and since we look at use cases for some of these more advanced things, why not do a really important thing well.

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

And a quick question for you Leslie. Is advanced directives the right title for that?

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

No, it's probably advanced directives, MOSLT/POLST, it's really care planning, but it's more around patient specific, patient-directed care planning. So we have not been able to come up with a name, we've tried several different times.

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

Because as you say, as I speak publically, I say the term advanced directives standardization, they say, oh, well how about physician orders for life-sustaining treatment or care preferences or something like that.

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

Right. So – and generally when people think of an advanced directive, they think of it as a document that has to be found, maintained and know which the current one is. When they talk about POLST it's actually an order set or MOLST is an order set saved and applicable to multiple locations. So they could be two different technical solutions. But right now, it's just pretty much a crying shame that we cannot find and have documents easily found that a patient has put a lot of thought into and it's very important for that patient's quality of life.

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

So, let me just ask Leslie. What do you think would be the incremental path? I've heard everything from there just needs to be a check-box that says there's the existence of something and here's the link to get to it. All the way to having sort of this notion of almost computable representations of what those advanced directives might be. So, part of the thing that would be helpful –

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

Um hmm.

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

– is what's the next incremental step? Do we make this part of Blue Button? Do we make this part of a content specification? Or do we make this part of a, here's a checkbox and a link to where you might be able to find it, even if it's a phone number.

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

We've talked to – we've talked about all of those and felt that the initial first set might be that link, where do we find it. But that's very difficult in itself and ambiguous, where is it? Is it a phone call? Is it a document? Is it a hyperlink? Is it – where do we get it? I think there's still a lot of discussion about that. The highly computable is somewhat desired, but most would say that the most important thing is a conversation that happens as a result or a conversation that happens with the patient as a result of having the advanced directive or knowing where that direction is. So it might be premature to have regulation around standing order sets. But right now we don't know how to find it where it is, is the approach just really a link? If it is, we shouldn't be so prescriptive as to say, boy that's a hyperlink or boy that's a phone number, what is a link? And we don't have a way to persist a link and maybe these newer technologies that we're talking about could help with the advanced directive problem. And so instead of an incremental step that gets us doing something perhaps poorly longer, what could we do to say, let's leapfrog, go to something new in a use case. This is very important, high cost, high value area could be addressed

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

I've talked in this committee about my father's death seven months ago and it wasn't so much that it was structured data and a vocabulary control, in transportable form. The fact it was written down and available, that certainly would have made a great help across multiple caregivers. I think we have Wes and then we have Dixie.

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

Okay, just a quick anecdote on advanced directive, a member of my family is a nurse, wrote out a very careful advanced directive. Her husband passed away, she didn't update it, she went into ICU, her son was asked for the advanced directive, it was in a safe deposit box that only she could access. So, we still haven't seen the advanced directive. I want to respond a little bit to what Doug said about FHIR because I almost think that we may be – we may inadvertently be the kiss of death for FHIR. There's another standards effort well intended, and I'm not going to name it on the public record, but I feel the involvement of that one was the kiss of death for that standards effort because it brought in federal government agency requirements that were so complex, it tripled the complexity of the work of that group.

And there is a, I don't want to say a negotiation, but there's more willingness to accept as is standards that are operational, in use somewhere rather than try to change it to specific requirements that inevitably become more complex. And I'd like to see us avoid having that impact on FHIR. To the extent there are ways to enable it, to create pilots, to create use cases, to – I think that would be a productive use by the federal government. But I am concerned that we're in a dilemma, we don't want to see something other than FHIR taken as an ad hoc approach to all APIs going forward. And we have the danger of running over it with a steamroller.

I – in the general area of APIs and requiring them, I think we have to recognize a specific balance point we're going to have to maintain, which is that in various sessions of this committee and the Policy Committee and in various regulations, we increasingly put the EHR vendors on the line for usability and safety. And then tell them they have to integrate all of these other products into their products. I mean, there's a fundamental conflict there that needs to be addressed by things like smart selection of the API. And I will argue that we're much more interested in interfaces around the edges of an EHR product than we are about fundamentally restructuring an EHR product where somebody could use one vendor's clinical documentation or another vendors order entry or something like that. And yet when you go out there and talk about APIs, until you've set constrained goals, there's the danger that we will put ourselves in and a vendor in a situation where we create a proposed regulation, it gets out there, it gets for comment, we find out we've jeopardizes safety or usability by it. So I think we need to careful on how we approach APIs.

Second, I appreciated your list of the five fundamentals and frankly, I had no idea what you were talking about when you started that discussion, so, it was very helpful. I will say that I think it was number three was security, is that right?

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

Four.

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

Four is security, okay. I think that that is one of those terms that implies different things to different people. And if there was one thing I could say would be to replace security with trust at scale. Because I believe the issues are as much about – well, just for example. The whole – all the discussion we had over Direct over the last three years. There were other ways to do things that depended on organizations springing up to provide services to make trust at scale and one of the things about Direct was to minimize the reliance on these third party, would they be a government contractor with a monopoly, would it be competitive and so forth. And I think that as we look at issues of security, it's not only about what encryption do use over the wire and how do you – and what kind of certificate do you use? It's about trust at scale. I think there's been great work done in that area, but as you look at each new area, trust at scale comes up again.

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

Thank you. Dixie?

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Yeah. Regarding digital signatures, just to bring this group up-to-date. Subsequent to when we heard – met with CMS, the Privacy and Security Workgroup held a meeting with CMS and we invited the Clinical Operations Workgroup, they were there as well. And CMS seemed to have softened the message quite considerably since they presented to this group. But it wasn't clear what the ONC wanted the Privacy and Security Workgroup to do at that point, so it's just sitting there.

But aside from that, I assigned a high to the digital signature category because I think that there's an immediate need for providers to be able to sign all sorts of things, including downloads to consumers and transmissions to third parties named by the consumers. But this is very different from what CMS use of digital signature was that they presented with this group. So I think that there's a real need for standards for digitally signing EHR downloads to consumers, transmissions to named third parties and assorted other exchanges of EHR data, anywhere where confidentiality, integrity and authenticity are important. So I'd like to see ONC separate the digital signature category apart from what CMS is doing.

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

Very good.

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

I'm going to take as an action item to get back with Joy around the Privacy and Security Workgroup, so that we can make sure that they're charged with things that would be helpful to ONC to advance the conversation. And we'll have the conversation about sort of separating the things that need to be signed from the specific use cases that CMS has proposed.

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**

Yeah.

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

Thank you.

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**

Thank you.

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

So we have 15 minutes left, two more slides. So just Doug, a very quick question before we move on to the next slide, and you may not want to answer this. But under CDS you've had a lot of experience with Health eDecisions. Do you have any comment for us about say the difference in difficulty of representing knowledge versus the notion of query and response of a distant knowledge repository ?

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

I should actually refer to the Acting National Coordinator about some of those activities, on the edge of my seat, waiting for you to respond.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

I see.

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

So this is the time where I don't respond actually, John. I think to sort of David's point and sort of some of the other conversations that we've had, having the ability to share information in not necessarily an executable way, but in one that is parsimonious and explicit is a useful thing. And that's kind of use case number one. Because we think that that's going to make it easier for us to both disseminate best practices as well as lower the cost of sort of hard coding a lot of the things and the complexity of some of this – of the quality measures.

I think use case two is actually a very nice one that sort of offers clinical decision support as a service, if you will. So when we think about APIs, this is one and you can note it, that this notion of an API for query response – resources, it's that sort of clinical decision support as a service. So rather than trying to disseminate the knowledge, send the data, here's what I know about the patient's vaccination history, for example, and here is the recommended vaccination schedule based on the information that you've provided. So I think both use cases are important. I think both use cases provide some value, but they serve very different needs and very different models, if you will. And I think it's one of those things that we talked about with regard to API is, where can we find the low hanging fruit that nicely packages meaning, structure, transport and security into a function that here's a way to ask a question and get a response. And so we've worked on both of these.

To me perhaps the most important thing was a comment, I don't remember who said it, was it Jeremy? Maybe it was Jeremy, someone over on this side, I think said it, that in fact as soon as – no, it was Arien.

[\[Note that it was actually Floyd Eisenberg who said this\]](#) As soon as you start talking about quality measurement you've kind of commit down a path of a whole series of other kind of related standards. So if you have one thing that's high and one thing that's low, but they are interdependent, we need to sort of think about those as a package. And I think CDS fits into the quality improvement package and if that's something that's high, I think it automatically raises or elevates the bar for some of the other things that are out there.

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

It turns out that in Massachusetts we have not been able to represent knowledge, but we have been able to implement multiple hosted in the cloud, knowledge services for real-time decision support. So, that's sort of our experience on the fringe. David?

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

Well I, and I think that that second use case is probably more likely to be successful than the first use case, but I think there's a third use case that's I bet in the long run is the most likely, which is essentially pluggable user experience from a decision support service in the cloud. So you need a combination of a pluggable UX, call it SMART platform as a placeholder or something that's like SMART platform, and some kind of an API to move core data structures back and forth between that pluggable experience, call it FHIR with an appropriate profile. If you do that, you can solve an immense number of complicated decision support problems that would not be amenable to either use case one, which most of the vendors have already done for the simple things, or use case two, which it's hard to imagine sending enough data so that the service doesn't ever need to ask for more data. And if it doesn't have a UX, it can't ask for more data.

So I think use case three, a visual pluggable, invocable either by triggers or on demand, like a CDC hosted immunization catch up wizard that lets you navigate through the choices to get your patient caught up with immunization according to their constraints and religious beliefs, etcetera, which is a really complicated service. You couldn't make that any other way, I don't think. So I think use case three is where the excitement will be once we get around to defining it.

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

So, just include that, both Arien and David, on your homework assignment, so when we're thinking about FHIR, what is the thing we're going to work on? I want you guys to get together and I want you to tell me what your opinion is, and we'll send it out to this group and they can kind of beat on it a bit. But –

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

Happy to do that.

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

That, I think, is the thing that we need to kind of get some clarity on.

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

So let me clarify for the record, it was actually option three that we have successfully implemented, because there's branching logic within the thing you call – but then it returns at the end of the process, a favorable response to – Arien?

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

I just want to follow up on that one and also on plan of care. So I have heard more times than I can count I think, over the last two months, from payers, pharmacies, technology providers that say, I've got this knowledge about the patient already. Or to David's case, I've got this knowledge about, for example, utilization management that nobody else has and if only I could plug that into the EHR, things would go well. And there's the case here around getting a focused gap or integrating a decision support module with UX into an EHR that has some legs. There's a bunch of people who would just love, and maybe there's a – problem, who would love to tell the provider, and already trying to tell the provider, you've got an adherence problem or you've got a gap in care that we're going to measure you by. And we already know about it because we already have the data. Or, to go back to David's – you could actually check yourself off because there's an exclusion for this patient and we won't bother you about it again. So there's something there that has some legs in it and has some overlap with the plan of care work.

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

Now Jacob had a comment.

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

I actu – so now I have to wanted “I already have the data, except for the data I didn’t have and I think that I have all the data, but I actually don’t,” and therefore that’s part of the problem is that we get spammed. Now I’m putting my stethoscope on, we get spammed by payers who think they have the data, but they actually don’t and our patients don’t actually have the gaps that they think they have. And this is why we ignore the guidance that they give us. Add to your homework David, a more explicit expression of use case three, because I didn’t quite get the difference between use case two and use case three, and would like very much to understand that.

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

Be happy to.

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

Great. Floyd?

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

First of all, I’d like to strongly support use case three because I agree and use case two, there’s always missing data you don’t know and it has to ask you again for something that you didn’t know to send up front. But, use case one, I think, has an additional value that hasn’t been mentioned and those who are trying to describe what they’re looking for, by forcing them to indicate the – and disambiguate what they’re asking is really important. Because many folks who think they’re getting to what you need in a guideline in decision support, just aren’t there. I just completed part of a commercial project looking at an HeD rule and thinking that through and going back and forth with client. It was really important that they understood, you need more specificity here. So I think use case one is very important.

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

Yeah, and my caveat about use case one was, for purposes of clarifying the specification, absolutely and for executability, maybe not.

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

And I agree fully, but to specify it clearly is –

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

Yeah, I don’t know that the VMR is the right way to do that, it’s untested at any scale. But –

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

I don’t disagree.

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

– it might be.

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

It turns out I’m using use case three to solve some of my ICD-10 problems, because a doctor types, heart failure and then it’s an app in the cloud that says, do you mean systolic – oh, systolic? Do you mean acute or chronic? And there’s multiple branching logic in the background to return that favorable response, but it’s all done in the context of a cloud based API that I call.

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

That’s why use case one uses value sets, but yes, I agree.

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

And I’m just coupling that to an HTML visual that’s pluggable.

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

Right, exactly. That’s what it actually it is, HTML.

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

So I'm going to move along because we've got like, I don't know, 30 seconds for the next –

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

No, come on, we have eight minutes, let's go ahead. Let's go to the next slide. The next ones are straightforward, no –

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

Yes, just like this one.

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

Next, if we can get to the next slide.

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

Lab orders, digital signatures, terminology. We didn't talk a lot about parsing and record sharing, but this is maybe an API kind of conversation that that would fit into. Advanced directives, API and CDS, I think we've covered all of that stuff. Now we've got three on this, defect reporting, registry support/SDC, query response of provider directories and patient identity.

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

So let me start with some very brief comments. So defect reporting, I know Doug you and I have had this discussion before. We have actually use – we have a PSO at Harvard and we have an incident reporting system that's commonly used across a lot of the Harvard hospitals called RL Solutions. And we believe that having a common format for electronic reporting from an incident reporting system to a PSO is a great thing. The challenge is does the EHR technology actually have the data elements necessary to actually complete a description of the defect in the case? And that's where, this is an interesting issue. Where does this standard belong,? I think it's to the point that Arien made, if you're going to measure quality, I mean that might be not an EHR thing, it may be something else. Are there other comments on defect reporting?

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Agree.

**M**

There's a subset of defects which are defects or near misses caused or possibly caused by the EHR and technology. And so, I'm a little – this is a much larger discussion. But I wouldn't push it up higher, I just think we could, if this committee itself wants to start talking about how to, in a routine, automated way, gather those near misses and misses that EHRs create?

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

And there's no question about – to the EHR, IT is fine. It's just, again when I look at the data elements that we report, a lot of them are not in the EHR itself. So, in fact, you'd be creating a mini-incident reporting system within the EHR and is that we're trying to do? Don't know.

Registry support. So today I support multiple registries. Oddly enough, I'm using CCDs and CCDAs over the Direct standard to push 5000 entries into a registry every day. And it's actually working really well. It's in production, it's the way we do PQRS and ACO reporting and everything else. The challenge is, that – you're a family doc, hey, the ophthalmologists, they say, well what I need is intraocular pressure and barometric pressure – every registry has some set of esoteric data elements in it that is slightly hard to generalize. And so, this gets – there's an interesting question, the scope of this one FHIR or some other content representation may work well for a generalizable set of templates, but how far do you extend the scope of this effort? Don't know.

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

This is Eric Rose, may I make one subjective comment there.

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

So Eric Rose, sorry, if you can speak up, we can't hear you.

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

So, I wonder if I could interject a comment there. Not that I know the answer to the question that I think it was John Halamka just posed, but I think we have a natural experiment with Stage 2 with the cancer registry requirements to maybe pull some organizations that have attempted to implement that and get their opinion. There were some interesting, unique aspects to that like the need to submit AJCC staging codes, which needed to be somehow pulled from the EHR and where those pre-coordinated into the problem fields in the EHR or where they appended as metadata, that can make a difference. So, I think that might be worth looking into to determine ~~when~~ when – how daunting that is and thus, influence its prioritization.

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

Very helpful. Thank you. And with regard to the query response of directories, I have to tell you – a Massachusetts thing. Dixie? We did all of them, so we have a DNS approach, an LDAP approach and a RESTful API approach, and it depends a bit on the architecture and use case, but we actually support all three formats for our provider directory query.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

It's what the Nationwide Health Information Network concluded, but it keeps coming back around to us.

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

And what's fascinating, as you said Eric, let the market decide. Well, so far we've seen exactly zero use of LDAP and DNS is actually used by some in pilots to retrieve certificates, and it doesn't work well. And the RESTful API approach works for everyone for everything. But anyway, that's a Massachusetts thing. Other comments on directories? Okay, you see, I told you we'd get through these. Next slide.

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

This is the last – we're not going to do the low priority because you've already told me that's –

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

But Dixie's already said, we've already done it.

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

And Dixie – yeah. So, query response consent management, data segmentation for privacy, clinical documentation for new payment models and local and targeted queries.

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

So real quick comment on the consent management side of things, Massachusetts had to develop a consent repository because we have an opt in consent to disclose. And we looked at ways in which the HL7 2.X standards could be used to transmit consent associated with an ADT transaction. We didn't really want to use a "Z" segment. We looked at multiple alternatives and the difference between 251 and 26 and then how you query it. So again, it was a bit like how we had to deal with the RLS, we ended up finding ourselves inventing a bit, trying to shoehorn existent standards into this bigger use case. It's probably necessary, however. Arien, comment?

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

Yeah, so for data segmentation for privacy, the trick here is cl – we've got a standard with very uncertain policy implications. You can code something, but it is hard for me to figure out what the EHR is supposed to do with the coding. In a paper-based world, for example, with segmented data, you could put a do not redistribute and stamp it on the file and put it in a folder. If you're requiring EHRs to get it into the record, but – and use it for decision support but not re-disclose, unless the patient tells you they can., but then later the patient comes in with the same data or you get it from a different source and you've suddenly built the need for a very complex rules engine in the EHR. If you don't clean up the policy requirements so that it's actionable by an EHR vendor, putting a standard out with uncertain interpretation is a bad thing and that's what I fear we've got right now, based on my review of that work.

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**

What about my comment?

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

And David.

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

I'll just – this is David, I'll pile on and say I agree as well. I think that the current paper world's policy is not implementable with the current – with any standard, it's just not suitable for the way we're doing EHR data. Because we're aggregating data. The whole point of the reconciliation is to tease the data elements out of their source and build an aggregated record. And if you do that with some subsets of the data there are restricted, but only under certain circumstances, and only for certain periods of time, for certain types of users, it's just unfeasible, it won't work.

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

So this is helpful, it sounds to me like that area of work that's required here it's not so much technical, but in fact, clarification around the policy aspects of this.

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

Yup.

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

So, that's helpful. That helps us know where to put some of our resources or how to guide the budget forward. Thank you.

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

So other comments on this page –

**W**

My comment is on the next one, clinical documentation for new payment models. From the limited results we're getting back on testing for ICD-10, we are seeing challenges with the clinical documentation supporting the coding. So I just want to say that's a – and I don't see a whole lot of emphasis on that, it's sort of more on the can we code, can we get paid, etcetera. But the clinical documentation side, I think, is going to be important to support going forward.

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

And again, certainly we're both in the trenches, the regulation originally assessing the impact of ICD-10 suggested that Beth Israel Deaconess should spend \$600,000 dollars and would achieve everything that was necessary. I'm now \$10 million dollars into the project and we're not quite done yet. So to your point, it's not the retrofitting of the financial and the clinical systems to hold an alphanumeric code that's seven characters long, it's re-engineering the clinical documentation processes to effectively support the code that you have to specify. So, that's hard work.

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

So John, to that point, is this a standards issue, is it an implementation issue, is it a guidance issue? I mean its – there are a lot of different factors to that. So the question I would raise is, if there's a challenge here that, at least as articulated, around ICD-10 and the documentation support that's necessary, what is the action that would help make things better?

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

Sure, so in our case we had to do de novo investigations, that probably many of you had to, and to computer assist in coding. I mean actually you're taking a multifactorial approach, which is, how do you have coders assist doctors? How do you have doctors specify codes from mapping and crosswalks? How does a computer make recommendations? What is the role of SNOMED versus ICD-10? Jacob and I had this conversation, we'd hope that SNOMED could inform the ICD-10 selection so that you would link the problem list, the documentation and the billing into one workflow. And we have yet to see products that really do that. So, boy, I guess guidance would certainly be helpful in this regard, because I feel like all of us are trying to solve the same problem. And if any of you have solved it completely, let me know. Good, okay. Well, so there we have it. There's a set of priorities but I think Doug and – we have a next step which is, we have some highs that there seems to be concurrence that those are important. We have a few of the mediums that have been highlighted as foundational. And it's teasing out now what goes from maybe medium to medium high and then figuring out a scope of work and how we can assign that to our workgroups and task forces.

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

And I will say, and this is directed to Keith, is that if you didn't submit your homework on time, we will accept late submissions, if you want to get that into the process. You will not be graded down at all, in fact, okay.

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

My alpaca ate my homework.

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

Totally – we should grade him down, you got to be tough.

**Keith Figlioi, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc**

No, no, B-.

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

(Indiscernible)

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

Let us turn it back to you, three minutes late, but in time for public comment.

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

What a marvelous discussion, thank you John for leading that and thanks to everyone for participating in it. I'm really excited about it because I was thinking about the prioritization list and in fact, through one lens, the priorities of high relate to some of the meaningful use requirements. Through another lens, there are priorities set that elevated during this conversation that has to do with fundamental capacity and innovation capacity as well. And it's really exciting to me because – and it feels a little bit like watching the transition from web 1.0 to 2.0, we're – there were certain things that were absolutely essential before 2.0 could proceed. In fact, that's the legacy of the past 52 meetings, a certain standards based that – and certainly the extraordinary work across the field by many, in terms of implementing.

And as we go forward, and clearly there's a set of activities that relate to this work of meaningful use specifically, but I think this last discussion really gave voice to the excitement around the capabilities development. That is something that I really look forward to continuing conversations on between this meeting and the next time we get together, we'll work with Jacob and Doug and team and come up with some assignments that seem logical for some of the continuing work that's necessary. Doug, just extraordinary presentation, I think MUSICO also was something that allows many outside of this room to visualize the relationships of the – capabilities and how they apply between entities.

Let me, before we close, turn to Jacob Reider, anything that you'd like to add in terms of closing words?

**Jacob Reider, MD – Chief Medical Officer – Office of the National Coordinator**

Unprepared but I think the terminology conversation toward the end, and as you described Jon, at our very beginning, reminds me that the standards conversation are really the Lego blocks of what we are aiming for. And I think what strikes me is that sometimes if you've been to Toys R Us lately, not that that's an endorsement, because our ethics officer is here today. If you've been to a toy store lately, you've noticed that you can't – it's hard to buy the Lego blocks of old, right. And so you can buy the Millennium Falcon Lego set which allows you to make the Millennium Falcon. They're very explicit about what you ought to build, and in fact, all of the pieces for exactly that are included in the box.

Some of what we've done through our certification criteria is gave you the Legos of old, and sometimes in our heads, we're Millennium Falcons. And what you're saying here is that sometimes those can't be build. So I think the SNOMED CT conversation, I can tell you that this group made recommendations to ONC and said hey, for capture of clinical documentation, clinical diagnoses, use SNOMED CT. And therefore, it landed in the regulation. And it was our hope, because NLM then created a mapping and provided a mapping from SNOMED CT in a very granular way, to equally granular, but perhaps not sufficiently, ICD-10 concepts.

And so these mappings exist and what I've heard is that, so we've got all the parts for the Millennium Falcon, but nobody's quite built it yet the way that we had imagined. It's interesting because we are often criticized for being too prescriptive, right, so we don't want to be too prescriptive. Yet we also need to provide some guidance regarding exactly what that Millennium Falcon looks like. I look to this group to also help us craft that picture, because I think because of the breadth of experience that this group has to offer, sometimes painting that picture is very helpful for the vendor community and also the implementation community to say, oh, this is the target we're aiming for. Because the – in some community hospital may or may not have that strategic vision that we assumed that they understood, but it's too implicit. I think we can do a better job of being more explicit about what targets we're aiming for as we march forward.

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

Thank you, Jacob. And again, thank you for taking the mantle of leadership. Michelle, the most important part of our day is always public comment, so let me invite you to –

**Public Comment**

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

So if there's anybody in the room that would like to make a public comment, please come up to the table. You will have three minutes for public comment. While we wait for people to go to the table, we can then turn it over to the operator and see if anybody has a public comment on the phone.

**Alan Merritt – Altarum Institute**

If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press \*1. Or if you're listening via your telephone, you may press \*1 at this time to be entered into the queue.

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

It looks like we have no public comment at this time. Thank you everyone.

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

Thank you Michelle and let me just add thanks to the entire ONC team, Jodi and Doug and Jacob and our colleagues, Michelle Consolazio, thank you very much for your help and support. And to all the members of the committee, great meeting and great discussion. Look forward – actually, any guidance for the next time Michelle?

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

Our next meeting will be virtual, it's December 18, so close to the Christmas Holiday. So, virtual meeting.

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

Great, well, I'm sure the virtuality is appreciated, particularly as ONC lives up to the Office of no Christmas moniker of old. We stand adjourned. Thanks all so very, very much.