



## HIT Standards Committee Final Transcript September 10, 2014

### Presentation

#### Operator

All lines bridged with the public.

#### Attendance (See Below)

#### Michelle Consolazio, MPA – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee; this is the 61<sup>st</sup> meeting of the Health IT Standards Committee. This is a public call and there will be time for public comment at the end of the call. As reminder, please state your name before speaking as the meeting is being transcribed and recorded. Also as a reminder, we will have time for public comment at the end of today's meeting that will be limited to 3 minutes. And if you are Tweeting, the hashtag for today's meeting is #HITSC. And with that, I will now take roll. Jacob Reider?

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

Present.

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

Hi, Jacob. John Halamka?

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

I am here.

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

Hi, John. Andy Wiesenthal? Anne Castro?

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

I am here.

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

Hi, Anne. Anne LeMaistre?

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

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, Anne. Arien Malec?

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

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, Arien. Martin Harris?

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

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Good morning. Charles Romine?

**Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology**  
Kevin Brady for Charles Romine.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, Kevin. Cris Ross?

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**  
I am here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, Cris. David McCallie?

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

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, David. Dixie Baker?

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates**  
I am here.

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

Hi, Dixie. Liz Johnson?

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

I am here.

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

Hi, Liz. Eric Rose?

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

Here.

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

Hi, Eric. Floyd Eisenberg? Jamie Ferguson?

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

Here, good morning.

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

Hi, Jamie. Jeremy Delinsky? John Derr?

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

Here.

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

Hi, John. Jon Perlin? Keith Figlioli? Kim Nolen?

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

Hi, Michelle, I am here.

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

Hi, Kim. Leslie Kelly Hall?

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

Hi, Michelle, Leslie is here.

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

Hi, Leslie. Lisa Gallagher?

**Lisa Gallagher, BSEE, CISM, CPHIMS - Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

Here.

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

Hi, Lisa. Lorraine Doo?

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

Yes, I am here.

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

Hi, Lorraine. Nancy Orvis?

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

Hi there.

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

Hi, Nancy. Becky Kush?

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

Here, I am here.

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

Hi, Becky. Sharon Terry?

**Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance**

I am here.

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

Hi, Sharon. Stan Huff?

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

Here.

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

Hi, Stan. Steve Brown?

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

Here.

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

Hi, Steve. And Wes Rishel? So we have pretty good attendance today, it should be a good meeting. And so if everyone who is not speaking, if you could please mute your line and I will turn it over to Jacob for a few comments.

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

Thank you, Michelle and welcome everyone to the Health IT Standards Committee meeting. As you recall, and I'm sorry for being redundant, this is the Federal Advisory Committee that advises the Department of Health and Human Services on standards and certification criteria for health information technology. This is not the Meaningful Use Standards Committee, although the Meaningful Use Incentive Programs have been a core focus of the work that this group has done for the last say four and a half, five years.

So we want to just remind everybody who is both present on the phone and members of the Committee and the public that the work we do has a broader scope than one incentive program from the Centers for Medicare and Medicaid Services. And that the work that we do may very well be leveraged by other programs both from CMS and elsewhere. And so we need to think about the work that we are doing in that context, a very broad context, rather than just the context of Meaningful Use Stage I, 2, 3 or "N."

So, in light of that, I would like to call everybody's attention to something that happened this morning. And if you have not been following the tweets and blog posts yet, you don't know that the Office of Federal Register today published the 2014 Release 2 Final Rule from the Office of the National Coordinator that expresses our second release of the 2014 Standards and Certification Criteria. Later in our program today, Mike Lipinski and Steve Posnack will do a short summary and answer questions about what that rule is, but I did not want to take folks by surprise that an addition to the agenda for this morning. And wanted folks to know about it.

We think that this regulation responds well to the comment...public comments that we received in response to the Proposed Rule that was published last winter. We are thinking of this as something that offers both flexibility and represents gradual rulemaking in the sense that it solves a problem of surprising the industry with, to use a medical term, a bolus of new regulations every say, 24 months. So we are expressing our future intent in terms of where we expect regulations to go and also providing a gradual approach to the iterations of how the standards and certification criteria are to be expressed by the government and to be understood by the industry.

So, without any additional delay, I will pass the baton on to John for remarks...his remarks and review of the agenda. John?

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

Great, well thanks very much Jacob. So when you look at today's agenda, there are multiple component parts that fit together extraordinarily well they are very complementary. We are going to start-off with

some recommendations from Dixie Baker and David McCallie on NwHIN Power Team query recommendations. And what they will present to you, of course in exhaustive detail, is the challenge that we all know that if we are going to get from push of data from point A to point B to a more comprehensive pull of data that there is a variety of novel standards and infrastructure required. But although, as the Jacob absolutely said, this is not the Meaningful Use Committee in any way, there is the reality of certain timelines for the Meaningful Use Program. And so of course our challenge is, how do we do what is right for interoperability while at the same time paying attention to some of the timelines that do exist for Meaningful Use and try to align those, too. So I think what you will hear from Dixie and David is actually a remarkable set of proposals that does not constrain us to an artificial transition point in the interest of Meaningful Use timeframes. It suggests a trajectory going forward that gets us to where we need to be but offers enough specificity along the way so that if certification criteria do need to be developed for 2017, they can be without creating wasted work.

So, that set of recommendations in many ways is very foundational to what we will hear about from the JASON report out. I am skipping the Steve Posnack and Mike Lipinski for a moment just to talk about the JASON report out. The JASON group makes a number of conclusions about interoperability and gaps in interoperability. So, listen to what Dixie and David have to say and also what Micky and David have to say because they are two sides of the same coin. How do we enumerate the interoperability of the future and the trajectory to get us there? And how do we avoid over specifying architecture, but at the same time, provide a set of standards that are going to be foundational.

So, a lot of common themes in those two presentations, especially as we think of the future that involves APIs, FHIR, OAuth, REST and moves us from just what is today document centric push via Direct to pull and patient record location services and novel ways to build trust fabrics. So, two very exciting presentations that are the bulk of our agenda.

Now St...as said by Jacob, Steve Posnack and Mike Lipinski will tell us about the data provenance and S&I activities and then brief us on the Final Rule, which Jacob, I have just had the opportunity to review the set of skinnied down proposals. And I do think that the group will appreciate the effort you have put in to move us forward, provide additional trajectory information, but not create such an exhaustive list that the industry will have a problem with voluntary certification. So your scope looks very good, look forward to that further discussion.

And then, if as a group you remember that we charged NCPDP with helping us understand what current processes, standards and projects exist for the real-time benefit check, so that if I as a patient want to get a medication at the point of prescribing, do I understand what my options are? What formulary is? What costs are? What are the likely consequences of my choosing a specific therapy versus another? And we know that in ePrescribing today, there are a number of gaps in the workflow so that you may not understand total cost until you arrive at the pharmacy and receive sticker shock. So, we will hear from NCPDP on all of the issues around the current ePrescribing standards and work in process.

So, as was said, the agenda has been extended to account for the release of the Federal Register this morning. But between the NwHIN Power Team, the JASON summary, the standards and technology updates from Steve Posnack and Mike Lipinski and the NCPDP Benefit-Check Task Group, I think we have one of the richest agendas of any recent Standards Committee meeting, so I look forward to it. I will turn it back to Jacob and to Michelle.

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

As a reminder, if you are not speaking can you please mute your line we have someone that is coughing; it would be appreciated if you could mute. Thank you.

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

Oh, and of course Michelle, I do believe there is the administrative task of approving the minutes.

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

Yes, thank you, John.

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

And those were circulated, so did anyone have any edits or amendments to the minutes from our last meeting? Well, none being heard Michelle, I think we have approval by consensus and we can move forward to NwHIN Power Team as you and Jacob decide appropriate.

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

Thanks, John, I'll...for those who don't have the googling skills that John has, there is a short link to the Rule and I will give that to folks on the phone. If you are interested, it is M as in Michael, D as in dog, L as in loser, K as in king, MDLK.US/ all caps ONC2014R2...so that's a quick way for folks to get the reg if they want to. But please, don't read it until after the meeting so that we have your full attention for the duration of the meeting. And I will pass it on to Michelle and then Dixie and David.

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

Well, I am just going to pass it on to Dixie and David. So Dixie, if you are ready?

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

Yes, I am ready but I don't have any network connection, either Wi-Fi or direct hardwire connection to the Internet today. So, I will just tell you when to turn the slides and I will try to indicate which page I am on. I don't know exactly how the all of the Internet connections went out here, two different service providers and everything. So, I do believe in redundancy but sometimes even redundancy doesn't work.

All right, today the Nationwide Health Information Network Power Team is presenting its recommendations for query for patient record and this was the final task that was as...that the NwHIN Power Team will be addressing. So this is our last hurrah. So if you go to slide 2, please. The charge that we received from the HIT Policy Committee was to recommend standards to enable query functions within the context of the current certification authority of HITECH. So, would not require any further regulatory authority to enact or to include these query certification standards. And they wanted us to build on the market developments in both directed exchange and query exchange where directed exchange is...direct exchange is toward a particular provider...known provider.

The slide 3, please. The policy team recommendation...committee recommendation included two things; one is the capability to search for patient information. And secondly, that all certified EHR technology

would be able to respond to searches that...from queries that they receive from other organizations. Next slide, which is slide 4, please.

The NwHIN Power Team asked Micky Tripathi, who was the Chair of the Interoperability Workgroup of the Policy Committee to meet with us. And we had a very productive conversation with Micky; the purpose was to clarify what they were thinking, what they expected and what they hoped to get from us. So these next two slides summarize some of the most important points that we had in that conversation with Micky.

First was to have any impact on the market that we must have some query capability in Stage 3. And he emphasized that the objective was to enable query exchange not to dictate how the exchange worked. So there was a lot of emphasis in what they were looking for were functional requirements and not necessarily standards that could be adopted. But more emphasis on the functional capability than on exactly how on would go about doing it.

They also...he also emphasized that EHR systems should be able to delegate the query capability to a third party. So if a certified EHR system showed during certification, how it used a third party to do this query capability that should be acceptable. They emphasized that query need not be synchronous, so it doesn't have to be that you...a transactional type query, it can be a synchronistic query and that is what would be highly desired that is where we ultimately want to get to. But for Stage 3 it should, again, it should be a set of functional requirements and so it could be asynchronous as well. So it could be requesting...sending a request and then the receiver sends a response of versus a transactional type of interaction between two parties.

And there are no presumptions regarding orchestration. So that is more emphasis on we should not dictate how it is done, but rather what are the functional capabilities that are desired by...in the 2017 edition. Slide 5, please.

The...Micky stressed that it was...what they were looking for was the ability to both search for and respond to queries for patient clinical information. He emphasized we should leverage existing standards that are currently in...required for certification, such as Direct and the IHE XCA wherever possible. The...he mentioned that in their working group they talked about how responsibilities for identifying...for querying for identifying information for patient matching purposes and querying for clinical information could be assigned to different organizations. They need not be performed...be within the same organization.

And finally, he said that standards for content are an open question and they did not want to restrict the query to the consolidated clinical data architecture. They wanted to allow for other responses, such as a FHIR query for discrete data elements as well as query for documents. Next slide, number 6...slide 6.

The Power Team invited a presenter from the Data Access Framework, S&I Framework project, to present that Data Access Framework to us. And this is work that is currently under way, so it is not work that has been completed, but it is currently under way. We concluded that the focus was very broad and probably too broad for the 2017 timeframe. It included both query within an organization and query outside an organization and it also included non-directed query where you would send sort of a broadcast query for a multiple organizations to respond. And we felt that we really needed to focus, narrow that focus for the 2017 edition.

Because the DAF is currently in development, there is not strong vendor support for these emerging recommendations, as you might expect. And it was...what they talked to us about is quite complex because it requires that...it would require that each EHR support both SOAP-based and RESTful query response capabilities, because we could receive queries in either way.

The second thing we looked at is the XCA profile, the IHE XCA profile. That profile, as probably most of you know, is document oriented. It is complex to implement, as the Power Team has reported on that in previous...under previous tasks. And the fact that it is not only document oriented, but it is limited to documents that is what it is used for. It really has not been well received by providers due to the workflow constraints and it sometimes can be a cumbersome process of extracting structured data from the CDA received. And finally, it is network dependent in that various implementations are not always interoperable. Slide 7, please.

The last two things that we looked at as options or potential options, one was the Direct Protocol, which already is an EHR standard. And you know Direct, which is secure email, is asynchronous so there is no guarantee of a response. You can send somebody an email and request their data and you may or may not receive a response. And responses are limited to document attachments and text that might be in an email response.

And then the final one we looked at, and we had extensive discussion around, is the new HL7 FHIR standard that is currently in development. And everybody on the Power Team agreed that FHIR offers very high promise a standard capable of not only doing query for documents, but also query for discrete data elements, like to you have the lab report for David McCallie for last Tuesday? It is not yet a finalized standard, there is a lot of activity around FHIR right now, so a lot of people are working on it, but it is not a finalized standard and we also would need special profiles to be developed that have not been developed yet.

So it's...we finally concluded, and believe me, we went back and forth about this one, but we finally concluded that it is unlikely that FHIR will be fully ready for national adoption as a standard by 2017 edition, although we think that we possibly could have some subset that could be fast tracked, and we will have to see. But based on the criteria that the NwHIN Power Team developed with respect to specification's readiness to become national standards, we had to conclude that it is unlikely that FHIR would be ready for 2017, especially knowing the 2017 NPRM is currently under development.

So, slide 8. This is...we wanted to note some of the challenges that we see to really having a query capability in the 2017 edition. You have already heard that the last Standards Committee meeting, Cris and Liz presented the Interoperability Workgroup's recommendations around the need to improve the implementation guides for the consolidated CDA. And we agreed with that and we think those challenges are also challenges for query. We...just as they briefed, the CDA needs further content encoding and constraint standardization, especially for a query between organizations.

Transitions of care documents can become very large and cumbersome and we thought that there is a need for a template, a C-CDA template that is more concise, maybe one or two pages, that is just a snapshot summary of the current state of a patient. There needs for more widespread support for other simpler kinds of C-CDAs as well, like the discharge summary. And then there are issues around how C-CDAs are wrapped to be exchanged as attachments in Direct email. Slide 9.

We wanted to emphasize that there are additional challenges that are major challenges, but that were outside the scope of the task that had been assigned to us. Probably the most significant of these are trust issues that persist between...across networks between provider organizations, also certificate discovery. There is no standard patient identity discovery and validation of the patient identity and there is no standard for record locator services. So the recommendations we give today assume that the querier knows the name of the patient or an identifier for that patient and also knows places where that patient's data may be held. And then finally, there are impacts that are just simply unknown, such as the recommendations coming out around the JASON Task Force and also the ONC roadmap activity, both of which are currently under way.

Okay, slide 10, we start our recommendations and the rest of these slides that we will be going through are all our recommendations that the Power Team ultimately reached. We clearly showed through our many, many conversations about this that the certification criteria...the need for the certification criteria for query for this 2017 edition is not well aligned with the long-range desire to move to HL7 FHIR as the standard for querying for both documents and for discrete data elements. And assuming that query must be included in the 2017 edition, which is what the Policy Committee was telling us, we are trying to recommend in the recommendations that we'll go through, we're trying to recommend a "least regret" approach. So we really do not want to compel vendors to expend unnecessary time, effort and investment on the certification of what will ultimately turn out to be a temporary approach.

First of all, we recommend that the scope of the use cases for query for the 2017 edition be limited to query of a named external healthcare organization for a document containing a specific patient's data. So that statement captures three points that I have attempted to make. One is, we are really targeting query of a known external healthcare organization for a known patient and thirdly, that we are limited this limiting it to document query, query for documents. And we also recommend that it be limited to the ability to respond to a query for a requested document or whether it be with that document or with a list of documents that may be the ones that the querier is asking for and that the 2017 edition allow for both synchronous and asynchronous queries. Slide 12.

For certification in the 2017 edition, we recommend including as the Policy Committee suggested, we recommended including functional requirements as certification criteria and allow vendors to provide documentation attesting to how their technology provides these functions. In other words, we are recommending that these functional requirements not be tested specifically as part of certification, but rather that the vendors be allowed to describe how they meet the query criteria. And recall that this is part of our strategy recommending the least re...course of least regret, we don't want to force vendors to really invest heavily in time and effort in something that might be a temporary solution.

We think the focus...the ONC really should focus primary efforts on the "low regret" activities that are well aligned with moving the industry in the direction of broad use of RESTful, FHIR-based services including, but not limited to, services that support query for both documents and query for discrete data elements. We believe that this...what we are asking for here is the simple query of a known external entity for a document containing an identified patient's information which could be achievable in a number of ways including using existing EHR certification standards, emerging standards, perhaps even including FHIR or membership in a query organization. So there are a number of ways that they could meet this kind of a criterion. Next slide, please, 13.

Slide 13 includes...this is the list of the functional requirements that we think would be appropriate for 2017. We believe that certified EHR technology should have attested to having the automated capability

that enables participation in the following query conversation. And so we don't want to dictate how it is done, but we want the functionality to enable them to participate as both the querier and a responder.

The requester would generate and address to a trusted and known external end point, a query requesting a document containing clinical data for an identified patient. And then the responder would, in response to a query, would return a list of available documents that contain the requested information or the requested information. And then the...if the provider doesn't hold any information for the patient, they would return some response indicating that the requested data are not available. Then the requester would have the capability to given...having received this list of documents, the capability to select the identifier for the desired document and then the responder would produce that document. So it is a pretty simple set of functional requirements. Again, no intent to dictate how that is to be done, it could be done using a third party query organization or it could be done by the healthcare organization. Slide 14.

As a high priority, "low regret" activity for the near-term, we recommend fast tracking these improvements to Consolidated CDA implementation guidance that were recommended by the Implementation Working Group at our last Standards Committee meeting last month. We...specific improvements that are needed to facilitate query and selection of documents for clinically useful C-CDA documents include but not limited to, implementation specifications to support on-demand retrieval of a simple current summary. So, we don't believe that every C-CDA needs to be a complete transition of care type C-CDA, but rather some of these simpler summaries would be clinically useful. And also, specifications for complete longitudinal summary in addition to the current encounter by encounter documents. Next slide, please. Slide 15.

And I'm not sure that yours show these numbers, but slide 15, our fourth recommendation is to recommend strong support for the efforts to accelerate the development of FHIR-based services and FHIR profiles consistent with the recommendations of the JASON Task Force that you will hear about later today. So with that, David, would you like to add points that I may have missed, understated, or misstated?

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

This is David. No, I think we should just go straight to discussion, I would be anxious to hear what others have to say.

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

Me, too.

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

Well hey, if I could start the discussion. So one of the interesting aspects of what we have seen in the Stage 1 and Stage 2 rules are that proving optionality for public health transport, what you ended up with was public health entities saying, oh I want HTTPS, no I like STP, no I like Morse Code and smoke signals. This functional description turned out to create enough heterogeneity that it caused vendors quite a lot of consternation. So I wonder, is there thought to a subset of FHIR that could be rapidly accelerated, we all focus on it and look for that 2017 trajectory of having something very specific FHIR-based in place that is good enough to get us started in 2017?

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

Well the...our recommendation, just to emphasize this, our recommendation would allow for that, but it would not require that. It would say, if somebody comes up with a restricted profile of FHIR that could be used for query and implemented it such that they meet the functional requirement that would be one of the ways that they could meet the requirement. But I don't think, given...this is...my opinion is, given that the 2017 requirements are currently being written, the NPRM and is being written, that was emphasized at our last meeting, I think it would be a stretch to develop a profile and resource descriptions in time for...to make it a requirement. And to make it consistent with the NWHIN Power Team's recommendations for readiness to become national standards.

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

And I think that is certainly a very good point, but what I also wonder is, there has been talk of decoupling certification scripts and development...test procedure development from regulation writing. And I only raise this as a devil's advocate, that's...I am not suggesting we do this, but obviously if there is any way to get to reduced optionality in the context of the framework you have described for 2017, of course that would be good.

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

Yes. No doubt.

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

John, the other...this is David. The other thing that we debated quite a bit around is the fact that interchange occurs in the context not only of a particular standard at the edge, but also in context of these networks that deal with governance and the legal, contractual and licensing issues. And that those issues are oftentimes just as complicated as the API issues and to focus too obsessively on a particular API is to distract from the broader set of problems, which are really hard to put in regulations around the broader network connectivity.

So, we thought that given the turmoil, and turmoil is the wrong word, but given the intense activity in the market as the demand for these kind of query capability is rising so much that it would be premature to lock it into certification. We anticipate that it is going to evolve dramatically over the next two to three years. So, I personally think that a subset of FHIR could evolve driven by vendor coalition efforts to address some of these issues and that would be something that we would love to see that happen. But we can't...we would not recommend that we try to lock it into a certification test, other than by attestation that you are actually achieving interchange according to these kinds of simple attainments.

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

Very good, thank you.

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

This is Jacob. Dixie and David, I have maybe a question that is similar to John's, just to make sure I understand exactly what is being asked of the committee here. So, there is a recommendation, I think, from the committee...from the Power Team that the Standards Committee make a recommendation to the National Coordinator that something be required for an upcoming iteration of certification requirements. But that something is what I am sort of grasping at.

From your presentation, Dixie, it looks like you are saying don't do X, Y and Z because X, Y and Z explicitly...such as FHIR, will not be ready in time. But I'm...so I think I have a good sense of what you are asking us not to do, but I don't have a clear sense aside from a very high level functional request, what you are recommending that be done. And along the lines of John's comment, if it is a very high-level functional expectation, doesn't that open the window to 99 ways of doing something and is that is the right way to go?

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

Yes, that's...Jacob, that's...I am glad you made that...gives us the opportunity to really stress this. No, we are not recommending that there be a requirement in the 2017 edition for query, that is not our...we are assuming that that is a requirement, because we were given the task and we are assuming, I think...well, one of the slides even says that, assuming that there must be a query requirement in the 2017 edition. I am not sure at all that we would recommend that there be a query requirement in the 2017 edition had we been asked that.

But we were asked that...to recommend standards for query capability and the Policy Committee told us that there must be a 2017, a requirement query in 2017. So, given that, and assuming that there must be a query requirement in the 2017 edition, our recommendations are to really focus on making FHIR ready as quickly as possible. But in the interim, since we have...have to have a requirement in the 2017 edition, that that requirement should be functional rather than forcing vendors to implement something they later need to tear out and redo.

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

Understood, thank you for that clarification.

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

Dixie and David, this is Cris.

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

Go ahead.

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

Quick question on, I think it was on slide 11 where you talked about the rules of the road on query and this discussion and proposal is just great. This may sound like a minor point, but it was that we would acquire, I think the language says for a record, implying perhaps a single patient record. I am wondering if you anticipated sort of batch kind of queries, particularly around perhaps a population health kind of viewpoints or around managing a cohort of patients. Is that anticipated by your proposal?

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

I don't recall any specific conversations, but it cer...this proposal certainly doesn't preclude that.

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

But Cris, to your...to the specific mandate that we were given by way of Micky's workgroup, it was really focused around targeted patient query, so a known patient, need to get data from some other place, go get that data from the other place. So as Dixie said, it would not preclude supporting more powerful capabilities but the particular question was around targeted query.

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

Yeah.

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

My guess is that those are...that in actual practice, those are going to be fairly different use cases and that the way the population style queries are done may be different than the workflow that makes it easy for a clinician to go fetch summary data from a recent encounter at a known hospital.

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

Yeah, actually I do recall when we had the briefing by the DAF team...

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

Yes.

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

...the DAF includes queries to support population health and that was one of the things that we thought was beyond the scope of our recommendation. So I would say our recommendation probably could accommodate querying for multiple patients, but not like a population, send me all your patients that came to the clinic in the last week.

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

Yeah, that is really helpful, that is exactly what I was asking for. So do you think that the population issue is one that you would return to at a future date?

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

Yes.

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

Okay, thank you.

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

This is Michelle. I just want to note that there are a number of people in the queue. So if we are ready, we will start with Stan Huff.

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

Yes, thank you. I think, as always, Dixie and Dave you have done a wonderful job in, I think, looking at what is reasonable and practical to do and I like all of the recommendations. One comment that I am sure you are aware of focusing specifically on the creation of FHIR profiles. We need to think about how we can coordinate that so that we don't end up with many different libraries of FHIR profiles that don't lead to interoperability.

So as things stand now, there is a process described and there are sets of people who are very interested in making FHIR profiles and some people making FHIR profiles. If...we need to find a way to coordinate that work without overly constraining it so that we don't end up with, if you will, sort of competing FHIR profiles from different sources that don't lead to true interoperability. And...so that is just a comment and a part of, I think, the reality of what we need to sort of pay attention to as we go forward. So, yeah.

And then I would also say, again just as a comment, I agree that there are things that we can do to fast track, I think you are exactly right that it is premature to try and say that we could do FHIR for everything by 2017. There...if we get to work on well-known areas that are the most advanced, for instance, sort of standard laboratory results or others, I think we could provide tremendous value and do that earlier. But again right now, it is premature to try and fix that and etch that in stone.

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

Yup.

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

So, I love what you have done here, I really appreciate it. Thanks.

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

Thank you, Stan. We had many conversations exactly li...people arguing even with themselves, just like you have iterated here. Because if you release any standard prematurely, you run the risk of really harming the adoption of that standard ultimately because you really want to...people kept, in our conversation, people kept emphasizing, we need to do it right, referring to FHIR. We don't want to really force it prematurely so that we end up really harming the implementation ultimately.

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

This is David. Just to pile on to that, I mean, we really have wrestled with this issue around how do you standardize in a rapidly evolving, technological space knowing that the decisions that you might make today, if they are quite specific, wouldn't really see widespread use for another 5 years, 4-5 years. And given the pace of technological change and the evolution of healthcare standards in particular, it is just painful to think of walking in on something today that wouldn't see widespread use in a certified space anyway, for another 4-5 years.

The world is just going to change dramatically during that time and we need the flexibility to try to keep up with how the market evolves and how these standards evolve, knowing full well that that is going to create some excessive optionality to the problems that we have run into in the past. It is just a trade-off that we've...our recommendation is to make that trade-off in favor of nimbleness, agility and flexibility, knowing that we will, in fact, create a few problems by doing so and that is just the best we can do.

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

Jamie Ferguson has a question.

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

Yes, hi. So I think...first, I would like to agree with the recommendations, but then there is also part of the presentation I want to disagree and take issue with and then I think I have something I want to ask for both the Power Team and ONC to consider.

So first, I agree completely with the long-term future direction for standardized FHIR profiles, but I also agree it is not likely to be ready for 2017 edition and I completely agree and am aligned with Stan Huff's comments on that.

For the disagreement, I think on slide 6, Dixie you mentioned that XCA is complex and not well received by providers, I really think that is false. Approximately 30% of US hospitals and over 10,000 physician medical groups are currently using XCA for query-based exchange today, serving approximately a hundred million Americans in production and so I don't think you can say that it is not widely adopted or not well received. And so I think because of this broad current adoption of XCA query, essentially the business case for change, really requires careful analysis for the timing and transition to a FHIR-based future. And so I really do think that XCA should be reconsidered as a supported option until a better transition plan can be figured out or devised. And I do think that that transition is likely to take more time and be more costly than you might expect.

And then, I guess, just a final note, I think that alignment with the Data Access Framework would be highly desirable and kind of echoing Cris Ross' comments on the more than one record or population-based query. Thanks.

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

I want to make sure we clarified that we are not excluding XCA at all. All of the vendors that currently use XCA for query I would expect them to meet this functional requirement using XCA. So we are not excluding it, but we are also not requiring that vendors who haven't implemented XCA implement it. So we want to make that clear.

And we do support a number of the capabilities that the DAF is implementing in its project...the project is implementing. I don't think...the part that I think we did not agree with is that we don't think vendors should be forced to support both SOAP-based and RESTful query responses. We really think that there should be a standard and that it be consistent. But clearly the DAF is addressing a broader scope than we think is...should be targeted for 2017 and that is what we were saying about DAF. We weren't being critical of DAF other than that and the fact that it required two different standards to support. And we were al...we also are not saying XCA cannot be used, but we just don't believe it should be made the standard for 2017.

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

This is David, just to agree with Dixie and Jamie, to agree that...or to clarify, absolutely there was an assumption in the group that the vast majority of people would meet this attestation requirement by using XCA. Because that is, in fact, standard in use by most of the networks that are emerging today. But we expect both those networks to be evolving fairly quickly and would hate to have everybody doing their certification tests in 2 years against XCA only and precluding vendor push and development to do better and more focused queries. So it's...XCA is the way most people will meet this, I think.

And the second point about XCA being cumbersome. Certainly, it is possible to deploy XCA in a way that is not cumbersome. But the feedback that the Implementation Workgroup got was that the current interpretation of the way people produce transition of care documents and the current workflows of some of the vendors makes it pretty difficult and pretty challenging to get simple answers to simple questions using the XCA approach. So it is possible to use it well, but I think maybe some additional work is needed on the creation of more clarity around maybe some new templates that could deal with huge documents that end up getting generated in some settings when what you really need is a quick one or two page summary. So, those recommendations are also kind of buried in our slides and they might have gotten missed.

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

Arien Malec?

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

Thank you. So obviously, I endorse and agree with these requisitions because I was part of the Workgroup. I just want to call out a couple of elements of the recommendation that maybe there hasn't been as much discussion of. First of all just to pull out one of the themes that we have been talking about, I think the recommendations are an effect of the questions that we were asked. And I have observed a number of times, and I think in many ways the JASON Report will be the two-punch for this one-punch; it will be the right hook for this left hook or what have you.

In this context, we were being asked a very specific question relative to certification for 2017. We have had, I think appropriately, fairly rigorous criteria for standards readiness relative to things that we include in universal certification criteria. And that if you proceed with that frame, you are going to hear us be very conservative in terms of standards readiness, looking for standards that are both at least relatively future proof, that is, not already past their time horizon and have broad adoption. I would comment, by the way, that XCA meets either of those criteria, there definitely is a single vendor network that is well established that uses XCA as its underlying technology. It's the technology we use in CommonWell.

I would note that in that experience, we discovered that most of the vendors actually didn't support XCA and they did support...they supported, for example, XDS but required some additional development work to get to XCA. So it met neither of those criteria in that lens. If you ask a different question, which is, how do you enable innovation over a longer time horizon, then I think you need to relax one of the constraints, which is certification requirements that apply to everybody.

Then the last point I want to make is, we haven't had as much discussion on the "low regret" activities that we recommended. But there are a set of activities that are required now, urgently, regarding Consolidated CDA and a set of activities that are required even in a FHIR-based transport, which is to better specify what you ask for and have better document metadata for the information that you ask for. So, we are trying to move the ball forward in these recommendations.

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

Thank you, Arien.

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

Anne LeMaistre?

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

Thank you for all the great work that you all did. And Arien beat me to the punch, I was actually wanting to endorse the "low regret" activities. The need, for instance, for that 1-2 page transition of care summary is great and would very much like to see that urgently moved forward.

But I also, and Dixie I appreciated your explanations and John and Jacob's questions, your response helped me understand the difficulty here. But also, I think it is our role to help push FHIR forward. So I

guess for you and David, I would be interested in hearing if we want to do this right, but we know we need to get it ready and get some traction, what do you recommend as the right timetable to move it?

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

This is David. I think that this will come up in the JASON Report later in the...our agenda today, so we might want to defer Anne's question until then, Anne, if that is okay with you? Because I think...

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

Oh, absolutely, yes, that's fine.

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

We will call that question out specifically, not that we are going to get an answer, but we...

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

Oh now David, come on.

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

And I would like to put in a plug for our criteria for determining when a standard is ready for...to become a national standard. I don't...I think the same criteria apply to FHIR. I do think, you can see that FHIR is getting very rapid adoption, so I think that those criteria will be...will still be the right criteria to use for determining when FHIR is ready and its profiles.

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

Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks for the great presentation. I have a couple of questions. First of all, I wonder if there is an opportunity in this "low regret" work to align with what we see going forward that will help patients specifically enter the ecosystem themselves. So that we can somewhat get a twofer and we can start to identify standards that will help patients directly involved in a way that doesn't create the rip out environment that you have described. So is there a possibility to align things like the patient-generated health data or any of the work that a patient will participate in? So that is one question.

And then, I don't know how to balance this idea of rip out because theoretically, if we name a standard in a future date, there is it ripping out, there is something that says when we are doing it now without a standard, now we have named a standard, we still have to do rework. So where is that fulcrum that says, this amount of work is realistic and that amount of work is not? I don't want us to be in a situation where we never named a standard because we are hesitant to ask for work to be redone, where we are actually planning for work to be redone. So that is the second question, how do you resolve that?

And then thirdly, just how do we make standards an informative go to? I hear so much work being done on FHIR and the promise of it and I don't want it to be caught in the chicken and egg situation. Again, where it is not quite ready for prime time, but it's not quite...and therefore it doesn't get used as an informative and go to strategy. Those are my three questions, thanks.

**David McCallie, Jr., MD – Senior Vice President, Medical Inform**

Hi, this is David...

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

(Indiscernible)...oh, I'm sorry.

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

No, go ahead.

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

No, that's okay.

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

So I think you could probably write a thesis on answering those questions, those are hard questions. I am not sure that this is, again, just maybe a little bit of this will come up in the FHIR discussion...I am sorry, in the JASON discussion which specifically the JASON recommendations address the consumer facing exposure of...services. So maybe we would defer that part of your question to a later discussion at the end of our call today.

On the question of when is a standard need to be redone, the rip out costs, I mean I think these are all just complicated trade-offs. There are some standards that are so stable and do their jobs so well and there's not a lot of innovation around them that people just accept them and use them and don't worry about it. And those are, in some ways, the best standards even though they may in fact use older technology, I mean, we are still using billing standards that were defined in the COBOL programming era and they work fine, tweak a little here and there, but nobody is too worried about that.

But in this highly...rapidly evolving world of population health and the realization that EHRs are just one node in a much more complex network of entities that are managing the health of a patient over much longer periods of time than a specific encounter, we just are anxious to avoid premature locking in on a limiting standard. Though that is, where our caution comes from is that this world is changing so fast around us it makes us really nervous to lock in prematurely.

One nice thing about FHIR and it will come up again in the conversation later, is by the separation of the core part of the standard from the profile of the data that is being sent over the standard, you can have the framework of FHIR in place and then evolve the profiles fairly easily. It is not magic, it is not automatic, but it is a lot easier than starting over, so that is one of the reasons that FHIR is appealing is because they have done a clever job of separating the profiles from the core standard, again not magic, but it is a step in the right direction. Dixie, I interrupted you.

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

I just wanted to clarify the rip out question and I...your answers were perfect for the other two, but the rip out. I think that what we are saying is that if you know that the industry is heading in a particular direction very rapidly and there is the kind of push behind FHIR that we see right now, we know the trajectory. And if knowing that trajectory, you step up and say well, because the trajectory won't get us there within 2017, let's make them...let's force vendors to implement something entirely different, that is irresponsible and that is the kind of rip out we are trying to avoid.

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

So Jacob, I wonder given that ONC has created such things as a 2014 Rev 2 rule and will next publish a 2015 rule and thereafter a 2017 rule, which may have rev 1, 2, 3 or 4. Is there a harmonious path

forward where we can, per the discussion that's been had, make a path of "least regret." Of course, we are going to enhance C-CDA, per the Implementation Workgroup, and get us a trajectory to FHIR without getting us derailed. But allowing some flexibility along the way, as Jamie has suggested, because we are going to have many bites at the apple with these yearly versioned rules.

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

Well, so, as my mom used to say John, don't make an ass out of you and me. Let's not assume the cadence of the rulemaking, in fact I think it would be of value and perhaps when Mike Lipinski and Steve Posnack discuss the 2014 R2 rule and the rationale for both calling it that and how ONC currently views a gradual rulemaking cadence to be of value. It would be interesting to hear what the Standards Committee would think about what we are doing and how we are doing it. And then, as you say, think about what might be a more gradual path toward success without thinking about this in a, I don't know, we'll use an SAT word, salutatory manner. Right, so it need not be giant steps where we have to stretch our legs too far to reach the next one, but what might be the iteration towards success that are more gradual that would be less onerous for the industry to stomach.

So, we have heard loud and clear that too frequent rulemaking is onerous, and yet too much rulemaking on a less frequent basis is also onerous. And so as you described, John, perhaps the next iteration of regulation is less onerous from a complexity and payload perspective and yet might be a little bit closer. Again, we will request Standards Committee's perspective on that and maybe that is all you are trying to say.

But I just want to caution folks against assuming that by putting out a 2014 R2 regulation that means that rulemaking will be annual. We said when we put out the NPRM that we were thinking about more frequent yet less significant rulemaking. And we are interested, we got a lot of feedback about that as folks will see, both from the presentation and when they take it home and read it, there is certainly less to this than was in the proposed rule and the next iteration we are obviously thinking about as we speak. So, did I answer your question, John?

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

Well, you did and so I raise this point, of course, in the interest of moving us forward. And what I wonder is, of course we will hear from Steve Posnack and Mike Lipinski and the Standards Committee will weigh in, that if the way out of this dilemma is that we take from David and Dixie certain guidelines like FHIR is the trajectory. We are working rapidly as is appropriate to achieve what we will call measurable standards maturity on FHIR is our goal. And that yet as Jamie said, XCA and other possibilities along the way would be allowed until there is sufficient maturity and a FHIR specification to make that a canonical specification and that we may not solve that trajectory today, but we can at least enumerate the principles of the trajectory.

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

Yeah I think that makes good sense and if the Standards Committee were to say next summer, gosh, this stuff is ready, ONC ought to put that into a regulation to solidify it, right. Because...so what a regulation then does is it makes it clear to everybody what the target is. So at some point, let's not assume that it needs to be too far in the future or let's not assume that it would be too near. And I think the Standards Committee has a lot of potential here to give ONC very clear recommendations for both what and when

and we need not assume that there is an explicit timeline. Because as we have said, the cadence of the Meaningful Use Incentive Program is an important factor, but not the only important factor in the cadence of how ONC releases its guidance to industry, which is instantiated in these regulations.

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

This is David, just one additional comment. I think that the cadence of the regulation is an important axis to think along. The...another axis that I don't think we have necessarily gotten figured out yet is where do you get input into the standard process or into the process that might lead to a certification regulation in a timely fashion? In other words, the cadence of generating the recommendations, in other words, how do you quickly reach consensus amongst the stakeholders that need to be present in the process of reaching consensus, so they have that kind of buy in?

And one route is through the standards development organizations themselves. The problem is their cadence is typically pretty slow, not saying it couldn't be sped up, but historically it is a deliberative process by design. We have had the S&I Framework, which in some cases, I think has worked really well and in other cases, has not worked well at all. And my guess is, that is more a function of who shows up for the meetings than it is any fault of the S&I process.

And then the question is, how do you get the right people to show up for the meetings? And that is a question of getting the vendors and the other stakeholders with really clear impression of why it matters and that devoting scarce and important resources to go to those meetings makes sense because it is going to have an impact on a particular well-defined regulatory cadence. We need to make sure we think of the whole process, it is not just that we need a new regulation every "x" month, we need the right regulation and that means the right participants with the right incentives to show up and participate. And I don't think we have that figured out yet in a reproducible way, I think we have instances where it worked quite well and instances where it has failed pretty badly.

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

And so Jacob, I wonder if we wrap up this discussion. Now, Michelle, are there others in the queue?

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

Eric Rose does have a question.

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

So, we will get to you Eric in just a second. If we just can say that ONC both has and will in the course of today's meeting, enumerate certain principles that will allow us to further consider timing and trajectory. But that we take the advice of David and Dixie as a set of principles that we will then continue to work on as a committee. Pushing a timeline, inventing that timeline so that it is both proceeding toward FHIR at a reasonable pace while not constraining other possibilities in the meantime when the standard is not mature, something of that nature.

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

I think that makes good sense and as David has been saying, I think we will hear more on this topic later in our day when David talks about the JASON Report.

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

So Eric, your comment.

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

Yeah, hi. So I think this is really creative thinking and trying to make the policy move things along and not bullocks' things up and I think that is very admirable. The one thing that I am not sure already crossed your mind, Dixie and David, is that a vendor might comply with the proposed requirement by instituting query functionality that does not conform to any published standard and only works for communication between their own...between the software applications that they manufacture. And so I wonder if one thing to consider is something along the lines of, if something other than a published standard is available...is used for the query functionality, then the technical specifications should be made public. So that any entity that wants to maintain a system that can receive and respond to a query is able to do so, so you don't end up in a situation where in a particular market doctor A is disadvantaged because she bought Acme's EMR that can only query Acme EMRs and there are no Acme EMRs in her community.

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

That is a really interesting observation. We...and believe it or not, of all the topics that we discussed, I don't think we discussed that one either.

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

Oh no, we did. We did, or at least I thought I did.

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

Okay, and what conclusion did we reach?

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

Well, I don't think we reached specific conclusions but one thing to consider is the difference between certification around published standards, which I think we all understand the role that plays versus on the other hand, incentive on how you use your system. So you could, in fact, create an incentive that says, your interchange...

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

Um hmm.

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

...if interchange is what you're creating the incentive around, has to be open-ended and interoperate with other vendors. That could be a part of the incentive measure and that may be a better way to get...to avoid closed networks in those cases where you care. You don't care about closed networks in every case, but in some cases where you really do care, you will create incentives that say it has to work broadly. So I think...keep in mind the distinction between what counts towards the incentive versus what is part of the certification.

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

Yeah, but the incentives are on the providers not on the vendors, you know...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation  
Well, but the providers will lean on their vendors and the vendors won't respond to the market if the vendor can't proceed in a market because their users can't achieve the incentive measure, the vendor will fix that.

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

Yeah, I just wanted you to clarify that.

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

No, good point. The other thing, and this will come up, as Jacob said, in the JASON discussion later, is I do think that this notion of public APIs, what the JASONs call public APIs, which we will discuss, will reduce the number of times when this becomes an issue. But, we will get to that later in the day.

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

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**

Well Jacob, we are behind schedule slightly, shall we thank these fine folks for that discussion and move forward?

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

And I want to apologize that I have to leave this meeting now. I have family visiting and they want to be entertained. So I regret that I will miss David's presentation about the JASON Report, but I will be sure to look at it a little later. Have a good meeting.

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

Well thanks you so much.

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

Thanks Dixie.

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

Okay. Well, so Michelle, do we next move forward with the Steve Posnack and Mike Lipinski presentation?

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

I think we're going to do...well, I don't know if Michelle and I coordinated all this well. I think we are going to do the data provenance spotlight first...

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

Okay.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

...if that's loaded. Nope...sorry, is someone advancing to it?

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

Caitlin and Lonnie, we need to go to the other deck. Yeah.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Yeah. Okay, so again, Steve Posnack here and I am joined with Johnathan Coleman, who is the initiative coordinator for this S&I Initiative. Jonathan, are you there?

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Yes, hi, good afternoon.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

So he and I didn't rehearse in person, but I think we can probably go through this pretty quickly. As many of you recall, Jacob led a discussion in June about the Standards Committee's interest in a number of the S&I initiatives and one of the ones that you all called out most frequently had to do with data provenance. So, I thought that we would begin and this may be a trend if folks like the idea, do some spotlight presentations during my, what appears to be regularly occurring presence on the agenda to go through some of the S&I initiatives as they continue to evolve and have worthwhile material to present. So before we got too far away from that June meeting, I thought it would be good for us to circle back and give more detail on the Data Provenance Initiative thus far. Next slide.

So, the question generally, why do we need data provenance standards? Healthcare providers needing confidence in the authenticity and integrity of the data that they receive, or that they send, or that they collect, that they get from patients. Especially bullet number 2, as discussed in terms of recent events and the current trends, the ever-expanding roles for individuals to contribute data to their health and their healthcare through the use of health IT. And then the third, which has been often discussed either as part of the JASON work or prior PCAST report. And this is a jargony term that we all use, right, the trend toward the atomizing or representing data at atomic levels and how provenance gets represented in that approach in particular Apps and certain context that may be included as one would look at a document structure. Next slide.

So this is the challenge statement that is represented from the community as part of the Data Provenance Initiative, the first one recognizing there have been and are continued efforts, international standards, that have been produced throughout the industry. There has not been a go to type of approach that the industry has adopted across the board and that is a challenge that faces us as we recognize the importance of having data provenance. And then also the variability in terms of health IT technologies and systems and software and services that are part of this ecosystem, whether it be

health information exchanges, electronic health records, personal health records among other different technologies that I think devices, many of you would throw in there as well. And how provenance could be problematic overall in terms of the data going forward. Next slide

So I am going to turn it over to Jonathan now to go...rip through, probably now at this point, the Initiative and use cases that they are currently considering and really the questions that the community is going to be answering over the course of this work.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Yeah, thank you, Steve and I will rip through this, so give you all a chance to catch up a little bit on the agenda. So the initiative purpose and goals, we are looking to establish a standardized way for capturing, retaining and exchanging the provenance of health information. And we think the S&I Initiative is going to be creating a number of artifacts, predominantly technical specifications to help us standardize data provenance at creation, so trying to address the point of origin question when information is exchanged and when data is integrated across multiple health information systems. And I have got a little bit more on that coming up in the next couple of slides.

The initiative is also going to establish and create guidance for handling data provenance in content standards. And we will also address questions about granularity, how deep should the provenance data go and what level should it be applied. And associated with that, establish the minimum set of data elements and vocabulary to help convey that in a standardized way. Next slide, please.

So the scope of the initiative is broad and the scope of the data provenance question is very broad. And so we have some questions on this slide and I am going to walk through these iteratively that we are posing to help us handle the bigger picture of what provenance is all about. And help the initiative get a handle on where to scope our efforts and where to focus in a way that can be most impactful to the community at large.

So the five questions that we have on the screen here are also on the following slides, so I am just going to jump forward to the next slide, please, and take these one at a time. So, the first question, when healthcare data is first created, what is the provenance information that should be created and persisted with it? So we know we have an information interchange as a pre-step of creating the data and the associated provenance information that goes along with that. And that is represented in this slide by the green box, which we are calling data source A. This could be a medical device, a PHR or an EHR system or some other system. Next slide, please.

So building on that, can a receiving system, which in this diagram is on the right-hand side in the gray box and it could be an EHR or a PHR, but can it understand and trust that provenance information that came from the data source? So we have various questions surrounding that particular seemingly straightforward interaction and gets into areas such as attestation and trust and authenticity and so on. So that in itself has raised lots of questions for us. Next slide, please.

The third question: do we need to know who touched it along the way? So if the answer to that is yes, what about if that intermediary or third party that touched it along the way is a pure transmitter, sort of akin to a conduit in HIPAA terms? Next slide, please.

And what if the receiving system then combines this information with data that it received from another source or third party? So how do we persist the provenance as it comes in for multiple sources? So you can see in the diagram now, and what we have tried to represent here is that the receiving system or the end point in this particular information interchange, contains data from source A with its associated provenance, potentially information about the route it took to get there, such as the transmitter information. And also, data from source B, the red box and the light blue transmitter information associated with that. So very quickly, this is starting to get complicated and it gets more complicated yet if we go to the next slide, please.

So in question number five now: when this multisource data is assembled and then sent to yet another system, so our gray box now has turned from being an end point to a start point in another information interchange. And we have a new end point or a new destination, which is the black box, how do we convey the provenance of the multiple data sources as well as for the system that is doing the assembly or aggregation of this multi-sourced data? And next slide, please.

And when the information is received at the new end point here, is this artifact or this data considered new data? And the final slide on this build up please. And what if the assembling system actually cherry picks from multiple sources or adds some new health information of its own rather than just simply aggregating everything that it had and sending it along the way?

So we can see from these five questions, though admittedly one of them is a multipart question that trying to understand the scope and depth and breadth of the provenance problem is actually quite challenging. And we have got a lot of work to do but we are well on our way, I think, in trying to understand where to go and how to get it done. And I think that this is going to be a multi-stepped or multi-phased project.

But if we go to the next slide please, I can proudly report that we have achieved consensus on the charter. So the initiative has set its initial goals and expectations. We are currently working on articulating the use cases, which will specify and define the functional requirements in a standards agnostic way, so that we can then move forward into harmonization and look at the potential standards that might be used to fulfill those requirements. The initiative did form a Tiger Team and has started working with HL7, they proposed a data provenance project in HL7 to create a document and implementation guide, which clarifies existing guidance on data provenance as specified in several different HL7 standards and artifacts. I think that might be the penultimate slide. Yeah, if we just move one slide forward.

This is the last slide in my particular portion of the deck and this is a summary of the S&I Framework phases. So you can see, we are still in discovery. We are developing the use case, as I mentioned and looking at risk issues, barriers and candidate standards is coming up. The community has already put forward candidate standards and I think we have about 15 provenance-related candidate standards so far that have been submitted for the community to take a look at. And as we move forward into implementation, we will harmonize the standards, develop the artifacts, the implementation guides and then look forward to piloting with one or more pilot ecosystems to actually test the validity and effectiveness of the implementation guides and other documents that we create.

So with that, I will pause, ask if there are any questions, and turn it back over to Steve and the committee. Thank you.

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

We have lots of questions in the queue. David McCallie...so, before we go to David, John, did you want to make any comments?

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

Not specifically, I mean, let's go ahead. I know this is a topic that many people have concerns about and so let's just make sure we hear the comments and make sure we understand and a go forward process.

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

So, this is David. Am I up Michelle?

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

You're up.

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

Okay, great. Thanks. So Johnathan, thanks for that nice concise summary. Boy, this is a space where you could get it really wrong or you could get it right and the challenge will be getting it right. You could make this so much more complicated than it needs to be. And if you tell me that there are 15 candidate standards that you are going to harmonize that makes me really nervous because just because something is out there as a candidate standard doesn't mean it is any good and I wish I knew more about what you are actually thinking of doing to give more specific input. And I will try to make a note to go and dive into the materials, but I just caution you that this is one that is really complicated and if you get it wrong, it could really hurt everybody. So, lots of pressure to get this one right. Not very helpful, but that is just my initial reaction.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Well thank you David, I appreciate that very much and agree wholeheartedly, this is of great deal of interest to many and of, I think, very high importance to many as well. As to your point about the number of candidate standards, so we are at the point in the process where we are still identifying the use case and specifying the actual functional requirements. And so while candidate standards are being proposed to the community, they are essentially being put in a list in a parking lot. And then once we have finalized the use case and actually have those functional requirements that we know we want to address within scope of the initiative, we will be able to look at the standards as being fit for that purpose.

And there are several standards evaluation criteria that we use that have been tweaked and used over the last several years that work quite well in helping us evaluate whether or not the standards are in fact fit for the use case. And it looks at various criteria including standards maturity, adoption and so on. So I would be glad to follow up with you off-line if need be to get into the evaluation of standards phase in a little bit more detail, but we are certainly not at that point yet because we have not finished developing the functional requirements.

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

And so that was very well said in that I know many folks who have emailed Jacob and I are concerned that we are jumping to a conclusion. But I think what you have said is there is a process, a requirements definition. We don't know precisely what problem we are solving. Is it data providence around FitBit data flowing to HealthKit? Is it patient-generated data that is structured provenance? Is it ePrescribing? Is it C-CDA? Is it HL7 251 lab provenance? Because the answer as to what standard is fit for purpose will be highly variable dependent upon requirements.

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

Yeah, and this is David, just a follow on. How do we get the Standards Committee more in the loop for refining the problem we are trying to solve rather than reacting six months from now to the solution of the wrong problem? What process can we get more in that loop somehow?

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Yeah David, this is Steve. I think I am hearing you ask that question of us or me...

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

Yes.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

...and that in part is why I wanted to bring this initiative in its early stages back to the Standards Committee first for this spotlight opportunity. And we can keep that in mind to have particular initiatives check in with the Standards Committee and report out and have some more bidirectional feedback as the initiatives go forward. So that we understand if there is a, and I put this in quotes with a hyphen, standards policy aspect of the work that you all feel collectively needs to be focused in a certain way, your input would certainly be welcome.

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

And maybe the new workgroups as well for more real-time feedback instead of having to wait three or four months.

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

So I would just say, we have heard this theme before that S&I is an extraordinary valuable structure and framework, but that sometimes the Standards Committee feels like it hears report outs of activity that has been done where coupling the Standards Committee and S&I more tightly might be more satisfactory and beneficial to both. So Steve, I think that is the input you are hearing.

**Lisa Gallagher, BSEE, CISM, CPHIMS - Vice President, Technology Solutions – Healthcare Information & Management Systems Society**

And John, this is Lisa. Perhaps it is something Standards Committee Steering Group could look at as far as how we can make better and more timely connections to those initiatives.

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

And that sounds like an excellent recommendation. So David, we will put on the agenda that as we finalize the membership of the Steering Committee, that making sure that there is more tight coupling and alignment of S&I and Standards Committee activity so it is not a report out, it is more of a collaboration.

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

Yes, that sounds great I like that.

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

Well Michelle, who else do we have in the queue?

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

Leslie Kelly Hall.

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

Thanks very much and I really appreciate the work that is being done on this because I think as the patient starts to enter the ecosystem, provenance will become even more important. And back to the problem that is trying to be solved, one thing that was heard over and over again in our patient-generated health data work or in view, download and transmit done at the patient direction, is the idea that good housekeeping seal that keeps the documents or the data tamperproof as it moves throughout the ecosystem with a high area of need. And then also, I had one question, in your approach you look at the data system of origin and not the person or role of origin and I wondered what was the rationale behind that. Because eventually things will...provenance is not a system level, it is the person who actually wrote or created that document or data in question. Thank you.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Yes, thank you Steve, this is Johnathan if I could take maybe a quick first pass at responding.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Yes, go ahead.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Thank you. So patient-generated health data is absolutely a topic of conversation within the community and many of our members of the initiative are putting forward suggestions for scenarios within the use case that include patient-generated health data, so I think that is right within our scope. And we are also actively discussing the role of individuals in the end-to-end workflow and how individual attestations, for example, can be carried forward so that we don't lose that provenance of the individual that is making an attestation.

But at the same time, recognizing that the standards and the information interchange addresses technical actors and it is those technical actors that are doing the things over the wire that we need

them to do, even though it is people that are causing them to do that. So, we have an interesting crossover in particular with this initiative, I think, where we have to span the gap between technical actors and human actors. And that is okay and we can handle that from an end-to-end workflow perspective. In context diagrams, it is more difficult to do entirely using standards, of course.

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

Could I just follow up on that, too, because one of...the high area of need, as I mentioned, is that tamperproof seal, but then the other was just versioning, knowing what version something was or it had been touched. What is continually talked that is care plan and this idea that care planning information can come from multiple sources and wondered if you had talked at all about that.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Not yet, but I am sure we will. So thank you, we look forward to that one. That is a great perspective.

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

Stan Huff?

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

Yes. I like the way that you have been specific about the use cases and this is a difficult area. And the one comment and this just comes from sad experience, one thing that is sort of so fundamental people might not think about it is a unique instance identifier for data elements. The context of this is, we have been in situations where we are receiving data from either systems within our own enterprise or from other systems. And one of the challenges is to recognize a given piece of data as the same piece of data you have received before. And we initially naïvely thought, oh, we can recognize it by a combination of a patient identifier, a LOINC code that tells me the kind of observation, the date and time it was done, etcetera. And then what happened is, in use, we found out that given real work conditions and corrections of data, corrections of collection time, even correction of potentially the test name, etcetera, that all of those things would fail in the actual operation.

And so the conclusion that we have come to is that the only way to really overcome that is make an expectation or a requirement that any system that originates...where the data is originally created, create a unique instance identifier that stays the same through the life of that data elements. So anytime that data element is resent, it has that same unique identifier with it, because there is no...sort of no combination of elements in the content that allow you to uniquely identify that guy again. And so I would just posit that as sort of one principle that you consider as you consider all of the other complex issues in this provenance area.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Thank you very much.

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

Nancy Orvis?

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

Hi, I also am very pleased to see the outline for it and I do want to reiterate the issue on creation of use cases, with an example. And I know...we need to know what the originating system or provider system, an organizational system where the data's...because in my instance, for my patients are 9.6 million beneficiaries, we are planning to be keeping this longitudinally over 20 or 30 years. And we will need to know what data is coming in, like if they went downtown for a stress test, so it went from an outside organization coming back into our organizational records.

And If there are more...I believe we put our use cases in, but I really do see that the future that benefits all consumers that we could be looking at is provenance, so that they know that when I was with this provider organization for 5 years, this is where my data came from. And then after that, it came from another one. So I just I wanted to double question, what is your timeframe for this project now to continue anymore in this area?

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Well thank you, Nancy for that. I think the timeframe, from the initiative standpoint is, we will be looking to finalize the use cases in the coming weeks and months, so not too far away. The initiative as a whole will go on into standards harmonization and then pilot and evaluation. And so this sounds like it is a sort of a 12 to 18 or more month process. But I think that we need more discussions with ONC on expectations and planning for what we can achieve in the time given, the resources that we have.

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

Okay, great. Follow up with you then. Thank you.

**Johnathan Coleman, CISSP, CISM – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.**

Yes, thank you.

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

That is our last question, so, Steve, I don't know if you want to transition over to your other presentation with Mike.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Let's do it. All right, you can go to the next slide. As Jacob mentioned this morning, the 2014 edition Release 2 final rule was put on display. As I understand, it will be published tomorrow in the usual tri-column Federal Register official version. We are going to cover a few elements here related to the rule itself in detail. You can go to the next slide.

So, quick background, right, we published this voluntary proposed edition, which we call the 2015 edition at the time of certification criteria in late February. Our goal was to include updates to our certification criteria to provide revelatory flexibilities, clarify our policy in a number of areas. You may recall that we were codifying...we were proposing to codify certain frequently questions that we had issued as well as to make some tweaks to certification criteria language that would allow for less

am...well, I should...that would allow for a greater clarity, less ambiguity and perhaps more flexibility as an option for developers to pursue our pathway to certification. The...we also had proposed some administrative changes to the ONC HIT Certification Program as a whole.

In response to the rule, which I would say was generally mixed, there were some areas that were widely supported, there were other areas that were probably more so commented on in a critical matter. One of the overarching points was that s full set, a full edition as we proposed to refresh, was too expansive to do in terms of the timing and overall global impact that the rule would have in the sequence of all of the events that were going on in the ecosystem.

And the approach for incremental...and I know we have talked about the cadence, etcetera, of more frequent rulemakings and what they would take on. I think the response for incremental rulemaking that addressed an entire set of certification criteria was where we largely saw this kind of mixed reaction. Saying, if you are going to publish 50 or 60 certification criteria as a whole every 12, 18, 24 months, that is going to be too much and it is going to be counterproductive to the aims.

And so the approach that we have taken and has been alluded to in the discussion thus far is that we hope that our 2014 edition released to final rule, which has a very narrow scope and a specific scope when addressing a few key issues, serves as a model for how ONC can update our rules as technology and standards evolve. And as the dialogue earlier pointed out, where we could with more precision update our rules and include a narrowly tailored rulemaking in the future that could subsequently be a “release” of a more stable overall edition as a way for us to gradually update our certification criteria over time. So, next slide, please.

I am going to cover the change to the edition naming approach, and I bet Dixie, who is not on the phone anymore, would have loved to have this out a week before her presentation so as not to confuse anyone. As we looked at the feedback that we had received relative to our certification program and the naming of the editions, we realized we could do better and that there was a way to make our rulemaking clearer for the industry as a whole. One of the things that I think personally for myself really sunk in for me in looking through the comments was, the fact that our...we had chosen, in our last rulemaking the one that we issued in 2012, to assign an implied meaning to the editions that we had released.

And you may remember, and I have a visual that I will walk through next, that In 2010 when we released our first rule, we just called it the initial set of standards implementation specifications and certification criteria. We did not have a year edition associated with it. When we put out the rule that accompanied the changes to Meaningful Use Stage 1 and Stage 2 that was published in 2012, we decided to name our certification criteria by yearly edition. And the approach that we took was to pick an edition name year that coincided with the first year in which that edition would be required.

So we retrospectively changed the edition...changed the name of the initial set to the 2011 edition, because 2011 was the first year in which compliance with Meaningful Use Stage 1 would be required. Subsequently, we prospectively named the edition that we released in 2012 the “2014 edition” because it made it easier for us to communicate that come 2014, providers, hospitals, critical access hospitals that participate in the EHR Incentive Program, needed to be using the 2014 edition certified EHR technology as they met either Stage 1 or Stage 2. And so that was a communication aspect in point for us to pick a year that coincided with the first year in which compliance would be required.

Now in retrospect, putting all the facets together with respect to the flexibility final rule that was just released related to Meaningful Use that bumped the year in which compliance of the 2014 edition would be required to 2015. And...not to say that we could forecast that happening every time into the future, but it did give us pause and a reason in the context of all the comments that we received, to look at how we were naming the editions of certification criteria. And whether or not the implied meaning specifically attributed to the EHR Incentive Programs was the right approach and most appropriate approach to take.

What we decided was, we would pick a more perhaps intuitive and plain, clear approach to name our edition of certification criteria in terms of the year in which the rule is published. And so that is really the third bullet on the slide here where we have articulated, as we release a full edition of certification criteria, we would name that by the calendar year in which the rule was published. So, other rulemakings, like this one, which occurred after the date of the full edition, we would assign it with a particular year edition that is the most current in play, with a release number afterwards. Next slide.

I have stolen a lot of thunder from this illustration, but just to show you what the path was and then what our regulatory future would like, the past was in 2010 there was an initial set. In 2012, we released what we called the 2014 edition and renamed the prior edition the 2011 edition. In February, we had proposed to call what we were going to publish a 2015 edition and add a full suite of 50 or so certification criteria. And then subsequently in that roadmap slide, which you may recall, we anticipated that the next rulemaking that we would issue that would be supportive of Meaningful Use would be published in 2015 but yet called the 2017 edition. And you could see how this prospective naming would continue into the future.

As we look to the future now with this decision, we have released the 2014 edition Release 2 in calendar year 14. We are working on a proposed rule that we have indicated would be published later this year that would be referred to as to the 2015 edition, because it will publish in final form, by our estimates, in 2015. And then into the future, whether it be that we...something related to FHIR in particular is ready or some other standards or certification criteria are deemed warranted, that could flow into a subsequent rulemaking that would be a 2015 edition Release 2. That could be three criteria, it could be seven criteria, and it could be an update to a standard. But this gives us a way to more gradually adjust our certification criteria and the edition that is most current in play as a...again as a way to gradually approach this and to give the industry time and ability to review our rules.

Also, as we have talked about looking beyond Meaningful Use, a 2015 edition Release 2 rule could be entirely focused on supporting another type of program need, whether it be through our colleagues, through the other federal programs and not related to the EHR Incentive Programs at all. And that is a way, again, for us to gradually update our primary edition in play without refreshing the entire set of certification criteria.

So now, I am going to turn it over to Mike to walk you through, very briefly. We have a FAQ sheet available, the rule itself and should have mentioned this up in the beginning. The approach that we took in structuring the final rule, I know it is close to 200 pages, but really the first 65 pages are all you need to focus on and read because that articulates the final requirements that we adopted in terms of the rule. So we broke the rule up into proposals adopted and proposals not adopted. The first 65 pages, which include some of the upfront boilerplate, take on the proposals that we adopted in the final rule. Everything else afterwards is additional insight and explanation as to rationale for not adopting those additional proposals in this Release 2 rulemaking.

So again, the size of the rule isn't necessarily a proxy for the substance of the rule, which really is in the first 65 pages. I will turn it over to Mike.

**Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology**

Okay, thanks Steve. I know we are significantly behind. Good morning and to those in control of the slide, can we move to the next slide? All right. So, as Steve said, we took a narrow scope, and actually, you can even narrow it down to 55 pages of read, if you don't want to read about the statutory and regulatory history of our program, because there is about 10 pages of that in there as well. But we took a narrow scope and what we adopted are 10 optional and 2 revised certification criteria and a few program updates for the certification program and then some administrative updates, which are really removing some outdated text from the Code of Federal Regulations. So I will try to go through this quickly, moving on, next slide.

All right, so here they are, the 10 "optional" and revised criteria. Based on the comments received on the rule, I want to just spend a few seconds on the optional. Optional simply means that it's a way for us to designate in regulation text that to meet the complete EHR definition, you don't have to do these criteria. So that was the reason why you had this term optional here. You will see, based on one proposal I will go over with, we hope to add some clarity and simplicity to both certification and our regulation text in future editions. But in any event, these are the criteria I will go over with you stepping through the slides so, on to the next slide.

All right, and then again, the next slide. All right, so CPOE, based on a lot of the rationale for what we proposed and the feedback, which was practically 100% agreement. All we did here was split the CPOE criterion into three separate criteria. So I do want to emphasize that current combined criteria still exists in the 2014 edition, but what we have offered now are three additional criteria broken down based on the capabilities of medications, labs and diagnostic imaging, which is what we are calling that criteria now versus I think before we had imaging/radiology. We feel that terminology is a little more clear.

Okay, so I want to also emphasize no standards association with these new criteria. So be...I know we had proposed the LOI for labs in the proposed rule, but with this final rule, we are looking at just three additional criteria added to the 2014 edition. And I think this will provide some of the flexibility we've...developers have asked for, and even providers have asked for both in creating products that are just specific to CPOE for medications and for providers who may not need certain capabilities, for example, participating in the EHR Incentive Programs. So, moving on to the next slide.

Okay, ToC. So, this is...we have another criteria that is...that we have adopted that is very similar to our proposal in terms of structure, related to the decoupling of content and transport capabilities. So what we have adopted is those three transport standards that were in the current criteria for transitions of care and we discussed in the proposal. And we have also adopted the EDGE protocol's Implementation Guide and this is a different version than the version in the proposed rule. It is a version 1.1 that adds more specificity to constrain, so we think that will help will interoperability. Again, this is another option for developers to consider for their providers and their situation.

Moving on to the next slide. Again, these are the three transport standards that I just mentioned, so I think we can move on to the slide after that. Okay, so this was...we have adopted now a "clinical information reconciliation and incorporation" certification criterion that I think adds clarity and response to stakeholder feedback about how in the clinical workflow this process takes place. So that is

all this criterion has, there are no other updated standards involved here or...both on content or vocabulary. This is just simply providing another option...a more clear option for certification. If we can move on to the next slide and unfortunately, my computer just...one second please. I'm sorry.

All right. Okay, syndromic surveillance; so if you recall our proposal here, we pointed out that the HL7 2.5.1 standard, the IG was not ready and we had expected an IG to be proposed that did not happen. We also noted about how public health agencies and providers were using other standards out there, CDA and the QRDA 3. But after...based off their feedback that we got on the rule, we realized that there are not implementation guides for these standards either, so testing and certification was going to be difficult. But how do we provide more flexibility for developers and providers in this instance, particularly with Meaningful Use as a consideration. So what we have done here it that you can get certified to this criterion using any method, and that means any type of electronic standard. So that's...and we've also, I wanted to point out, included a path forward, how we see things going in the future and offer some optional certification related to this standard...excuse me, to this criterion. In which there are data elements that if you can show you can capture and send to a public health agency, you can get certification to that optionality, within this optional criterion.

Moving on to the next slide, all right, so these are what I would call like technical corrections. So the safety-enhanced design criterion had to be updated to include these new optional criteria, the CPOE and Clinical Information Reconciliation Incorporation criterion. So that is all we have done here, those criterion mirror the already adopted ones, which we include in SED, so, that is the only change here. And then the automated numerator calculation, we have made it optional because before we had to issue a FAQ that said, for that whole...again, the complete EH R certification, that if you didn't necessarily have to get certified to this, tested to it, if you were already doing the automated measure calculation, which is G2. So this helps from a regulatory standpoint provide some clarity, so that is what is going on there.

Moving on, next slide, please. All right, I just want to point out quickly, I think most of the folks on the phone are familiar with Gap Certification. Seven of these criteria of the 12 qualify for Gap Certification they are listed there. Again, it is up to the ACBs final judgment and discretion on that. Moving on to the next slide.

Okay, so quickly, the certification program changes, two I think not as significant as the first proposal that I will discuss, which is, the complete EHR definition. We...and I want to make clear and the first thing I want to say is, this has no impact on complete EHR certification or any future ones or prior certifications to the 2014 edition. What we have done is said, going forward, any future edition, there will no longer be complete EHR certifications. We have made this decision based on the feedback we received on the proposed rule and the rationale that we provided in the proposed rule. So, that is what I want to say on that.

I am sure we will have some questions or comments, but I just want to get through this. So I am going to move on to the other two finalized proposals which is, we have finalized the proposal for the certification mark called the ONC Certified HIT mark which would be issued by an ONC ACB, which is an Authorized Certification Body. I want to emphasize, which I know we got some comments on that a developer does not have to use this mark. The developer, if they choose to use the mark, then the ACB would make sure that they use that mark consistent with the terms of use. So that is, I think, something that stakeholders asked for clarity on and we are obviously willing to provide. It was never our intention to require these by developers.

We would encourage its use and hope that they would use it, as it would provide clarity so you knew where this prod...how this product was certified and for what purposes. Lastly, here we just made...we just adopted a standard that the industry in its respect for certification and accreditation purposes has moved to an updated ISO standard for certification and that's listed there 17065.

All right, moving on, all right, so the administrative changes. As you recall, we proposed to remove reg text related to the temporary certification program in the 2011 edition. Obviously, since the time of our proposal, there was a proposal related to the use of 2011 edition to meet the certified EHR technology definition during this year. So, taking that into account, we have made the effective date for the removal of the 2011 edition criteria and related standards March 1, 2015, which would be after the end of the attestation period for this EHR...for the 2014 EHR reporting period. Moving on, I think that may be it.

Okay, so what is next? As you have heard, we are in the process of working on a new edition of certification criteria that would be in a final...oh, excuse me, in a proposed rule jointly issued with the EHR Incentives Program proposed rule. And I think publicly we stated we are trying to get that out by the end of the year. And then again, of course that would be looking...that edition would support the EHR Incentives Program's proposals. And then I also want to point out that we obviously took, or asked for a lot of comments on this next edition, which is now going to be called the 2015 edition. Or we anticipate it will be called that. We had asked for comments to inform that...this edition and we are definitely taking those into account as we formulate proposals for that next edition.

So that is it, I think that wraps up going through everything we finalized in this Release 2 Final Rule. So I think we can open it up for comments at this point.

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

Thank you, Mike. Arien Malec has a question.

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

So thank you. First of all, I think the direction that you all went in was one that I applaud and endorse. I have a number of questions related to the optional designation. I understand the optional designation was included to provide additional flexibility for a complete EHR. But I am having a hard time figuring out what is actually required for a certified EHR technology that is adopted in Meaningful Use by a provider. So with respect, for example, to transition of care, what...can you help me navigate that? And then as a sub-question there, we at some point discussed making the EDGE protocol a required capability as opposed to an optional capability and I'm just selfishly...

**Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology**

Sure. Yeah, I know. I will take a first stab at this...

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

Great.

**Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology**

So yes, so the optional designation obviously, it leads to confusion. It does have a dual meaning in some sense. And so in this respect, not only for the complete EHR definition, but it also...I want to...developers

don't have to get certified to any of these criteria...any of the optional criteria that we have adopted in Release 2. Particularly if you have already been certified to, for instance, the transition of care criteria. This is just another way, if you have neither been certified to any 2014 edition criteria or if you feel that this is another means that could help your customer base. So, it is optional in that regard.

But if you do choose to say get certified to the new transition of care criterion, then you would be required to be certified to the EDGE protocol. So that...so once you choose to get certified to that criterion, anything within it that isn't listed as optional becomes required for certification, if that helps at all.

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

Yeah, it's...that is probably the same question for orders and the like that we have a hard time figuring out how to navigate all of this. So in the future, maybe an improved chart might help, but thank you.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Yeah, this is Steve, just to emphasize a point that Mike made. The purpose of adopting these criteria was to make them available for certification. And in some points, they are, with their availability if the developers so chooses to get certified to them, can be and we have built into the regulatory modifications, alternatives to the originally adopted 2014 edition, which we could call Release 1 criteria. So, it would be an equivalent approach. To give you an example with transitions of care, today, using the original 2014 edition, a provider needs EHR technology certified to, and I will have to be specific and name the criteria by reg text, and the certification 17314 B-1 and B-2, in order to meet the base EHR definition requirements.

Going forward, a provider could, if their EHR developers so chose to get certified just to the transitions of care content certification criterion, which includes the EDGE Protocol requirement. As well as using a separately certified HISP, for lack of a better word, that is certified to the new transmission...transport capability at the new section of criteria that we have adopted in the paragraph 8 area, to do Direct. And so they could pursue an equivalent alternative approach in pairing together the overall health information technologies that they want to use to meet the certified EHR technology definition. And we built that in to the regulatory structure to support that equivalent alternative approach.

**Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology**

Yeah, just...If I can emphasize, think of them as alternatives, there is no requirement here to upgrade or...either for you or your customer base. It is an options and alternatives that could provide more flexibility, more opportunity for exchange meeting MU, things of that nature, whether it be with public...so that is, I guess, the way to look at it is alternatives.

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

Just to be really clear, I am trying to figure out what this could mean for 2017, and obviously, you can't answer that, but that is many ways...the intent of the question.

**Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology**

Okay, understood. Yeah, and I can't really answer anything related to how this would impact any future proposals by us.

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

Understood.

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

Kim Nolen had a question, I am not sure if you still do.

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

Yes, thank you. I wanted to ask a question about the CPOE and it is really, I guess, for my knowledge. Just because I work on the backend of getting the data after the information has been put into the EHR around population health management and quality measures. And what we have seen is, when people enter, especially the medication part into the CPOE section versus the ePrescribing module, that information may not flow to the medication list or to the same places on the backend of the EHR. And it is hard from a population health management to view that information. If through the certification criteria, and maybe it is done and I am just not seeing it, is there an opportunity to make it where the CPOE and the ePrescribing models for the medications are better linked together? We see this a lot with vaccines and so I am just trying to get an idea of how that works through the certification process.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

I will...this is Steve. I am not sure that that is an explicit requirement today. And are you...can you bring that up in the context of an inpatient setting more so than an ambulatory setting? Or for both?

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

It is probably more in the inpatient setting, but you do see it in both.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Yes, I think we would certainly be interested in feedback that you have, but that is not an explicit connection in how certification approaches this functionality today. It is...particularly it is a pretty general criterion about order...enabling a user to electronically record these types of orders.

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

Okay, thank you.

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

There are not any more questions in the queue. I realize John, I did not give you the opportunity to make a comment before I went to questions.

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

So, and I had made an introductory comment having read the materials at the beginning of the meeting that the scope of these seems to be appropriate. And certainly, I applaud Steve, your separation of transport and content, enabling health information exchanges now to actually certify a module for transport using Direct.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Thanks. The one other point I would like to mention, which I didn't include in the slide, obviously with additional Release 2 criteria. There will be updates to...or I guess the production of additional test procedures for those criteria, some of which will look largely the same for those where there are just splits, like with CPOE, a matter of taking out the content that is in three sections of one test procedure and making them their own test procedures. There is work underway to have those refreshed test procedures out for public comment that will occur in the next couple of weeks, as well as building out the testing tools for especially the EDGE protocol implementation guide requirements. So those are things to look at down the pike, but also for all those interested in providing feedback to the test procedures as they go out, as we have before, working on a way to allow for the public comments to be made on the test procedures for the Release 2 criteria.

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

Very good. Well Michelle, since I think we are now about half an hour behind, but I am guessing that Dave McCallie, that maybe you can make up some of the time on the JASON presentation.

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

I will take whatever you give me and we will work with it.

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

Well, so let us move on to NCPDP and then we will, between now and 1:15, do double time on both these final presentations.

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

I am not sure if Tricia Lee-Wilkins is on, but she was going to make an introductory comment. Tricia, are you available? Okay. Well, we will just get right to the presentation then. Do we have Margaret, Bruce and Roger?

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

This is Bruce. Can you hear me?

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

We can hear you.

**Roger Pinsonneault – Vice President, Business Development – RelayHealth**

And this is Roger Pinsonneault.

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

And do we have Margaret? Roger, I think it is you and me then because I don't know where Margaret is.

**Margaret Weiker – President – The Weiker Group**

This is Margaret, can you hear me?

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

We can hear you.

**Bruce Wilkinson, MBA – Chief Executive Officer- BenMedica**

Oh, there you go...

**Roger Pinsonneault – Vice President, Business Development – RelayHealth**

I think it is Margaret.

**Margaret Weiker – President – The Weiker Group**

Okay, good. As we previously stated, Roger, Margaret and Bruce and I are the Co-Chairs of the Real-Time Benefit Check Task Group within NCPDP. Our presentation will include a brief overview of NCPDP. We will talk about where we are as a task group, what industry implementations have been done to date and then our request to this committee. So, next slide.

What is NCPDP? For those of you who may not know, NCPDP is an ANSI accredited standards developments organization that has around 1500 members that represent almost every sector of the pharmacy industry. NCPDP is a member-driven organization. Our membership provides the leadership for the organization, as well as develops the business solutions and creates the standards. NCPDP standards have been named in HIPAA, in MMA and in HITECH. Next slide.

The structure of NCPDP and how we do our work is primarily, if you look at it or think about it from...in an organizational type of move. We have workgroups and under workgroups, we have task groups. Workgroups develop the actual standards and specifications. Workgroups can be attended by anyone; however, voting in workgroups is done by members only.

Task groups report to workgroups and we typically form task groups to deal with a specific issue or problem that has been brought to a workgroup. Anybody can be a member of a task group; you do not have to be a member of NCPDP. Most of the task groups meet virtually. And if you want more information about the task groups, we provided a URL and if you want more information about the workgroups, we also provided a URL for that as well.

As part of the 2015 EHR certification criteria, there was a discussion around new or updated standards or transactions that would be needed to have the functionality so a patient-specific formulary check could be done against the patient's actual drug benefit for a specific drug and dose, done in a timely manner. In regard to that MBRM, NCPDP submitted a response and volunteered to convene industry stakeholders to facilitate such a solution. Next slide.

So NCPDP formed the Real-Time Benefit Check Analysis Task Group and one of the first things we did as a task group was to recruit a wide range of implementers and subject matter experts around us. To date we have about 95 members, some more active than others that attend the task group meetings. We set about defining what does constitute a prescription benefit as reported by the actors in a use case. The task group's work is focused solely on defining the use cases and business requirements. The task group's scope is not to select a standards base or to define a solution. Right now, the task group is focused on what is the use case and what are the business requirements. So, based upon the scope of the task group, Bruce is now going to give an update on where we are.

**Bruce Wilkinson, MBA – Chief Executive Officer- BenMedica**

Thank you, Margaret. Next slide, please. So as Margaret mentioned, this is a more recent task group that was formed starting in June 2014 through NCPDP. What we did is we did define the scope of the task group, to make sure we stay within our mission. We drafted some assumptions that we believed where the transaction goes within the flows and identified a number of use cases, which we will go through shortly. Our next steps to the group is to have them prioritize which of these use cases are important to them and then to flesh out the use cases in more detail. One of our concerns as a task group is that we do not want to try to boil the ocean to solve a problem that is more immediate, so what is important to the people now and then we will add on additional functionality in future versions. And one way to help accelerate this process, too is once we have the use cases defined, to break out into subgroups to manage each use case and then come back to the task group and report on the findings and recommendations. And that will help us establish that base functionality. Next slide, please.

So, some of the questions of the use cases that we are trying to answer are what is the patient's financial responsibility for medication? Is the pharmacy a preferred lower cost pharmacy? Are there any coverage restrictions, like a prior auth, quantity limit or set medication protocol already in place that may help...that may prevent the drug from being covered? Are there any lower cost therapeutic alternatives? What is the remaining deductible?

We want to look at the health plan's financial responsibility, which is much more relevant in the ACO mind frame? Then what if the health plans PBM needs to communicate additional information at the time of the real-time benefit check transaction was requested? So is this another chance for the physician and the patient and the payer to have that communication channel? And then also, how much longer is the patient covered by a health plan? Is the health plan the primary insurer?

So those are the main use cases that we have identified today. There are a lot of sub...I would say sub-use cases underneath each one, for example, for the pharmacy benefit side, it might be what is the price for 30 days versus 90 days? Or 30-day retail versus 90-day retail? So these are very high level, but then within each one of these use cases...look into more detail, what additional questions can be answered. Next slide.

So we are going to go through a number of the proposed standards that are available out there today. The first one would be what Surescripts created over 10 years ago and has been piloted by a number of pharmacy benefit managers as well as vendors with a first version or first release back in 2003. And then based on that feedback and interest in the vendors and the pharmacy benefit managers, they went back to that transaction and said, we need to update it and make it more useful. So Release 2 was created in 2008 and then was piloted in 2009-2010 using a subset of the release. So Release 2, the first pilot was all around pricing and then the second pilot was on alternatives.

And then from there in 2014, Surescripts is proposing that the NCPDP to be a potential standard for real-time benefit check, so it would be adopted in the public or NCPDP. A little bit more about the real-time benefit check. And first of all, Surescripts has two different pilots on the real-time benefit check and the whole point here is, you want to have that real-time benefit check be a part of the physician's workflow. That way the physician can identify what is the cost of the medication and what should he be aware about that prescription before that prescription is prescribed and sent?

He...of an integrated part of the workflow and...appears before at times prior auth, concerns of patients...prior authorization, for example and is very complementary to the formulary and benefit

information. And the Surescripts real-time benefit check is based on the NCPDP script standard. And the idea here was, people are familiar with the standard already, let's make it similar so that way it is easier to implement. Next slide. Roger, I hand it off to you.

**Roger Pinsonneault – Vice President, Business Development – RelayHealth**

Okay, so this is Roger Pinsonneault from RelayHealth Pharmacy and what I'm...what we are proposing here is another demonstration project with another NCPDP standard and that would be the telecommunication standard. And at the encouragement of ONC, we are proposing this demonstration project and pursuing it for quarter 1 of 2015. And the goal of it is identified here that we want to be able to originate a request transaction out of a provider's EMR system, route it through standard transaction routing networks to a pharmacy claims processor, await their real-time response and deliver it back to get back to the provider in under 5 seconds.

To do that, we are intending to leverage existing standards and that would be the NCPDP telecom standard, version D.0 and sort of the technology backbone supporting that standard in the industry. The goal of the demonstration project is to demonstrate that we can accomplish sort of the integration and the turnaround time as desired...as described and to deliver a patient pay amount. So that would be, in our vernacular, a...the patient's financial responsibility for a medication and a specified quantity of that medication.

And then the last goal is to align all the stakeholders. So, there has been historically sort of a trust gap between the stakeholder groups and so our current efforts are focused on bridging, as best possible, that trust gap by bringing together pharmacy claims processors, pharmacies and physicians into the demonstration project. The only other thing I would add would be that again, our goal is Q1 2015.

We have engaged pharmacies representing approximately 30,000 pharmacies to be participants in this. Of course, we will only do a subset of that, but they represent 30,000 pharmacies. We have spoken or very shortly will complete discussions with all the top pharmacy PBMs in the industry so they represent a very high percentage of all commercial plans. And probably the bigger challenge is the outreach to the EMR community and integration with them. We have two physician technology aggregators and we are talking to a third one right now. Next slide.

**Margaret Weiker – President – The Weiker Group**

And then, of course, what exists today is the ASC X12 270/271 transaction, which is a healthcare eligibility benefit inquiry and response. It is HIPAA mandated for dental, professional and institutional providers. It does provide an inquiry and a response to obtain eligibility information, coverage, as well as what benefits are associated with that particular coverage. About 1.98 billion transactions using the 270/271 are done today on a yearly basis as well as the transaction is used by all healthcare industry sectors. It is used in the ePrescribing function to obtain the formulary and benefit pointers as well as it could be used for medication history as well. So back to you Roger.

**Roger Pinsonneault – Vice President, Business Development – RelayHealth**

Okay, thanks Margaret. Do you want to go to the next slide? So one of the requests was to understand what is the ask from the committee and the ask would be, NCPDP does a very good job of bringing a variety of stakeholders to the table, but I would say that we are insufficiently represented when it comes to provider participation in some of these discussions. And so there is an ask to encourage participation and dialogue from the provider community.

And the other request has to do with the success criteria. So looking at the...along the lines of the NPRM that was released at the beginning of the year and the request from ONC to look at the viability of using the NCPDP telecom standard, we would at some level, believe that it can be used and we are going to demonstrate that it can be used. But we would also like to understand a little bit of the...some of the guidance on what would be considered success criteria. Would that be number of physicians adopting this? A turnaround speed? Types of information available? Any number of...cost to implement, cost to maintain, and any number of criteria that might be used in consideration of advancing a standard here. I think that is our last...is that our last slide, Margaret?

**Margaret Weiker – President – The Weiker Group**

Yes it is. So, we will open the floor to questions.

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

John or Jacob, do you have any comments before we open to questions?

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

Sure, I think just one of the things we wanted this feedback, this is a very valuable discussion and I would just ask the committee, because I think there are some stakeholders who would like to comment, as to what our next steps might be? What will be the scope of what it is that the Standards Committee will try to come forward with now that we have heard the state of the art projects and process and gaps information. And for those who e-mailed ahead of time, happy to hear your comments now.

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

David...sorry, Jacob did you want to say anything?

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

Well, no. I was going to say something similar and apologize for the beginning, Tricia Lee was going to introduce our speakers, she is in my office and I pressed the hang-up button instead of the unmute button, and so, sorry to cause that challenge. So, go ahead commenters or folks who want to make recommendations.

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

David McCallie?

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

Yeah, so first, I thought your enumeration of the use cases was extremely helpful to sort of clarify the potential scope of all things related to the actual financial aspects of a prescription decision. But I also would encourage you to focus on, as I think you are doing on the really simple use case that is of most concern to the patient is, how much is this going to cost when I walk into the pharmacy for this particular decision. And it sounds like, at least in the pilot that Roger describes, that that is the focus and that makes a lot of sense to me.

But my question is, I am confused that...are you proposing that there would be a new pure NCPDP standard that is not based on the telecom standard? Or are you proposing that the NCPDP standard would be wrapped around the telecom standard and would use that? I just lost that train of thought, if you could clarify, please.

**Margaret Weiker – President – The Weiker Group**

Sure, David, this is Margaret. At this point in time, we are not recommending any standard at this time, what we are re...the task group's goal and scope is to develop the use cases, the business requirements, what is the data that is needed to find out how much this prescription is going to cost me when I walk into the door? At this point, we are not focusing on a particular standard, we are focusing on the use case, business requirements and data elements. Now we have pilots where, Roger explained, he is using the telecom as a base. Bruce explained where a previous version of script was used and I explained where the 270/271 was being used today. But at this point, the task group's goal and scope is to use case, business requirements, and data elements.

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

Okay, so that...this is David again, that helps clarify. Because I did hear, three separate standards mention and now I understand why.

**Margaret Weiker – President – The Weiker Group**

Okay.

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

So I will let others ask some questions, but I will just put a suggestion in your ears that this might be the kind of service that could be delivered to the EHR vendors via a plug-in App rather than by giving them a raw transaction to deal with. Since the use case is so focused and the number of data elements necessary to drive the proper decision are relatively modest. So, just put...if that makes no sense to you, I would be happy to explain it off-line, but put that in the back of your minds as a thought for the future. And now I will shut up.

**Roger Pinsonneault – Vice President, Business Development – RelayHealth**

Yeah, this is Roger and that makes perfect sense. Appreciate it.

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

Kim Nolen?

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

Hi, thanks Margaret, Roger and Bruce. There were a couple of points that I wanted to make and a couple of questions. From a conceptual and functional standpoint, when I look at the benefit transaction for medications, today how we see it, we have two different sources or payloads that are providing that information. Like the pharmacy has a source of information that they are getting, but the providers have a different source, so one of the things that I would like to see as we move forward with this real-time benefit transaction or benefit verification transaction is that the provider and the pharmacy are getting the same information from the same source. Because I think that would help minimize any disparate information that the two parties could be getting. So that is one of my thoughts around this.

And then when I looked at slide 7, with the questions that the real-time benefit transaction should answer, and kind of build off what David has mentioned. I looked at the...what is in scope and what is out of scope? And when I look at question one through five, those are the basic in scope, you know, what does the provider and patient need to have to know the cost and coverage for a chosen medication for that patient's specific condition? And those questions help provide that, whether it is co-pay, cost sharing, that that's the bulk of...are coverage restrictions?

When I look at question six, that one, I don't see that as being as much in scope. It seems more...when I think about what this information is giving to the provider, their primary concern is for the care of the patient, so when you're sh...I understand if they are in an ACO model or similar model where there is shared financial risk, this information may be valuable. But is it through the transaction, I guess is the question. So I would want to throw that out to the group.

And then when I look at question seven, and you all know that I am an active member of NCPDP and participate on all the calls, this question has metamorphed many times. It started off with a physician from advocacy group asking to have a messaging...a way to message the PBM or payer. And then another person brought up, well what about if we provide DUR messaging, and then it turned into the PBM or payers having a way to message the prescribers.

And when I think through those three scenarios, I think we have to keep in mind that whatever that messaging is, it needs to be related to benefit verification for a medication. And it would be great for a provider to have that messaging capability with the DUR messaging. Is that clinical messaging or is that the benefit verification messaging? So those are two things to think about. And then for the third one, if it is the PBM messaging the provider, I think we need to be really careful with that and there need to be a boundaries around it. And there should be standards about the types of communication that could be done to ensure that it is truly a benefit verification and not pushing a commercial interest. So those were a couple of my thoughts.

And then back to be Surescripts pilot. Through the years, I have heard different things with that pilot and what was mentioned back in October 2012 is that they actually stopped that pilot. And I was just trying to understand, why at that time did they stop that pilot, was it a technology issue? Did it not fit the business needs of the owners? Or was there some other reason? So if one of you all could answer that that would be great. And then the second part of that question is, like the one Roger presented they mention using the telecom standard, but with the Surescripts ones, I don't understand what is within that transaction? I don't believe that has ever been made public, will that be made public and will we get to see it? Those are my questions.

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

This is Bruce. You have a whole bunch of questions there, Kim and I'm trying to...answer them each one at a time. The first one is that every one of the I think the proposals for RTBC are sourced with the pharmacy benefit manager, so whether it is telecom...benefit check or X12, the source of truth comes from the same adjudicator, the pharmacy plan's adjudicator. So I think that would address your concern about more than one source of information that is consistent? Or are we talking about medication history, which would be something different totally?

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

No, I mean, my point was the pharmacy ping into a source to get the information. And then if you look at the information the provider gets today, it is a completely different source of information. It is

provided by the PBMs but it is provided in the different format and it is coming from a different place in the...I mean, I don't know exactly where it comes from but I know it is different. And so I think whatever the pharmacies are getting should be what the providers are getting so that there is...it is the same information. It seems to me like that would be the best way.

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

So, you are talking about the...benefit information then, Kim?

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

Yes.

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

Versus the real-time benefit check information?

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

Today, that is what is happening, so what I was trying to say was, today, there are two different sources of information going to two parties who are taking care of the patient, how can we make it, as we move to real-time benefit checks, so they are getting the same information? So it was just a concept, you know, as we move forward, you know, how can we make it so that both parties are getting the same information from the same source?

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

And I would think that the difference between a real-time benefit check versus formulary and benefit is the timeliness and the specificity of the patient-specific versus representative. And typically, both of them come from the same source, so you can...more general when you send representative data across. So I understand your concern and I think it is one of the reasons why people are looking at real-time benefit check to help physicians know more about that drug and how it applies to that patient versus relying on formulary and benefit for drug-specific information.

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

So let me just illustrate Kim's point. You've heard me tell the story before where I e-prescribed an EpiPen for myself using a certified Surescripts compliant system and it selected appropriate formulary and had no idea whether in fact it would have a co-pay or not, got to the pharmacy, was told it had a \$330 co-pay. And then the pharmacist did a mysterious preAuth transaction behind the scenes with Caremark and suddenly it was \$25. So it was clear that as EHR user, a physician had different information than the pharmacist and different transaction types. So to Kim's point, shouldn't we have the benefit of telling the patient costs and co-pay and the same data as a pharmacist?

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

And that...this is Bruce that is hard for me to understand without more information to understand what was being conveyed before. So it might have been a tier 3 drug, for example, or was it \$100 and then it would be \$133 dollars. I don't have enough information to answer that question.

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

It was a tier 1 EpiPen for which it was just very interesting that the information available to a doctor and the information available to a pharmacist seemed to be quite different. And that was just my anecdotal experience and you are correct, I know not what I speak about.

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

Hey John...

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

I am not saying that, I don't know what information you were given, so I said tier 1 and \$133 was obviously pretty high for tier 1.

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

Yeah.

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

And John, this is Arien. In some cases, there are additional co-pay reductions that are available not through the PBM but through other actors for example, manufacturers may offer additional co-pay reduction programs, so that may have been what happened in your case.

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

And this is David, isn't that the goal of the real-time transaction is to supplement the information that is available in the formulary with the...at the breaking moment, this is what it is actually going to cost? I mean, I understand why those are going to be different because the formulary is generic and can't take into account the specifics of a particular patient's current limitations, co-pays, how much they have used up, etcetera. Whereas the real-time adjudication can and that is why we need it as a backdrop, my understanding of the value of this transaction.

**Roger Pinsonneault – Vice President, Business Development – RelayHealth**

Yeah, so this is Roger again and I would like to mention that, the goal of using the telecom standard out of the physician's EMR system, is intended to match that price to the penny so that it perfectly replicates what is going to happen a matter of minutes or hours down the road at the pharmacy. And to accomplish that, the transaction coming out of the physician's office and delivered to the PBM essentially looks identical to the same transaction coming out of the pharmacy.

**Bruce Wilkinson, MBA – Chief Executive Officer – BenMedica**

That would be the same as, I think...a real-time benefit options too, Roger. I think we are all looking at saying, what is the actual price for that patient at this moment and what should they be aware of?

**Margaret Weiker – President – The Weiker Group**

And what I have done is Kim, I have captured your comment and John's as well about the same source from a prescriber point of view versus a pharmacy point of view. And as part of the task group, what we can do is upon task group agreement, have it as an assumption to the use cases to state, very pointedly, that it has got to come from the same source. So I have captured that note and we can talk about it on the next call, Kim.

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

So what I might propose is, this has been a very rich, very helpful discussion is that certainly Kim, we have heard your concerns. And what I would think a next step is that the Steering Committee will take a look at the items that the NCPDP folks have enumerated as their project task list. And then we will also take a look at some of the ONC and Standards Committee goals and then ask, how might we move this forward and what might be the subset of those goals that we focus on as a committee? And I think we just heard the overwhelming support for doctors and pharmacists getting the same timely data and ensuring that a patient will have the benefit of consistency as they navigate the system. That is certainly something that will guide us.

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

Thank you John, this is Jacob, I completely agree and of course would add, patients, nurse practitioners, PAs, etcetera, other participants in the care delivery continuum. So that is a great recommendation that we bring this up at our Steering Committee to think about next steps and maybe I would ask Michelle to guide us toward our next hurdle here.

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

Well good, and so I know we wanted to leave plenty of time for Dave McCallie and the very important JASON Task Force report. So with this going to the Steering Committee for that list of work, I will...Michelle and David, let us move on to hear about your JASON Task Force recommendation.

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

Umm...

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

Can I just quickly, before we move on Leslie Kelly Hall and Eric Rose had questions. If you want to send those to me, we can follow up with them. And sorry, David, go ahead.

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

We are running short on time and the JASON stuff is so important to us all, please go ahead.

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

No worries, I will email. Thanks.

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

So Michelle, would you clarify what my time limit is, I have lost track of which schedule we are on and I am in the wrong time zone, so it is 12:20 in your time zone now, when do I go until?

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

Well, you have until probably about 1:20 PM and then we need to leave time for public comment. But you also need to leave time for questions as well, so, as quickly as you go through the presentation would be appreciated. I know it is not a quick presentation, so...

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

David, basically you have an hour.

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

Okay and I will go through this as fast as I can to leave as much time for discussion, because I know, we queued up a bunch of open questions. And to that end, just by way of introduction, I apologize on Micky's behalf that he could not be here to tag team with me. He had a prior obligation, family obligation that prohibited him from joining in. He sends his regrets. It would be much nicer for you guys if you could listen to the two of us back and forth instead of me droning on for an hour, so again, my apologies.

Second apology is, as a lighthearted comment I made at the introduction when we presented this last week to the Policy Committee that I quoted...I thought I was quoting Mark Twain to say that if I had had more time I would have written you a shorter letter. It turns out it was not Mark Twain who said that, in fact, a lot of argument about who did say that, but the sentiment is true that this represents the interim report of a very active and busy workgroup. And we are not finished and we are finished, it will be shorter. So I apologize for the length, but we will go as fast as we can. So let's go to the next slide.

There is my agenda, I am not going to dwell on that, we will deal with it as we come, so let's go to the next slide. The charge we were given, you can see here, discuss the implications of the report and its impact as well as the feasibility and impact of the report on HHS and the broader HIT ecosystem. Map it to current experiences and then see what the applications for the forthcoming Strategic Plan and interoperability...IT Strategic Plan and Interoperability Roadmap are. And then our final charge, which was added after the group was initially kicked off, with a direct request to us from Karen, was to correlate with the PCAST Report, which is quite similar, just so we can see how things might or might not have changed in the time in between the two reports. Next slide. And then the next one.

You will see the list of the task force members. I want to publically thank the members, we had excellent participation from most of the members on most of the sessions. We had terrific support from ONC, who we kept scrambling to try to assimilate the knowledge as we were accumulating it. And I want to also specifically thank Jon White from AHRQ, who is our official channel to the JASONS and facilitated some of the conversations that we needed to have with them. So thanks to all who participated in this.

Next slide shows our remaining schedule. And this is important to point out that we still have four meetings on our calendar to work through refining the report and shrinking it down to a core set of recommendations based in some measure hopefully on feedback that we get today and that we got from the Policy Committee last week. So, our work is not done. But we will present the final recommendations in the joint Policy/Standards meeting on October 15. So, next slide.

We had a two-day listening session. If we go to the next slide, you will see what we covered in the listening session. We had panels focused on HIE exchange service providers, from the research community, the standards development organizations, we had some consumer facing ecosystems, some vendors as well as some mHealth, if you would, App providers. I am not going to go through the detailed findings of our listening session, they are captured in an appendix that will be attached to the final report.

On the next slide, you can see the terrific representation that we had of stakeholders who presented to us. Their testimony is online as well as what we capture here in the summary of the report. We had, I think, 100% turnout of the people that we invited to participate, which I believe is testament to the importance of the subject matter and of the interest in the broad community in the items touched on by the JASONS. Next slide.

Let's go to the next one. I asked Micky, when we started the process, if he was able to give me the elevator pitch summary of what the JASONS actually said and he did a nice job of it and I said, why don't you write that down and maybe we should introduce our report with a one slide summary of what the JASONS discussed. It is an 87-page report with lots of content in it, so this is, by necessity, a very high-level summary. But for the Policy Committee, many of whom were not very aware of the JASON Report, I think this played an important role in our presentation.

For the Standards Committee, I am going to be more liberal and assume that you all are aware of it and have actually read it, so I won't go through this in detail. But as you know, the report is fairly critical of the progress made towards interoperability and went so far as to fairly charged phrases like "Stages 1 and 2 have not achieved meaningful interoperability in any practical sense" for clinical care, research and patient access due to a lack of comprehensive, nationwide architecture for health information exchange.

The report went on to focus a lot on the need for standardized APIs, we will discuss that in great detail here in a few minutes. And continued to circle back to this notion of some kind of an overarching or unifying software architecture. And you will see the phrase there in our third paragraph of a centrally orchestrated architecture, that is actually language coming out of the Task Force to kind of touch on the question of what is an architecture and what does it mean when you are talking about something as broad and complex as the healthcare system in this country? And we'll describe a little bit more about that.

And in the final paragraph here, the phrase public APIs comes up in the number of times in the report and describes...it captures the essence of what the JASONS are pushing us towards. And we will cycle in on what we think public API might mean. Next slide.

Of necessity, there are lots of caveats given the short timeframe and the complexity of the content touched on by the JASONS. And they are enumerated here, this may not cover everything but a couple of them are pretty important. Maybe the most important is the JASONS themselves do not engage following the release of their report, this is just the process that has been followed by this group through the years. They release a report and that is it, so you don't have the chance to interact with them. We did have one or two critical clarifying questions that Jon White was able to pass back and forth, but fundamentally, we are reacting to the report in absence of a conversation with the JASONS.

Second is the recommendations that we will pull forward here in this report don't line up exactly with the JASONS formal recommendations simply because their report didn't line it up either. So they mentioned a number of important issues in the body of their report that they didn't bring forward in their formal recommendations but we felt they merited discussion. So we have pulled out some things that they just touched on.

Third is the timing, you need to keep in your mind when you react to the report that it was conducted a long time ago in healthcare process terms, conducted in early 2013, which if you will think about it was

prior to any Meaningful Use 2 attestations using the CDA. So, some of their comments have to be taken with the tempering insight that they were reacting to the state-of-the-art that is now two years out of date.

The scope is they focused mostly on this high-level technical architecture and did not, on purpose, address legal/policy, federation/jurisdiction and business model questions that are critical to high level interchange...to successful interchange. And we will call out where we feel like that needs additional attention.

Number five, they touched on security, didn't propose anything that we thought was dramatically new or different from what our current best practices are, so we are not going to comment further on the security technology issues. And likewise number six, they touched on the problem of the absence of a national patient identifier but didn't propose any specific remedy for that problem, so we likewise will mention it, but not touch on that hot, third-rail problem either.

And then finally, number seven, take this as a preliminary report. I am going to, by the way, go through this whole thing and then open for questions. And the reason I am going to do it that way is that it is kind of an onion layered presentation and we nest into our recommendations as we go forward. So there are things that may be glaring questions when I present, you know, recommendation number one, which we will address in more detail in recommendation number three or four or five. So it is better, I think, to react at the end than to stop for questions after each specific recommendation. Next slide. And then the next one.

So, we have organized our recommendations into seven categories, which you can see here. This doesn't exactly line up with the JASONs, I think they had six categories. We swizzled it a number of different ways, we tried to line it up with the 10-year vision roadmap categories and it just didn't work as well as coming up with our own categories here. So we are going to go through these seven in the next few minutes, so let's get started.

Number one, state of HIE. Next slide. The format of our recommendations needs a little bit of explanation. I am not 100% sure, this is the best way to do it, in fact, I am pretty sure it is not the best way to do it, but this is sort of where we got. We will refine this and simplify it in the final report. But what we start with is the background where we try to explain the JASONs assessment and liberally quote from the actual report so that you get a reminder of the things that they said. Then we follow that up with our recommendations, our preliminary recommendations and then we follow that up with the discussion that led to those recommendations.

So, I am going to present these in kind of that inverted order where we do background, final recommendation and then touch on the discussion that led to the recommendation. This was Micky's insight from numerous presentations that he has done where he felt that it is easier to keep focus if you jump to the recommendation before you get into the depth of the discussion. But you will find a couple of places where it seems like we are going backwards, but anyway, hopefully it doesn't throw you off.

So number one, current state of HIEs, on the background, the JASONs made a pretty strong statement that, as you see there, "meaningful interoperability" is virtually nonexistent. Now again, remembering that this is in 2013, prior to Meaningful Use Stage 2 attestation. They conclude that interoperability is hampered by the lack of published APIs that enable more automated data and document exchange

across systems. That there is little consumer access to the data and no “rational access” between organizations for clinical care or research. Some pretty strong charges.

Our recommendations, again, I am going to go into more detail as I get further into it, but at the high level is we think that ONC should take into the account the current state of interoperability as well as current trends before reacting to the JASON findings, which are based on their analysis from several years ago. We believe that the JASONS did not adequately characterize the progress being made in interoperability, although we certainly agree, as you will see as we go through these recommendations, that there is considerable room for improvement, which we will touch on. So, don’t overreact to the view from mid-2013, look at where we are going and our progress before locking in on a set of recommendations.

Now the discussion behind that, in the next slide, which should be number 15, is I think probably clear to all of you these are 18-month out of date findings, six months before Stage 2 attestation. And there have been lots of changes in the market in that timeframe, as well as, of course, progress towards Meaningful Use Stage 2 and now working on Stage 3. And the demand for interoperability from the market itself, the supply side as we call it, has grown dramatically in the past 18 months. This is partly due to Stage 2 and Stage 3, but it is also due to the shifts in the market towards value-based purchasing, population health management, accountable care organizations and other business drivers that value interoperability perhaps much higher than the fee-for-service environment of the past did.

The second point in our discussion, the JASONS focused on their fear that the combination of Direct plus the C-CDA would be sort of the stopping point for interoperability and that that was a dead end. But we felt this was misplaced and didn’t really account for the fact that Meaningful Use is structured intentionally to stage interoperability over time and to allow for market adjustments as that progress moves forward. However, we agreed that they correctly identified that interoperability does not enable standardized API mechanisms for both documents and for discrete data, as we will get to in a few minutes. And we see also that immediate attention should be focused on improving...we agree that immediate attention should be focused on improving interoperability for document and database exchange through these APIs. Next slide.

Next slide. Architecture, the JASONS talked a lot about architecture. They appear to be recommending what I think you could describe as a centrally orchestrated, nationwide architecture. A couple of choice quotes there, you can see number one, bullet one, sub-point one, “interoperability issues can be resolved only by establishing a comprehensive, transparent and overarching software architecture.” Bullet number 2, they do note that the proposed architecture would have a heterogeneous implementation modes, including a mix of some centralized and some federated approaches.

So they are fairly clear that their notion of an architecture is not actually system engineering or system design, it is really what I would actually call architecture patterns and we will come to that in a few minutes. But they do recommend that the ONC define this overarching software architecture and direct the development of its requirements and technical specifications. So that’s where JASON...where they left it.

In the next slide, our preliminary recommendations around architecture are that...could we go to the next slide...there we go. That the industry should accelerate the current path of a loosely coupled architecture based on iteratively tested and proven standards-based APIs and data model standards that

support both document and discrete data access. That is maybe the most useful sentence in our entire report. We will come back to the details of that.

ONC should help shape and accelerate this process by assisting with converging industry stakeholders to define the minimum components necessary to loosely coupled market-based implementations. And ONC should not attempt to impose a detailed architecture on the market. ONC should help shape and accelerate this process by aligning and leveraging federal infrastructure and programs to support rapid development and adoption of these minimal components once they are defined.

In the next slide, you will see some of the fairly complex discussion that went on behind-the-scenes here. We felt that a monolithic architecture is just not feasible in the US market. I think with our group, our Standards Committee, that goes without saying, a top-down monolithic architecture is just not technically feasible or certainly not feasible from a business and market-facing perspective. And that the JASONs architecture is really more of an architecture pattern that will require a rich ecosystem of specific implementations to become useful.

We focus a lot in our recommendations here on this notion of loose coupling of multiple sort of compatible, but distinct implementations. This is not a change, this is what we do today. But the JASONs were sort of hinting of something a little bit more controlled than the loose coupling model of today and our group did not agree with that. The JASONs also talked about notions of a “virtual repository in the cloud,” in particular in the context of their providing data to the research community. And we would simply note that something like that would require much coordination and legal and business manipulations...agreements...coordination business and legal agreements above and beyond just the technological architecture. And I think the rest of these as somewhat redundant.

So let’s go to the next slide in absence...or in spirit of trying to keep moving fast here. Core clinical and financial systems, this is our phrase for what they referred to as “legacy stovepipe systems,” or I believe they used the phrase stovepipe legacy systems and I several times identified myself as a proud vendor of stovepipe technology. So, some of us took offense at that on the first blush reading the report, but I think if you’re understanding the context, it is not quite as harsh a judgment.

But they do say fairly boldly that current EHR and financial systems need to be replaced in order to meet the goals of the proposed architecture. They even focus on specific database technologies like MUMPS technology, and I think our group felt that that was an inappropriate level of detail for an architecture pattern governing higher level HIEs.

They focused really only on the data aspects of what EHRs do, not on the complicated workflow, order entry, decision support and orchestration functions of EHRs, so they have a fairly naïve view of what an EHR does and I think that colored some of their recommendations. So we note that as well.

They also pointed out that the current structure of the EHR market may be inimical to innovation. I think the phrase “suffocates innovation,” I am not sure if that is a direct quote from the JASONs, I think it may be, but that is a pretty strong phrase. And they felt that the current approaches for structuring EHRs and achieving interoperability has largely failed to open up new opportunities for entrepreneurship and innovation, something you will see in a minute that we took some exceptions to, this is their background.

So let's go through our recommendation on the next slide. We felt that the industry should accelerate the parallel paths of improving current document level encoding standards while introducing new standards for discrete data access APIs and the associated data elements that would be moved over those data APIs. And that the ONC should seek guidance from us on the Standards Committee and our various workgroups on the maturity of development of standards that would enable interchange of both document and data level data...document and data level APIs.

And the foundational API requirements for document and data level access can be reasonably included in 2017 certification to help launch an ecosystem for more robust API development and implementation in the future. So this is the debate that we were having earlier in our conversation on today's call about are there things we can do to get started as part of the 2017 edition certification that would get us moving towards this goal of joint document and data level access. And I can tell you that we aren't going to be definitive in that at this point either, that is something I think we can discuss in our discussion now and in the subsequent meetings of the workgroup. And we noted that focusing on standards-based APIs may open up opportunities for more of the modular certification that seems to be the preferred choice moving forward, after we have left behind the complete EHR certification set.

So, the discussion on this point was obviously pretty intense. In the next slide, a couple of the highlights are summarized here. We noted that the JASONS took a pretty narrow view of EHR functionality in that current EHR systems are more functionally sophisticated and technologically dynamic than the JASON Report gives them credit. Many of the functions that they call for in their architecture are already part of today's EHR environment including semantic and language translation services, data search and data indexing capabilities and even open APIs.

And to that point, many of the vendors who testified, in fact, all of the vendors who testified pointed out that they already have APIs and that they expose them for numerous third-party Apps to be integrated into EHR workflows to one degree or another. However, the vendors all had proprietary APIs, the three or four vendors that spoke with us all described vend...APIs that were specific to their own products. So the JASONS note that...the JASONS observation that there isn't a standard API is certainly consistent with the current market.

We also discussed that the demand for interoperability is growing rapidly and the supply side is responding and that the technical barriers, although challenging are usually eclipsed by the policy, legal, business and the sociotechnical issues around things such as licensing, access to the API, regulating who can use the API and for what purposes and so forth. And then finally, in our discussion, we decided that innovation and entrepreneurialism are best promoted by focusing on functional interoperability goals rather and open architecture through the standard APIs rather than on trying to prescribe internal software design of these core clinical the financial systems, a theme that you have heard us...you have heard me say before.

Next slide on APIs. This is really in some ways is the most important gist of what we are calling forward out of the JASON report. They basically have...the JASONS urged moving beyond, this is the API background, moving beyond C-CDAs to a more robust, data level public API. They quote here, "simply moving to a common markup language will not suffice." The common markup language would be the CDA approach. "It is equally necessary that there be published application programming interfaces that allow third-party programmers, hence users, to bridge from existing systems to a future ecosystem that would be built on top of stored data."

And maybe my favorite negative assessment of our industry, “at present, large-scale interoperability amounts to little more than replacing fax machines with the electronic delivery of page formatted medical records.” And you will see in a minute when I talk about our discussion is, we certainly took strong issue with that statement.

They propose accelerating this development through regulatory requirements, primarily tags to MU3, which in the time that they wrote this, was so far into the future that I think it felt like there was plenty of time to do all the work necessary, although we will debate this. Maybe that is not the case. And I think the other points here we have covered in essence of time...to conserve time, I am going to not drill into that.

So what were our recommendations, on the next slide, for the APIs...preliminary recommendations? I keep having to remind myself, these are preliminary, and we will continue to revise them. Number one, ONC and the industry should support and pursue the JASON call for development and adoption of published, standards-based APIs and data models for both documents and atomic data in a framework of legal, policy and business rules of the road.

Number two, to this end C-CDA refinement, the document encoding standards of C-CDA and FHIR for data level standards and the standards-based APIs should be targeted and accelerated through ONC contracting with existing initiatives and standards organizations for development of tight specification and implementation guides focused on specific high-value use cases and licensed for public use. ONC should encourage rapid public/private experimentation and iterative improvement processes as these APIs emerge to ensure that they work as intended. And these experiments should include uses targeting the primary areas that the JASONS focused on which included clinical care, research and population data, as well as exposure of data to consumers and patients through EHR portals. We also felt that standards development and certification should leverage existing industry and HITECH structures, where possible.

The debate behind this is fairly complex, this is on the next slide. I am going keep moving fast here, I apologize that it feels like I am just racing through this, but that is my time constraint. Open APIs are typically based on standards and are published and documented at sufficient level of detail so that they can be implemented without intervention by the source system. That is kind of our working definition of an open API. The JASON’s definition when they call it public API is probably going to need a little bit of additional clarification. I think we will probably try to nail down what we think public API means in our future work.

We also note that...trying to...the important ones. Yeah, I am going to just skip to bullet point number two. The growing industry adoption of standards-based API like HL7 FHIR, focused on these high value use cases is the most appropriate and sustainable task towards accelerated use of standards, data level APIs that we have identified. We got a number of discussions from the standards organizations and FHIR was the one that kept coming back as the most promising.

In particular, there was a good amount of discussion around at FHIR profiles, as Stan Huff mentioned earlier in our call today, as one way to deal with the semantic interoperability problem that the JASONS had assigned to sort of an ill-defined metadata translation service. We note that if FHIR profiles can be negotiated across users of an API, that you could radically minimize the amount of semantic mismatch because the profiles effectively pre-agree on the meaning of the message on the wire. However, this is

work that is yet to be done, as Stan pointed out, we need convergence towards those profiles before FHIR will be able to solve some of the semantic interoperability issues that the JASONs raised.

And as noted in earlier parts of our call today, we certainly agree that in parallel to any movement towards adoption of discrete APIs like FHIR, we need to refine document level C-CDAs to enhance their usability. So we absolutely do not see that data level APIs are a replacement for CDA, you need documents in healthcare. Documents capture the assessment of a patient at a point in time and they are perfectly capable, if well implemented, of capturing a lot of structured detail as well as narrative details that can't be captured in structure alone. So, we should...we certainly want to make sure that we are not interpreted as abandoning the C-CDA but rather supplementing it with an API that allows for drill into discrete data, where possible.

Next slide. I think I have covered most of these points, but I will touch on one important discussion that we had around the notion that APIs should not be overly proscriptive. So a well-documented API is in some ways almost equivalent to a standards-based API, not completely so, but very powerful, and we envision that if you have standards-based API that is supplemented by well-documented APIs, you could avoid the unintended consequence of an overly constrained API that isn't flexible enough to deal with emerging data access needs.

I think we will try to refine this in our final report to clarify what we are getting at here. But just to put it into my own words, we envision a core part of the APIs that would, in fact, be expected to be supported by everyone, but there could be the need to extend it around the edges for emerging use cases that would not be a part of the standard, but which would follow the APIs framework.

And then the final point of our discussion is we didn't like the idea of creating any new standard deeming or new kinds of certification bodies. What we would really rather see is some way to focus on enabling and facilitating the existing SDOs and existing private industry efforts at developing these standards. So you can see there, the last bullet point, streamlining current ONC certification for end-to-end testing through public/private iterative, agile processes is the best approach for testing and validation through certification. I see the 2017 edition crept in there, I am not sure that we are going to say that that is going to hold on our final discussion, because of the time tables.

So number...next slide, number five consumer access and control of data. I won't say a ton about this. The JASONs, when they wrote their report, they had the statement in there that the patients "own" their healthcare data. They got quite a bit of feedback immediately from numerous sources that that wasn't an accurate description of current regulatory laws...regulatory framework. So, they actually clarified and modified that statement to say that patients participated in the management of their data...their healthcare data.

But nonetheless, under whatever control the patients have, the JASONs called for granting fine-grained consumer control over the uses of their healthcare data. They use...they introduce a concept they call a privacy bundle to enable this consumer control. Privacy bundle would basically be common patterns that a patient could just pick from a pick list and say, I want to follow that pattern. And that that pattern would contain the details of exact fine-grained control that would match most patient's needs. But we note that these privacy bundles would require the equivalent fine-grained data tagging, provenance and segmentation to make the privacy bundles work. So, this concept in principle is very appealing, but in fact, there is a lot of work that would have to be done to implement it.

Let me go...that was background, let me go to our recommendations on the next slide. We said that patient facing EHR functions should indeed expose similar discrete data APIs as discussed for the clinical care and research needs. We point out that the Blue Button Pull Project, which is a little bit I think these days in kind of a state of hibernation, is a logical starting point. And if you expanded...early use of FHIR and OAuth 2, perhaps following the models of the SMART platform, open specification, that we could enable discrete API exposure via patient portals in a way that would really jump start some innovative approaches.

So we recommend OCR should help...HHS, OCR in particular, should help clarify the degree to which patients and consumers indeed control access and usage of their personal health data. Much confusion about the degree of patient control exists, I think as evidenced by the fact that the JASONs got it wrong, even though they were actually studying this issue in some detail. So even amongst experts, there is still some confusion.

Next slide, our discussion about this; we didn't go deep into the privacy bundle proposal, we were focusing our energies on the API and critiques of the CDA. But we certainly, as you saw in my previous slide, agree that consumers should have access to these APIs through the patient portals. And in particular, we heard from a number of patients and consumer facing App developers, what I am calling the mHealth App industry here, that there is a strong interest in gaining access to the patient's data via a patient authorization to provide services that go beyond what the portal provides directly.

The technical availability of these APIs would need to be accompanied by business processes to support all of the particular concerns that healthcare brings to the table around privacy, appropriate use of the data, data rights, liability and so forth. And then as I noted a few minutes ago, we felt like there is still a fair amount of confusion about the degree to which data access rights are carved out away from patient control through existing regulations like HIPAA and the Common Rule. As opposed to the consumer's right to have a copy of the data and their subsequent official, full control over access to their copy. So that confusion, I think, needs some clarification so that not...there are more people in the world than just a few that understand how that works.

Next slide, on research; again, we didn't go as deep into this as we might have liked. The JASONs seemed to assume, by way of background, that clinical and research and consumer access use cases were all essentially supportable by the same architecture. And they assumed that existing clinical data could be used for large-scale research purposes with a quote there that I will call out in what amounts to an ongoing clinical trial with over 300 million potential enrollees. So the JASONs vision was of essentially all of existing clinical data could be exposed to the research community. And they noted, or concluded, that the lack of EHR support for consistent data level API creates this fragmented research environment that is underutilizes existing clinical data.

So, our recommendation in the context of that background, was a little bit more tempered. We felt that standards-based...this is the next slide, by the way, slide 30, yeah, thank you, that standards-based discrete data APIs to improve researchers' access to routine clinical data should be strongly supported through both technical and policy development. We agreed with their recommendation to convene the research community to identify these use cases and the technical requirements and to align with existing data collection analysis structures and processes and existing legal and policy barriers...existing policies as well as legal and policy barriers and opportunities.

The research community should participate in decisions about where structured APIs can support use cases for research. And they should do so including the numerous initiatives where research is actively leveraging routine clinical data, such as work being done at Kaiser and work being done at numerous institutions using tools like I2b2. We also felt that policy work to address the regulatory, governance, and business barriers would have to occur in parallel to any work on APIs. So that the notion of 300 million patients participating in a massive clinical trial is obviously as much a regulatory, governance and business issue as it is a technical issue.

And on the next slide, the discussion that went in to those conclusions is documented here. I am not going to dive too deeply into this. We did note that the JASONs were really describing observational research, exploratory hypothesis generation kinds of studies. Because clinical data as captured in routine care isn't rigorous enough for full-blown clinical trials. And we had that pointed out to us by numerous of the panelists from the research community.

And in addition, we heard from CDISC and others that there are already pretty good standards in use for management of the clinical trial data and that any new APIs should certainly take into account the existing work that is underway so as not to disrupt something that is working well if it is already out there. We also, in the next to last bullet point, noted that they called for additional work on de-identification of research data and they aligned with the most recent PCAST report on big data that suggests consideration of regulatory framework changes that would focus more on the attempt to re-identify data than on the conditions of what constitutes de-identified data.

And that was driven by this awareness that protecting patient privacy gets more and more complex as more and more data is captured digitally. Because there will be so many cross-reference points that makes masking identity almost an impossibility. So perhaps the regulatory framework should focus maybe more on misuse of that data rather than on strictly trying to de-identify it.

Next slide, accelerating interoperability; this is where we get back to the discussion from this morning. They proposed that Meaningful Use Stage 3 is the primary lever to get to the vision of these public APIs. And we will just note that they made that recommendation more than two years ago or around two years ago when it Meaningful Use Stage 3 seemed like such a future consideration that that was an infinite amount of time.

Our recommendations, in the next slide, are that we should consider MU3, and by Stage 3, I think that we really mean the 2017 edition, as one of many levers to promote advancement towards the JASON goals. Especially because the 2017 edition sort of facing timetable does not appear to allow sufficient time for widespread adoption of discrete...of the standards-based discrete APIs at the core of the JASON's architectural proposal, certainly not in its full scope, perhaps some of the fast-tracked stuff that we talked about earlier today, but not the full scope.

The federal government should also align and leverage the other means at its disposal to promote advancement of the JASON goals, it is not just Meaningful Use, as Jacob and Steve pointed out several times in our call today. And ONC should immediately assess and implement, where possible, streamlined approaches for incorporating these new standards into certification, as we have been discussing all day.

And the next slide our discussion of these points. I think is now fairly redundant given that that we have talked about it a number of times today. I will just note that market demand for interoperability may be even more of a driver than the regulatory framework. So coordinating private industry agreements in

the context of rising market demands may actually be a faster way to get some consensus than waiting for regulatory processes to kick in.

So the next slide is our last step on the agenda, our next steps, and I am going to land here on the last slide here that we will get some input from you today. We got some good input from the Policy Committee last week, we have four additional meetings starting next week and will go deeper than that if we need to, to try to simplify these findings and remove some of the redundancy that you heard me walk through today. We will also do this promised cross-reference to the PCAST report and a cross-reference to the Interoperability Roadmap, to the degree that we can. So, I didn't quite land it on time, but I went pretty fast, so John.

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

Well, that was very impressive. So as I started the meeting today, what I said is, you would see the alignment of Dixie's recommendations and David's recommendations. Now of course, that was probably because David was there for both of them to align them. But, I think that it is so important that you read the JASON Report thematically and not as a word for word document. It is meant to have trajectories and trends and as was said by David, some of the things that it says were oversimplifications or over-generalizations.

So to me, what you have done is a masterwork, taking us from the generalizations of the JASON report and giving us some concrete recommendations, further driving us to look at things like FHIR as one of those over the wire API formats. So, I certainly want to open it up to discussion of the group and then I would ask, do we want a kind of formal reaction to it Jacob, or was this basically just to have a discussion amongst the Standards Committee members for ONC's benefit.

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

I think in the interest of time, we need to be concise in our discussion, but I think a discussion would be of value. I know that the Policy Committee really enjoyed the presentation, I suspect our present company did as well, so thank you so much, David. But let's have a quick discussion, I don't think there needs to be an explicit set of recommendations unless the committee is so driven to express that.

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

Okay, well hey Michelle, are their hands up?

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

There are and I just want to clarify. So the intent of today's meeting is to have a discussion, provide feedback to David and Micky if you are here, so that they can finalize their recommendations in October.

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

Very good.

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

So the first person up is Eric Rose.

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

Hi, I will try to keep it brief. Thank you very much and boy, this was really a fantastic, I think, synthesis and response to what was a very interesting and also at times very confusing report. The one question I have of David is, the biggest confusion I had when reading the JASON Report was the...there seems to be at times the report seemed to be recommending this kind of uber-architecture where the data...where clinical data would live. They talk about migrating...you have some quotes, “migrating from the legacy systems to this new architecture” and there is talk about the data living in the cloud and so forth. And so at times, it seemed like they were proposing an actual infrastructure where data would reside and at times, it seemed like they were proposing an infrastructure for flow of data between systems. And I just...I was wondering if having looked at it probably closer than I, and others on the call, if you or the other folks who were on this Task Force Workgroup could have any further insights into what it is that they were actually suggesting?

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

Yeah. That is a great question and we wrestled with exactly those concerns. And one of the caveats that I introduced way back at the beginning that we were unable to sit down with the JASON group and ask that question of them, limited us as well. So we had to parse our way through the document and try to come to our own conclusions.

One of the things that I didn't show you today that we will put in the final report is they have a diagram of their architectural pattern. And we have started the process of going through that diagram and kind of mapping each of the boxes on that diagram to either current or future approaches to solve for the diagram. In other words, map it to reality. And we will put that in our final report, and I apologize that we just didn't get it done in time for this one.

But the gist of it, I think you are going to discover, is that this notion of loosely coupled, standards-based APIs with appropriate business and legal policies in place around how you use those APIs is what we are going to draw out of this as being the really critical insight here. So to your question, is this more about persistence...where the data is persisted or how data flows, I think our conclusion will be closer to the latter, it is really about how data flows. And I think that is the gist of their report, as well. But, I will make sure our group dives into your question in detail because I think that really is the heart of one of the confusing parts of it.

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

Thank you.

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

Sharon Terry?

**Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance**

Hi, I agree with John, your comment at the beginning. This is one of the richest meetings we have had so far. David, excellent job synthesizing all of this. Two comments, one is with regard to governance, and I realize that is probably more the provenance of the Policy Committee. But I think we do want to make

sure that we are coordinating with one of the biggest projects that is looking at this probably is PCORnet, in terms of observational and clinical data and access and governance and those sorts of things. And there are lots of overlap, Dixie and I are both serving as advisors on various task forces, I am the Co-Chair of the Governance Committee for PCORnet, so I think we want to make sure that we are mapping to that activity as well. And Deven McGraw is also involved.

And then the second is the concept of the privacy bundle. As you know, there are live attempts at this, in part of the project that we are working on in the dynamic and granular data access sharing and privacy realm in context I think touches on this. And while I agree with you that it will be not easy to implement some of those ideas, I think there are pathways to doing so and we will want to make sure that those are at least considered when we are responding.

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

Yes Sharon, thank you for that, we did try to get some input from PCORnet in our hearing, I believe it was Sarah Greene spent some time with us so we recognize the overlap there. We were not able to go very deep into it in the limits of the hearing, but in our recommendation that we...that ONC to the degree that they coordinate this overarching architecture, needs to have the research community at the table to make sure that we don't replicate or duplicate unnecessarily. I mentioned CDISC and the standards around clinical trials, but PCORnet is certainly also one of the major efforts that we would want to synchronize with. So, I think you call out something important that maybe we should put a little more focus on this.

As...on the privacy bundle, I agree that there are some people out there doing really interesting work in this space, some of whom you know well. And the question in my mind is, to what degree does the consumer have realistic control over how that data is used? And how can we both clarify that and then structure it so that consumers have interesting choices. Because they have a copy of their data that they can do interesting things where...that today it is just too difficult, even if they have the legal right to it, it is just not feasible to build that database of your own data. So, I look at that as being a huge potential win in the long-run, but certainly one that requires careful attention to governance and probably a lot of education on both the provider side and the consumer side.

**Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance**

Thanks very much and obviously embedded in my comments are the idea that as we do move into this interface, as Kelly said earlier, with the consumer more involved. We are going to see some culture clashes, we are going to see some very different ways of doing business and keeping the consumer involved in this process as we go, is obviously very important.

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

Thank you.

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

So Michelle, others in the queue?

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

No, we actually don't have any other questions in the queue.

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

Oh my God.

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

We might end on time.

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

I put everybody to sleep...

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

So...question, David, what I think is raised by this discussion is you had Dixie and your initial presentation this morning suggesting a trajectory and allowing optionality along the way. You have the PCORnet activity, which its own set of architectures and standards. You have described a need to go to FHIR and the kinds of APIs and discrete elements. I just, after your now multiple presentations, it is just worth asking ourselves the same question I asked this morning? Is there a harmonious path forward that would get us to reduced optionality, FHIR-based APIs of some limited structure that could be accelerated if we all put our efforts and minds to it over the next 12 to 18 months?

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

Yeah, so this...David here, my opinion is yes, that would be doable with the right stakeholders and the right sense of urgency. Whether or not we need to do it and should do, it is a broader debate. I mean I know that I have gotten feedback from the vendor community, very...of two opinions on this, there is kind of bimodal distribution. Numerous ones in the industry really understand the limits of the current document-centric model, the XCA and moving CDAs around. But also recognize that is a valuable approach, that it does solve real-world problems and that we have invested an awful lot of energy and time into getting it to where it is, knowing that we still have some T's to cross and I's to dot to get it to work right.

But at the same time, a number of other of my colleagues just want to move forward and say, let's put these powerful fundamental models in place that FHIR gives us, which is simple RESTful manipulation of resources. And then spend the rest of our time arguing about what resources should be manipulated, because that is a much more facile and rapidly iterable discussion that can occur much faster than core API discussions. So, I think it can be done, the question is do we have the will to do it? And I think we do, but that is a broader set of decisions than I can represent from my own personal shoulders.

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

And as you said, the ACA and private HIE actually may be an even more important motivator than Meaningful Use stimulus or penalty, so I think you are right.

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

Yes.

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

There will be the combined alignment of incentives and the will to move forward as we look to a 2017 world of some constrained FHIR implementation. But of course, I will follow the wisdom of the committee so I hope today's discussion gave you a lot of food for thought. And Jacob, do you have comments you would make on David's presentation or should we move to public comment.

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

I think we should move to public comment in the interest in time and we look forward to the next iteration of this, David, and once again, great job. And thank you very much.

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

Thank you, Jacob.

**Public Comment**

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

Thank you, Jacob and thank you, David. And on that note, please keep in mind that the next meeting is on October 15. It is a joint meeting with the Policy Committee and we are planning a longer agenda than we typically do, so you will need to plan travel accordingly. We are thinking that we will be going until about 5 o'clock, so as soon as we finalize the agenda, we will let everyone know because that will affect travel arrangements. And with that, we will go to public comment. Operator, can you please open the lines?

**Public Comment**

**Caitlin Collins – Junior Project Manager – Altarum Institute**

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

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

We do have a public comment. As a reminder to our commenters, it is limited to 3 minutes and I will have to cut you off after 3 minutes, so my apologies in advance. Mariann Yeager?

**Mariann Yeager, MBA – Chief Executive Officer & Executive Director – Healthway**

Mariann Yeager, Executive Director and CEO of Healthway. Our comments pertain to the NwHIN Power Team's recommendations and actually similarly would apply to the JASON Task Force report. We rec...we agree with recommendations to focus on enabling query-based exchange and doing so by defining functions and by enabling multiple approaches without prescribing how query-based exchange is conducted. So our comments really focus on three specific areas.

One, there was really a disappointing lack of recognition regarding the significant adoption of query-based exchange in production today using existing mature national and international standards such as SOAP and IHE XCA, XDS, XCPD, PIX PDQ. And we recognize that all vendors may not wish to support

those standards, however, there really should be a stronger recognition regarding the extent and breadth of adoption today. As an example, the eHealth Exchange alone has nearly 80 participants with an additional 20 nearing production, representing more than 30% of all US hospitals, 10,000 medical groups who treat a hundred million patients. There are literally millions of query-based transactions exchanged each year, both within and between networks using these standards.

So really, industry has already embraced query-based exchange and it is important not to disrupt it. We believe that there should be more recognition regarding the level of production use of existing query capabilities and assure that there is more balanced support of both existing and emerging approaches in 2017. We have seen issues caused by radical course changes and need to learn from those experiences and also to the extent that there are new approaches being considered, to consider how to bridge between what exists in place today.

Second, we acknowledge that there is growing interest in using FHIR as it progresses towards a pilot implementation. It will take years to fully develop as well as long-term planning. We caution having national policy primarily focused on an unproven, although potentially promising approach. Anointing an unproven technology before it is ready for widespread implementation, and in the absence of having supporting markets would essentially increase costs, introduce burden and would unnecessarily disrupt current production efforts.

So we believe that emerging approaches should be properly vetted through real-world implementations with measurable evidence that they will work as predicted and that there is some level of demonstrated maturity and stability. In addition, there should be carefully coordinated and communicated industry-wide implementation planning that allows sufficient time to migrate without disrupting current production effort, with input from public/private collaborative effort such as Carequality. And finally, we believe that technology should be a tool for enabling interoperability policy, but should not serve as the policy in and of itself, as the recommendations suggest.

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

Thank you, Mariann. We have another public comment from Scott Brown from MyDirectives. Go ahead, Scott.

**Scott Brown – President & Co-Founder – MyDirectives.com**

Hi everyone, Scott Brown with MyDirectives. I just wanted to make a couple of comments on the NwHIN presentation that Dixie and David did at the beginning of the morning. In their presentation, they recommended that certified EHR systems have the ability to electronically query external EHR systems for patient medical records and patient clinical information. They also suggested that the EHR system should be able to delegate that capability to third parties.

We just wanted to call to the attention of the members of the committee that the recommendations we think to ONC should also include the ability to search for patient-generated information, such as advanced medical directives. We wanted the members of the committee to know that MyDirectives and CRISP, which is the Maryland HIE, are already using APIs just like John Halamka is talking about, to allow 15,000 doctors in the state of Maryland to seamlessly search for advanced directives via the Maryland HIE and MyDirectives. That means that if somebo...if something happens to a resident of Bothell, Washington, who is normally a patient of Evergreen and she is in Baltimore, her advanced medical

directives can be located and they can be retrieved and a secure dynamic link to those directives can be embedded in the provider's EHR in a matter of seconds. That is just one example we have others.

Other HIEs and hospital systems across the US, including the organizations of some of the folks on this call, in various stages of integrating MyDirectives into their EMRs, their EHRs, and their HIEs and so on. So real-time, seamless searches for advanced medical directives can be done, it is being done. And not just that kind of information, we are talking about preferences on organ donation, we are talking about preferences on hospice care, palliative care, all of these things that are consumer driven and not just data-driven.

Second, as I believe Leslie Kelly Hall and some of the other experts in the industry have demonstrated previously, the presentation of advanced medical directives within CDA is entirely possible and work is already being done to improve that process in the content encoding and the constraint standardization, which was another recommendation of the Power Team. We believe that standardization and presentation of advanced directives content in both CDA and FHIR will be completed long before the 2017 edition ever becomes effective.

So again, we would respectfully submit to the committee at this time to upgrade the status of advanced directives within the Meaningful Use standards. And ensure that we can...that we have the exchange of a consumer's voice, their values and their treatment preferences, if they ever should become a patient and not limit that exchange to patient data. Thank you very much.

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

Thank you, Scott and that is the end of public comment. So, thank you everyone and we will see you in person on October 15.

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

Thank you everyone and have a wonderful afternoon.

Meeting Attendance						
Name	09/10/14	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14
Andrew Wiesenthal		X	X		X	X
Anne Castro	X	X		X	X	X
Anne LeMaistre		X	X	X	X	
Arien Malec	X	X	X	X	X	X
C. Martin Harris	X		X	X		
Charles H. Romine			X			
Christopher Ross	X	X	X	X		X
David McCallie, Jr.	X	X	X	X		X
Dixie B. Baker	X	X	X	X	X	X
Elizabeth Johnson	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X
Floyd Eisenberg		X	X	X	X	X
Jacob Reider	X	X	X	X	X	
James Ferguson	X	X	X	X	X	X
Jeremy Delinsky						X
John Halamka	X	X	X	X	X	X
John F. Derr	X	X	X	X	X	X
Jonathan B. Perlin		X		X	X	X
Keith J. Figlioli	X				X	
Kim Nolen	X	X	X	X	X	X
Leslie Kelly Hall	X	X	X	X	X	X
Lisa Gallagher	X	X	X	X		X
Lorraine Doo	X	X	X	X		X
Nancy J. Orvis	X	X		X		
Rebecca D. Kush	X	X	X	X	X	X
Sharon F. Terry	X	X		X	X	X
Stanley M. Huff	X	X	X	X	X	X
Steve Brown	X				X	X
Wes Rishel		X	X	X	X	X
<b>Total Attendees</b>	<b>22</b>	<b>24</b>	<b>22</b>	<b>24</b>	<b>21</b>	<b>23</b>