



HIT Standards Committee Final Transcript June 24, 2015

Presentation

Operator

All lines are bridged with the public.

Michelle Consolazio, MPH – 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 a public meeting and there will be time for public comment at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. And the Hashtag for today's meeting is #HITSC. We encourage you to use that today to acknowledge some of our departing folks which we will get to later. And so to do roll we will start around the room. We will start with Jodi.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Jodi Daniel, ONC.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Arien Malec.

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

John Derr representing long-term post-acute care.

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

Dixie Baker, Martin, Blanck and Associates.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Liz Johnson, Tenet Healthcare.

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

David McCallie with Cerner.

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

Kim Nolen, Pfizer.

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

John Halamka, Beth Israel Deaconess.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Karen DeSalvo, ONC.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Jon White, ONC.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Steve Posnack, ONC.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Leslie Kelly Hall, Healthwise and Informed Medical Decision Making Foundation.

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

Martin Harris, Cleveland Clinic.

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

Lisa Gallagher, HIMSS.

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

Floyd Eisenberg, iParsimony.

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

Anne Castro, BlueCross BlueShield South Carolina.

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

Lorraine Doo, Centers for Medicare and Medicaid Services.

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

Nancy Orvis, Department of Defense.

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

And on the phone do we have Cris Ross?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I'm here.

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

Hi, Cris. Keith Figlioli? Anne LeMaistre?

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

Present.

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

Hi, Anne. Steve Brown?

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

I'm here.

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

Anyone I missed on the phone? Okay, I'll turn it to you Karen to make a few remarks.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thank you, Michelle and good morning everybody it so nice to be here and see a lot of wonderful familiar faces who have been working with ONC, many of them, for the last six years. But it is also a sad day because we are losing some of that talent from this FACA and I wanted to make certain that I had the opportunity to tell this Standards Committee how much I appreciate and value the work and the guidance that you give to ONC in this work that we're doing to see that every American has access to their electronic health information, that is the policy goal, and it is incredible how much progress we have made and that is largely due to the input and guidance that we get from both our FACA's but this one is so critical because it's helping us with this really central issue around working toward having a set of standards, and all the meaning of that, that allow market competition but still there to be fairness and some opportunity for the data to begin to move in a more seamless fashion.

So, today I know you are going to have a chance to talk more about your feedback on our Interoperability Standards Advisory as an example. This is a really important sub-regulatory way that we want to move folks into a place where we have a set of non-proprietary standards that we can all work from, that is going to see that this information will flow. But there is so much other important work that you are doing.

And I just want to specifically call out the folks that we are going to be...that are going to be rolling off. I do not think we are losing anybody, I hope that you will all stay as part of this family and that we can continue to call on you for advice and that you'll continue to be speak truth to us about what we're doing right and when we might be getting off track to help make sure that we are all rowing in the same direction.

I just want to acknowledge very specifically the folks who are going to be leaving us after...some after I think a full six years, maybe everybody has been on for six years, Michelle, of this group, so Dixie Baker and Anne Castro, Marty Harris, David McCallie, Stan Huff, Liz Johnson, Sharon Terry and John Derr, Derr, sorry. And just really appreciate all of your intellectual input and help and really look forward to continue to work with you guys as we go forward. So, applause for everybody if we could, thank you.

Applause

And I think with that...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Dr. Halamka.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Dr. Halamka.

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

Okay, well, so as you said, we are really at a fundamental change in the composition of the committee, I think it is Wes who said, as the committee composition changes so does the consensus. And what I hope is that if we look at the years we've had together, and I'll still be here through January, that we've set a trajectory. I think back in the HITSP days more than 10 years ago where the arguments we had is whether your XML was better than my XML.

We had arguments about LOINC and SNOMED, and UCUM, and all those arguments of 10 years ago don't exist any longer. So, of course there are always arguments and we can disagree with this or that congressional action but the nature of the conversation has fundamentally changed. And so now we are on a very positive trajectory of simplifying our standards, of encouraging ACOs and new forms of payment to flourish based on exchange of data.

So, even though our membership changes you hope that trajectory we've put in place continues and we don't reopen the old arguments and we just continue going forward to refine the standards that we need.

And I want to reflect just for a moment on the names of those folks that you just read. So, Anne has always been a champion of the provider and payer data exchange because as I was telling Karen it used to be that there was animosity between those two groups but I think we recognize in a world of global capitated risk the pie is fixed in size and we'd better work together.

So, this idea that we send labs and continuity of care documents, and clinical data between provider and payer is essential to care management and disease management so she has always had that view. It isn't just about administrative transactions. It's about patients, providers and payers working together.

Dixie, well, I tell you I have from Michelle a list of every Task Force, Workgroup and activity Dixie has ever been on its about three pages long here. So, what we could just say is that I'm the...I mean I love all children equally, but I am most sad about Dixie's departure because she is the person who not only provided us with some of our most detailed work products but always kept me completely honest.

I was telling Jon White that I do not speak at the 50,000 foot level I speak more at the 10,000 foot level and she is always at the 1000 foot level and that is so important because as we make regulation we need to be specific and so Dixie I certainly thank you for everything and I think so much of what you have done will carry forward especially in the world of FHIR and OAuth, and RESTful transactions because she's written some of the fundamental implementation guides that I think all of our vendors will use for years to come.

Dr. Harris, of course has represented the boots on the ground CIOs, the providers of America and so he knows the difference between under regulation and overregulation and is always able to look with that provider/implementer eye and give us good advice. So we certainly want to thank you for that.

David McCallie, well, David has to get the kind of praise that Dixie got because David, every call, every Workgroup, every activity in and outside of this committee he has fundamentally shaped the direction and we all have to look at what he did for the Provider Directory of America as an example of his talent.

We all have debated, as we'll do again today, oh, whether LDAP and HPD, and these other standards should be used in we've all argued they're too complex. Well, he got tired of the argument so he just wrote a provider directory for the country and he put it live on his laptop.

In fact it became so popular he had to move it to the Amazon cloud where he is now paying \$15.00 a month for the Provider Directory of America to be available. And of course it does not have every Direct address of every provider in America but it is an inspiration to us all of the kind of simplicity that we need to strive for. One person in a weekend and 300 lines of Python should be able to revolutionize America and we shouldn't require some giant, monolithic infrastructure. So, thank you, David.

Stan Huff, of course has been the champion of our vocabularies and recognizing that as we were on a discussion yesterday, one can't achieve interoperability unless we're all speaking the same language. And so understanding that interoperability needs to be beyond PDFs and I was going to say where's Stan.

W

...

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

Okay. That PDFs are not interoperability. I mean, it's a start, that's fine and patients and doctors who have a PDF can certainly do good but far better if we're going to do big data analytics and have a learning healthcare system to actually speak the same language and Stan is our constant champion.

Liz Johnson has always been the voice of implementation reality. I mean, that is she and I have to share some of the similar characteristics of I had to do the same certification that EPIC and Cerner had to do so I actually speak from that voice of experience following the regulations with 19 people that these organizations with 5000 people had to follow. She always told us, well, this is what is going to happen to the doctors and nurses in the field if you do this. Here is a good and here is the bad and so importantly has tested every one of those NPRM drafts against the reality of implementation so we thank you for that.

John Derr, has always told us that we have an ecosystem, it isn't just acute care hospitals and providers, it is a continuum of care where cure, palliation and hospice are all part of all part of good outcomes and goal-based care. So, his group of course has told us to always keep the patient at the center in every site and condition of care and recognize that there are other alternatives to downtown expensive ICU staffed with professors and those are absolutely going to provide the patients and their families with the care they deserve.

Jon Perlin, who is not here today, of course served as Chair of this committee for so many years and so we all relish his guidance and his political savvy and thank him for his contribution.

Sharon Terry, also not here, kept the genome and genetics in mind and we all know that as precision medicine advances Sharon Terry's contributions will become increasingly important.

And Jeremy Delinsky has chosen an interesting career change, so he is leaving our committee not because he hit a term limit, because he decided that consumer-facing Internet companies would allow him career growth so he has left the healthcare industry and is now going to ensure that e-commerce of furniture is done wisely with technical accuracy.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

In a standardized way.

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

And security and standards and so Jeremy of course during his tenure here represented an edgy, agile cloud-based advanced technology company, which as we think as service delivery across our country, I hope that all of us believe that Facebook, Amazon and Google can inspire the healthcare industry to embrace the cloud and mobile, and social networking ideas.

So that is the group and, you know, as I said, Michelle, to you last evening, this adult supervision has just left the building and it's sad and what we hope, as Karen said, there will still be opportunities to serve on Task Forces and that there will be wisdom gathered from this group going on and that the number of informatics thinkers in this country is relatively constrained. So, whether it's working on Task Forces or in the private sector on initiatives like Argonauts we are confident that this group of people will have influence for many years to come.

So I thank you all. There of course will be a lunch and an opportunity for celebration and reflection later this afternoon but in the meantime we do have an agenda. And that agenda is to hear from our various committees about the standards that will ultimately be recommended as the NPRM revisions are done, those that go forward and those that don't go forward, those that are ready for implementation and those that will soon to be ready for implementation.

And we recognize ONC has several levers that is has the lever of regulation but it also has the leverage of sub-regulatory activity and so we will hopefully provide advice in our role as FACA with all of the adult supervisors here to guide them through the next step.

And we'll also hear some foundational work from folks at ONC on the Data Access Framework and on the Interoperability Standards Advisory Document and its next revision. I think we'll also hear from Michelle on what we will do with our Workgroups transforming into Task Forces.

And I had a conversation with Jon White about the Precision Medicine Initiative and my advice to you all is that precision medicine now has real political visibility less you think it's going to be narrowly focused it actually can be somewhat broadly focused. Some of the things all of us have talked about, enablers such as governance, provider directories, patient identifiers, voluntary or otherwise, can all be discussed in the context of precision medicine. So, use that set of Task Forces as an opportunity to take us to the next steps of interoperability.

So, with that, Michelle, I think we have our agenda forward. And, you know, Dr. White hasn't made any opening remarks. I mean, do we want to give him an opportunity?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, something you should know about me is that I'm terrible at goodbyes. So, I will simply say this, I will share...

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

What?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

No. So, I will simply say this, I will share more at the end after we, you know, kind of formally close and then get together for lunch but committee work, you know, is like war long periods of boredom punctuated by moments of sheer terror and you all have experienced those over the years. It is hard work, it is grueling work, it is critically vital in its importance in actually moving the country ahead.

I cannot upstage any of the things that have been said about you individually. As one of the Co-Chairs of the committee I am incredibly grateful for each of your individual efforts and as a group over the years. It really is monumental work as you look back over it. So, I am incredibly grateful for the service that you've given.

And fortunately, since I'm terrible at goodbyes I don't have to say goodbye because this is Health IT and nobody ever really leaves Health IT. So, I will look forward to continuing to work with you in different capacities in the future. Thank you.

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

Michelle, I know you wanted us to approve the minutes of May 20th so if folks had an opportunity to review those minutes, any edits or changes? Well, no objections being noted the minutes are approved and we will turn it back to you.

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

So, we have a presentation from ONC, John Feikema and Dragon will be here to discuss the S&I Data Access Framework. I think is Dragon on the...

John Feikema – Coordinator, Standards and Interoperability Framework – Office of the National Coordinator for Health Information Technology

Yes, this is John Feikema, remote and I know Dragon is in person there. Thanks very much for the opportunity this morning to walk folks through what we have been focused on with the Data Access Framework. Next slide.

We're just going to take a little bit of time to go down memory lane and give folks an idea of how we got here but spend the majority of our time talking about the deep collaboration that we've been having with a number of SDOs and bring people up-to-date with where we are with those and also spend as much time probably talking about the relationship of DAF to other projects that are going on. So, next slide, actually two slides forward.

DAF really from the very beginning has focused on enabling providers easier access to the data within their organization and secondly within organizations that they are tightly aligned with or have a direct connection with. So we focused within those for the last two years on what we call the local DAF and secondly on what we call targeted DAF where there is an existing relationship between two providers and access to a patient's information is needed.

Within those two areas we looked at a variety of different approaches. Again, we see our job as largely to identify and extend, where necessary, building blocks and standards to make those available to the community at large so that they can be used for regulations, if appropriate, but also so that they can be leveraged by other organizations even in sub-regulatory and other open means. For example, a lot of the work we're doing with FHIR is being leveraged by the Argonaut Team and we're excited about that and that's exactly the kind of thing that we're trying to enable by identifying some of these tools and making them available.

And we'll go through this in a little bit of detail and talk about not only what the uses of these are, but the mechanisms that we went down this path trying to make sure that we could identify modular and substitutable standards so that we didn't have to create a monolithic profile every time we turned around.

On the next slide is really how we looked at this from a 10,000 foot level trying to make sure that within each of these vertical areas, local access, targeted and then the one that we're just about to launch, federated access or distributed access, the kinds of issues within the standards ecosystem that we needed to deal with making sure that we focused in on the query structure layer and making APIs available for data access, identify issues associated with the authentication and authorization just as an example.

And within those we also identified that there were some cases where data element access was going to be most appropriate and in other cases where a full document, a full C-CDA for example would be the desired target from a provider and those often required different kinds of standards and different approaches.

And they also led us to work with multiple SDOs. We've spent a lot of time working very closely with HL7 on our FHIR ID and we spent considerable time as well working with IHE on SOAP-based alternatives especially around the document-based query work.

So, that is kind of the overarching. As we get into the federated we'll be trying to put together tools that will enable initially the research community, folks like PCORI and PCORnet tools that they can use hopefully leveraging a great deal of the work that has already been done in the first two phases, but hopefully the standards that we put together there will have longer-term uses even beyond the research community, although that's our likely first focused target for that work.

Now I would like to turn the podium over to Dragon and let him walk you through some of the more detailed aspects, you know, the 1000 foot level stuff that is important to making all of this work.

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Thank you Feik. So, getting into a little more technical data, like Feik said, in terms of the overall initiative scope, like Feik said, we focused on the local access which is within the organization and then the targeted access which is from a single known external entity.

Also, you know, orthogonal to that we also focused on enabling both document access, like C-CDA, accessing C-CDA documents from data sources and also discrete data elements like, you know, problem list, medication list, demographics and so on and so forth. Those are like the, you know, bounding boxes that we went after.

What was out of scope is also equally important so we did not address the trust establishment between organizations for a targeted query or an external query. We also did not address the discovery of end-points, how end-points would be discovered across the networks, patient matching rules and algorithms that organizations may use before they figure out which patient data to return and the policies that allow or disallow the disclosure of patient data. So, we did not address those aspects of the overall initiative knowing fully well that there are other industry efforts and other ONC work that is going on in those areas.

Also, we took the modular and substitutable paradigm and decomposed what would be really required to make the Data Access Framework operational in the real world and came up with these building blocks which are essentially, you know, most of you are familiar with which is the transport layer, the security layer, the query structure, query results and the data model.

Each of these layers can be used and decomposed and reused across various use cases. So, we came up with these building blocks that we can, you know, leverage and specify implementation guides or profiles that we can take to different use cases. And the idea being each of these layers can be replaced if a better profile comes out, a better standard comes out without having to disturb the whole infrastructure. We call this the query stack and we refer to that as the query stack throughout the rest of the presentation.

So, using this building block model we built out three different query stacks that we use to enable the local data access and the targeted data access including accessing documents and data elements and the first one is what we call is the data access framework data element implementation guide. So, this is to access discrete data elements like, you know, problem list, medication list, medications and so on and so forth.

This is built on FHIR, using the FHIR profiles. So we developed FHIR profiles for each of the Meaningful Use Stage 2 data elements that were specified in the rule and those FHIR profiles are used as the mechanism to return data.

We also used the FHIR underlying mechanisms like the transport, which is HTTP. We also used the FHIR query mechanisms and search mechanisms, which is the FHIR search parameters and so on and the FHIR APIs. And the information model is also basically built on FHIR. So, there is not an information model outside of FHIR that we are using.

In terms of security we are using OAuth 2. The big thing there is, as all of us know, there is a lot of work evolving work in OAuth 2, you know, in terms of SMART on FHIR work, the HEART work and even within the IHE and other HL7 Workgroups. So, that is an area that is still evolving and it is not finalized as of yet.

So, this implementation guide basically allows both local access and targeted access for discrete data elements using RESTful approaches which is based on FHIR.

The next one that we created was basically using RESTful approaches to access documents and in this case we used what was developed by IHE called the mobile access to health documents. So, we used that particular profile from IHE and as you can see we are now basically using a FHIR-based RESTful approach with the FHIR resources plus the XDS metadata model that was already there.

So, we used the XDS metadata model and the FHIR resources in combination, which is already specified in the mobile access to health documents and that is essentially how this implementation guide is built out. So, this allows like both local and targeted access to get documents out of data sources.

And lastly, this is the third stack that we have kind of specified which is the SOAP-based. This is to bootstrap all of the existing implementations, which are using SOAP standards, which are based on XCA profiles, and again this is mostly a reuse of all of the existing work that the industry has invested in or vendors have invested in to kind of make sure they can be bootstrapped. It is built on XCA and SAML and SOAP 1.2, a little more complex to implement than the other two approaches.

So, those are the three query stacks that we developed as part of the implementation guides. And these were developed in collaboration with the SDOs like Feik mentioned. And the way we approached the SDO work, from the beginning we kind of worked with both IHE and HL7 to determine how we go about building these implementation guides.

So, the first artifact that we published was a White Paper working with IHE, basically doing an environment scan on what exists, what are all the profiles that exist, specifications and implementation guides that exist and where the gaps are.

So, coming out of that the big thing was we identified that we could use the mobile access to health documents profile for document access...we also identified that there a big gap in terms of data element access, discrete data element access.

So coming out of that White Paper we kicked off two different work streams, one with HL7 and one with IHE. The HL7 collaboration was basically initiated as a project to go develop profiles for all the FHIR resources for the data elements specified in Meaningful Use Stage 2. So, that is essentially the work that we went through, we put it out for ballot for comment in the fall of last year, winter of last year, we got the comments back, we reconciled them now, we have put it out for DSTU publication and we got the comments back from that and we are going through the reconciliation process. And we expect the DAF implementation guide to HL7 to be published later this year.

Similarly, on the IHE side, because we are reusing the mobile access to health documents from IHE and also the XCA-based SOAP stack, we created and implementation guide using the IHE processes and those collaborations, and again, that is in ballot right now and it will be published later this year.

A quick run through on relationships to a couple of other projects. The first one being Argonaut, which is, all of you know, is an industry led collaboration with very discrete goals in terms of advancing the mapping to C-CDA and FHIR providing security guidance for FHIR implementations and accelerating the FHIR implementation in the real world.

So, as part of that particular project some of the DAF content profiles, from the DAF data element IHE, are being reused specifically for example the patient, DAF patient profile is being reused and some conformance requirements around what such parameters to enable is being reused.

We are getting very good feedback from the participants and the implementers who are implementing these profiles, which are also part of the reconciliation effort and we are taking that into consideration as part of reconciling the DAF data element IHE.

The other project is the HEART Project. The HEART Project, again, is an MIT project with ONC as a committed member, again, the project's goal is to develop a set of privacy and security specifications, profiles to enable individuals to control access to their own data through RESTful protocols and they are planning to use OAuth 2, OpenID and UMA, and develop some open source reference implementations and profiles around that.

There is a lot of synergy that are occurring in terms of like discussions and mailing list chatter on aligning the SMART on FHIR work with the HEART work and hopefully that will end up in a good place where, you know, there is commonality in the core components of HEART and the SMART on FHIR work.

So, those are two important projects that we are kind of monitoring and trying to leverage the industry expertise to reuse their work as much as we can in DAF.

Lastly, the next phase, like Feik mentioned, we are looking at the distributed access across, as a next phase of DAF. The key finds being, you know, we are trying to send queries or query multiple data sources, so you are expanding the data sources from a single known external data source to multiple data sources.

You are also trying to enable the use for secondary purposes like Feik mentioned PCORI and PCORnet are research purposes. So, there is going to be a lot of policy work that will be required along with, you know, data model work that will be required in that phase.

This is also going to be leveraging many of the other work that is being done by the Standards Committee Workgroups like we want to leverage the work that is done in local access and targeted access as like the core composables and build out the orchestration patterns for a federated use case and see how that works out. So, that is coming up, it is not launched as of yet. So, we would like to hear your thoughts on that aspect of the overall framework.

And that is pretty much it. I think we are open for questions.

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

So, just a general comment that for those of us working on the Argonaut Initiative we've tried very hard to look at the DAF Foundation work and align it where possible. So, a number of us were on a call with Stan Huff yesterday regarding the CIMI and HSBC Initiative and I think our general feeling in the world of informatics is if someone has already created a foundational data model or an approach and you can just pick it and leverage it, the last thing we need are five competing initiatives. So, we have absolutely looked at the DAF work and considered it foundational to everything going forward. So, thank you.

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Thank you.

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

So, we did have cards go up in a certain order. Jon White?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you very much.

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

There you go.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you very much both Feik and Dragon for your presentation. I simply want to encourage the members of the committee to, you know, pile on, this is a time when we really need to hear about this, I mean, you'll hear about precision medicine later, but this is one of those things that kind of bubbles along under the surface with a lot of hard work that has been going, very proud of the work that our colleagues have been done.

And now is kind of when we need to hear about where you think this is going and if this is good of course adjustments that you might make because, as you might imagine, this could play a significant role in other things yet to come. So, I'm just encouraging your discussion. Thank you very much for your attention.

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

Thank you and we had Arien and Dixie.

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

So, first of all strong work, as you note we've been able to leverage some of this work in the Argonaut work. The general comment that I have or the general concern that I have and we've been having some off-line conversations about HEART for example and have the same thoughts with respect to distributed query.

It is important to make sure that the foundational standards development work stay in close concert with implementation. We've seen a number of examples over time and quite recently where a too enthusiastic approach to develop innovative approaches that go far ahead of the ability of data holders, of provider organizations and others to implement what's being developed means that we end up with shelf-ware.

One of the most unfortunate recent examples of that is some of the foundational Blue Button Plus work that promised to open via API access patient data via portals. I think we're coming back around to that with the Argonaut work, but it's an example of...that work wasn't lost, but it's an example of getting too far ahead of the implementers means that an awful lot of people spent an awful lot of time on work that never got incorporated into the real world.

My general feedback with respect to HEART and with respect to distributed query is to the extent that we have a community of interest who is interested in implementing it and where that community of interest includes the Health IT systems and provider organizations that are the sources of data and Apps that are the consumers of data then great, keep going, you know, keep running, you've got a community of interest who is there and ready to implement.

My suspicion is that the Health IT developers and provider organizations are frankly pretty head's down in trying to implement the Argonaut work and our observation in the Argonaut work is that we're still somewhat ahead of the ability of implementers to implement.

So, as an example we've had a lot of App developers and EHR developers implement DSTU 1 based FHIR without security. We've got a big work effort to get DSTU 2 implemented, a big work effort to get security in place and my suspicion is that this kind of implementation work, that kind of putting all of this stuff to the real-world test is the rate limiter in terms of our ability to make progress.

My great suspicion is that if you do a lot of upfront work you're going to end up like Blue Button Plus ended up with a lot of really innovative work with nothing to do.

So the general comment I'd have is find the community of implementers and by implementers I mean again the provider organizations with data who are willing to stand this up in the real world, the Health IT developers who support those provider organizations and the data users who do that and if you can't do it then my recommendation would be hold your fire a little bit and see if you can team forces on some of the foundational Argonaut work and other work that is frankly behind where you are but where learning from implementation and learning from the real-world will help you over time get to some of the additional innovations that you're doing.

So, you know, there's a balancing act of surfing right on the edge and doing foundational work just ahead of implementers. My concern right now, again, is that you are kind of ahead of the wave right now. You'll be on the flat part where you can't surf, I guess, to extend the metaphor.

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

Thank you. Dixie, David and Wes. Dixie?

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

Yes, obviously this is really good work and further I think it's a really good model for how ONC can be working with private industry at the more initiative level than these individuals all piling on. So, I think it's a really good model. So, I certainly commend you there.

I also was also pleased to hear that the first target for the federated access is the PCORnet and I have a couple questions that are both related to PCORnet.

First one of your slides says that the focus is on the information model for the network. And PCORnet already has an information model and it's based on the FDA mini-sentinel approach. And, I was wondering will you be placing that current data model or will you be harmonizing it some way?

And the second question is closely related to the first, the PCORnet approach is to perform these internal queries and to then extract the data from the internal systems based on their own internal data models that are being used, and to bring it outside and then to do a transformation into the PCORnet data model before then sending it to the coordinating center.

And so I was wondering also, there are two questions, are you going to change the data model, is your objective to I should say?

And secondly, will you be looking at changing that overall approach of doing the query-based on these myriad of data models that are working internal to one that really capitalizes on the standards that are available for exchange?

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Thanks Dixie. I think really important questions. Honestly, we have not had the technical level discussions with the PCORnet community as of yet. So, you know, I really cannot speak to what the approaches will be as of today.

However, we have looked at the PCORnet CDM, the common data model, and we have a mapping of it to the FHIR data model and how it aligns or does not align and where the gaps are in terms of vocabulary, content, data elements and so on and so forth. So, we have done the analysis but we have not taken it further than that saying, you know, we should take this approach or that approach we have not done yet.

So, I think going forward if the work continues, you know, then we will basically have to have those technical discussions with the PCORnet community and PCORI Institute to figure out what it is.

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

Well, I'm on the data working group of the PCORnet.

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Yes.

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

And I'd be happy to talk to you a little bit about that if you like...

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Yes, I appreciate it.

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

If it would be helpful to you?

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Yes, absolutely, I appreciate it.

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

David?

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

Thanks. So, I'm going to be a little bit more critical, maybe I'm the designated curmudgeon of the outgoing members and so I'll play that role up today and I want to be sure that you don't take anything I say as personal criticism because, you know, I've enjoyed working with you and with John, and others that are active participants in DAF in many other projects and have great respect for your abilities and your work.

But, I question why you're doing this? And the reason for this is you're doing work that's in the middle that's not sufficient to determine the lower level standards you've designated/delegated that to HL7 but it's also not sufficient to address the network aspects that are critical to making something like this actually work in the real world.

So, you're fleshing out an architecture in the middle that's not driven by a business model and it may or may not be relevant to somebody's business model but it is certainly going to confuse anybody who wants to go put a business model in place because it has this quasigovernmental imprint that it came out of a government process. So, I think it's actually harmful to do this and it's harsh to say that, but it's what I think.

So, you know, in contrast when you have a business-driven process that needs to go implement a standard they go figure out what they need, they figure out the entire architecture including the things that you've conveniently left out which are things like a trust establishment for targeted query, discovery of end-points, patient matching, patient identity and patient matching and then policies for data access. If you don't have those in place how can you do an architecture that will actually work and will scale?

You need, obviously, the low-level agreement on things like nomenclature and we've got existing entities that do that. You need agreements on things like FHIR but we've got very good process in place to do that.

What you need to make it succeed in the real-world are groups like Argonaut where people put money on the table and say there's a business case here to go do this work. That group may turn around and ask for help and seek input from ONC or from other groups but if you go and just invent it in the hope that somebody like PCORI will use it, it just seems like we're wasting...we're confusing the bandwidth, we're putting a lot more signal into the bandwidth that nobody maybe care to listen to.

PCORnet should drive their architecture, right? And if they come and say, we need help with this and come to HL7 or IHE and say "we don't know how to use FHIR to do this." Then let's all, as a community, react and help them. But to invent it up front and hope they use it doesn't seem like a smart use of things.

I mean Query Health is kind of the same way. A lot of work went into Query Health, to my knowledge, very few people use it because there was no business driver behind it. There was no need to be solved by widespread application of Query Health.

HPD+ we've seen the directory stuff, you know, an elaborate standard emerged because it could be written but in fact it didn't solve anybody's real world problems and is probably a distraction from the long run.

So, I just wonder what's the future role for work where you're doing architectures in the middle that are not dealing with the low level stuff that's the real reusable stuff and are not driven by the top level, business case that makes it make sense in the markets. And by business you know what I mean is the business infrastructure across our industry not a particular business, but, you know, a market-driven case I guess is a better way to say that.

So, it is not a question it's really a rant and I apologize for the rant, but that's my rant.

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

Well, I mean, I can make just a quick introductory comment to smooth out the rant which is to say, I think DAF was started previous to a lot of other initiatives. So, I look at it as it was work that was initiating what is now a business-driven set of use cases and we're leveraging their work going forward.

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Thanks, David for these comments, really appreciate your critical candid feedback there. You know with respect to...I'm assuming most of your criticism is on the phase 3 of the future work which is related to the distributed/federated queries is that accurate?

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

Yeah, but even your targeted query, I mean, you know, I'll take CommonWell as an example, when CommonWell put together their network architecture, I was working obviously with CommonWell, we had to solve the patient identity thing first.

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Yes.

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

That led to a bunch of decisions about how to manage identity across a federated network. We had to decide on a trust approach next and that led to a bunch of decisions on how to do trust. Then we had to decide on how to do the brokering of a federated query to fan out and fan back in, and then finally, we got around and figured out, well, let's use a particular query tool to get the data from...sites.

The easy part was the last step and we took advantage of the fact that there was XCA out there and that we knew a number of vendors had already implemented so it was a reasonable thing to subsume but we wouldn't have used it if it didn't fit the needs of the network. So, it's the needs of the data sharing network that drive the architecture rather than the existence of a standard that somebody has worked on.

So, I would question even the value of the targeted peer-to-peer query. I think those things will emerge and people will figure out how to do them but they'll be driven by some business driver and it will have to have solved for the identity and the security and trust which may change the architecture.

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

I think Jon White may have a comment related to this?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes. So, as always genuinely appreciated and that was the kind of feedback...it is part of the kind of feedback I like the detailed stuff too, but, you know, the big level of where are we going with this. So, we need to go probably a little bit further back into the origin of this to talk about that.

So, the Affordable Care Act created PCORI, okay and it created a PCOR Trust Fund. The PCOR Trust Fund, 80% of it goes to PCORI, 20% goes to HHS, of that 20% 16% of that goes AHRQ for dissemination of patient centered outcomes research findings and 4% goes to the Secretary managed by the Assistant Secretary for Planning and Evaluation for development and dissemination of a data infrastructure to support patient centered outcomes research. Okay? Funding for DAF, okay, flows from that 4%, okay, so at the time, when was it initiated Dragon I can't remember?

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

Maybe '13.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, yeah.

Nagesh Bashyam (Dragon) – Independent Enterprise Systems Architect

In the fall.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, at the time there was a gap that was recognized that we didn't have this kind of thing so that's why this has been moving forward in the way that it has. John Halamka's comment is spot on, it's that it's really kind of been trying to move the conversation ahead.

I'm open to different ways of kind of, you know, taking what we've got and moving with it in different places that includes working with PCORnet, I'm open to other things too. So, that kind of feedback. But that's where it came from. Does that help the perspective?

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

Well, no, I mean, I understand the funding channels and that's helpful, that's knowledge I didn't have about that particular channel, but the fact that Dixie who is working PCORnet innards and has never heard of this work and its relevance is telling to me that it's a disconnect there that just because you organize a meeting and standard's goers show up and write standards doesn't mean a damn thing. I mean, we did that...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes, well...

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

I mean, we did that all the time and it wastes all our time.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes.

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

I know they were asking for exactly this kind of thing when they launched PCORnet.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yes. So, that is also an equally good point. So, here's what I would say, and the folks who are working on DAF are going to smile as I say this, so there was an initial outreach to the PCORnet community to try to engage with this and everybody is so dang busy, it was just like, I can't, I don't have time and so there has been a renewed effort, a significant renewed effort to go out to the PCORnet community.

There was a steering group meeting a couple of weeks ago, Ed Hammond has been plugged in now and is engaged with it. So, really as we get to this next phase, we want, we need really, not just the PCORnet researchers but other people who are interested in this kind of thing to be engaged with it moving ahead and helping guide it.

So...but, I mean, it really truly has been at a point...it's not necessary because that information hasn't been there it's because the, you know, the fire hydrant has been opened so wide that, you know, people's bandwidth has been...

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

But one shouldn't have to shop your standard around. If you've got a standard looking for somebody to use it you probably aren't doing it the right way.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Fair enough.

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

People should invent your standard because they need it and come to you and say help us standardize our business process because we're struggling because we don't have a standard here. That will succeed but if you've invented a good standard and have to shop it around, you know, it will get into our standards advisory list but that doesn't...there is a lot of stuff in there that no one will ever use or nor should they.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Will Rogers of the HIT...

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

Right.

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

So, for an elaboration of David's thinking I highly recommend you look at my Blog post, which he wrote, on June 10th of 2015 which is entitled "standards alone are not the answer for interoperability."

So, again, you know, he is not, Dragon, trying to be critical of any person, he is simply saying that as we think of encouraging interoperability in this country it's a combination of factors which include an urgency for interoperability, a guiding coalition for interoperability and governance, and enabling infrastructure and other things.

So, we think, you know, over the last 20 years as all of us have been involved in the standards making efforts it is certainly not sufficient to create a standard and hope they'll come. So, we are running a little bit behind so let me just ask for quick comments from Wes, I think Arien put his card back up, did I see another? And Nancy. Wes?

Wes Rishel – Independent Consultant

Let me first say that I am in the process of recovering from shock because until about 7 o'clock this morning I thought I was coming off the committee today too either that or they just didn't want my picture that's the other possibility.

In thinking I was coming to my last meeting I have done a lot of thinking about what have I learned and most of what I've learned, and I think I speak for a lot of the people who have been on the committee these six years, is the complexity of the ability to achieve interoperability. The standards are never perfect. There is regulatory driven implementation of standards does not seem to be able to allow for the evolution of the standards on a rapid cycle that allows them to be right and you can take this all the way back to the HIPPA transactions and farther and see this same pattern.

The advice from my much more knowledgeable and committed colleagues, in the six-year club here, that you can't get too far ahead of implementation is another way of saying the very same thing.

It has struck me that no standard interface has worked unless both sides of the interface have a business reason to see it work. And then it works regardless of how good the standard is because we work around.

And I've felt, for a long time, that we could artificially create a business interest through the Meaningful Use incentives that, you know, the build it they will come, the flaw in build it they will come has always been getting them to do it, what you've built, if you use Meaningful Use incentives then you can get them to implement and if they do one then they'll do many, that's the theory we've been operating under.

And we've found some difficulties with that approach and they're the same difficulties that I think many government agencies run into in regulation which is to say in the end they can't shut the industry down. They can produce regulations as strict as mandated by congress but in the end they're going to take the blame if industry shuts down, the people who write the regulations.

And so our ability to use Meaningful Use incentives or disincentives as a hook to get people who don't really have the business interest in interoperability to do it has had limited success I think we've had some but it's very limited.

The other thing that I think makes a difference is when you try to do standards, get interoperability with a group of 100 screaming monkeys versus seven chest thumping guerrillas and so some of the standards that we most rely on, in the technical infrastructure, like distributed SQL came the seven chest thumping guerrillas route rather than the 100 screaming monkeys.

And I don't know the specifics of Argonaut and I'm sure that a lot of people are piling on, but I'm delighted that we've got some of the baboons together in a room and they seem to have a true business interest in making it go.

I don't understand how an agency like ONC can function in the government world and then say "oh, well let Argonaut do it and then we'll regulate it." But if anyone in the policy world can figure that out I think we can make a lot more progress and I'm not specifically talking about Argonaut or even FHIR, although I share everybody's hopes about those things. I'm talking about finding a way to get interoperability through economic dominance of the business leader without giving over ultimate control to a possible monopolist. It's a very tough walk to hoe but hoe to...whatever it is, never mind.

M

...

Wes Rishel – Independent Consultant

Yeah, right, but it gets a lot worse if you perturb the words. So, anyway, I've...this is my six-year club speech, thank you.

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

Thanks very much Wes and Arien, and Nancy.

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

So, I would note that Stan and I did a bunch of hard work with an S&I Task Force at the request of ONC and we put together a framework with recommendations to ONC for how to convene S&I-like initiatives, that framework specifically addressed the notion of initiatives that are justified because somebody wants to fund them and concluded that this alone...that maybe an indication of national interest, but that alone is not a reason to go forward with an initiative.

It also made recommendations in terms of establishing a coordinated set of national priorities and funding in priority order. It also made specific recommendations of not doing initiatives that did not have a community of interest and enablers, a network, as David notes, behind it.

So, I don't know what the status is in terms of ONC's ability to accept the recommendations that we made as a committee, they were formally recommended by the Standards Committee, but Stan and I and the members of that Workgroup put an awful lot of thought into those recommendations. We made them for a reason and believe that ONC should indeed align its policy with those recommendations.

Clearly, ONC is able to ignore those recommendations, but we did put them in place for reason reflecting a lot of the thoughts that have already been expressed.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Great, do you have time for a quick response from Steve?

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

Absolutely.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Sure, Steve Posnack from ONC. So, we are processing through those recommendations which are and have been very valuable. I think as Jon alluded to as well, we can't retrospectively apply them and so, you know, this is a case where investments have already been made, contracts have already been, you know, let, and to the feedback that we've already received, I think we're in a process right now where in recognition of those recommendations and the other industry efforts that have sprung forth since this project was initially launched, finding a way to converge the two efforts in a way that the government resources that are already committed can help amplify and support, and react to what the industry is doing now, you know, we don't want to be out there on the sidewalk hocking a standard just because we funded one. It wouldn't be wise investment of your taxpayer dollars, you know, from our perspective either.

So, to the degree that at the point now where we're able to pivot and we're able to converge with other activities that are accelerating close to where we are if we are ahead based on other people's comments where there could be a natural point of convergence in the investments jointly that could be made from the industry and us that will be of I think great value and interest to us.

And the work that we have going on right now is, you know, the provenance of it or the origin of it is primarily focused on supporting the patient centered outcomes research work. So, that's where we hope that there will be a community of interest and as Jon mentioned earlier, Jon White, sorry, I'll just be specific, you know, that's where we are attempting to re-engage with folks since, you know, prior efforts had fallen a little bit flat in terms of everyone's busyness.

But I think it's a fair point and overall we are still working through the processes of going through the recommendations that were issued before which were pretty sound in our opinion.

I was joking with Arien earlier that, you know, agile for us is four months. So, you know, we're still in that timeframe and, you know, there will be more to come on that as we have an opportunity to look at our current model for how we engage in cooperative and collaborative industry initiatives and then how prospectively going forward we can attempt to infuse the recommendations that you all provided with our kind of go forward execution style.

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

Thank you. Nancy?

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

Just a notice that I was really grateful to hear the status of the Data Access Framework, a lot of work has been done and I think it's been valuable that all of these different entities said we're not connected and we need to converge.

And a personal observation as a provider and trying to get HIEs to...I think there's been some stasis on where do HIEs go next and how do they exchange information? So, perhaps one of the business focus areas is to refocus this effort and help it look at what are we doing to ensure a continuity of care, a continuum of care across so we...and how are we going to do that so that we reduce redundant ordering of services. That will affect patient outcomes.

But the driver to me is what are provider organizations...are they going to go retest somebody because they don't have the information and if not do they have it so they have a fuller picture and can order a new course of treatment?

So, I'm thinking the driver, I think for...our participation in these HIEs is to ensure that this continuity of care, the information is getting to the providers so that we don't have to retest that patient or can move onto the next stage of diagnosis and treatment or better outcomes. All right.

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

Thank you. Well, let me just quickly summarize because there were a lot of comments around the room and I think if we were to offer feedback to ONC from the perspective of hindsight, it's 2015 looking backwards at the last decade, that the role of government in 2015 may be different than the role government was a few years ago and in fact today those enablers may not be the government as standard's maker. It may be the government as convener or making sure that business has mutually aligned self-interest for interoperability and data sharing to provide us with a governance framework or enabling infrastructure.

So, those are the sorts of things...I mean, I think we just reflect to you that we've all had enough experience around the room to know that just convening a whole bunch of people and creating a standard is probably, as we go forward, not sufficient that is we hope that government provides us with some of the enablers and we may see some of the standards making activities shift to other groups like the private sector.

Well, let us make sure that Chris Muir has plenty of time for his presentation which I promise will be less controversial. I looked at the agenda today and I thought, oh, there is nothing that will generate controversy.

So, thanks, John and thanks Dragon and we will hear next from Chris Muir on the Interoperability Standards Advisory update, which as you guys may remember, is non-binding and the Task Force that will be created going forward to ensure that those interoperability standards advisory sub-regulatory activities are wise. Thank you, Chris.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Thank you very much John I appreciate it. As John said, my name is Chris Muir I work at ONC in the Office of Standards and Technology. I've been asked to come here and talk to you today about the public feedback that we received from the 2015 Interoperability Standards Advisory and also to talk about the next steps as we work towards publishing a 2016 ISA.

So, let's see, see how we advance this...okay, so I'll start off by giving just a little bit in the way of background on the ISA just to provide some context setting for the rest of my slides.

About one year ago we started developing the interoperability roadmap and we had talked to a lot of our stakeholders and various groups and one of the common themes that we received from the stakeholder feedback is a need to have a list of standards and implementation specifications that would enable interoperability for a learning health system.

At the time the only thing that we really had was a list of standards and implementation specifications in regulation in relation to the certification program supporting Meaningful Use and we felt like that wasn't adequate, our stakeholders didn't think that was adequate. So, therefore the need for something like ISA became a requirement within the roadmap and it was within the standards building block. ONC decided to take ownership of that based on our mandate and so we published the first version of the ISA, the 2015 ISA, and published it at the same time as we did the interoperability roadmap. We had a period of time in which we received public comments.

The advisory document itself is not only a list of the standards and implementation specifications but also it spells out a process in which we will follow in order to continue to develop the ISA, to refine it, to expand upon it so that we can work towards that interoperable health learning system.

So, as John mentioned, the ISA is non-binding but it is our anticipation that those who develop regulations, those who are writing certification programs, those who are doing procurements and other program activities will look to the ISA as they develop their interoperability requirements, that is governmental and nongovernmental.

We hope the advisory will provide clarity, consistency and predictability for the public. And we acknowledge that the ISA does not yet represent the full spectrum of standards and implementation specifications that are required for the learning health system but over time following the process, getting stakeholder input, that we will incrementally get there.

So, now on my next several slides I'll talk about those who provided public comments and a summary of what they told us. So we had...we received comments from a total of 59 people or organizations that represent a diverse set of stakeholders, 32% were from those that provide Health IT capabilities, examples are like EHR vendors, HISPs, HIEs, 29% were from those that delivered care.

So, we received comments from entities like Mayo and Kaiser, but also from very small, you know, single doc people as well, 13% of the entities were research or quality organizations, 12% were from those that certified, govern or provide oversight, these are organizations such as EHNAC, Healthway and the State of Minnesota, 10% were from entities that develop standards or implementation specifications, entities such as IHE and HL7.

We had one entity that supported the public good but didn't necessarily fall into any of the other categories and then finally one organization where its main purpose is to pay for care. And interesting enough we didn't have any organizations or people who, you know, were like patient advocates or consumer groups and so that was kind of an interesting side note from my part, because, you know, we hoped to hear from some of those.

So, of the 59 entities that provided public comments we did a lot of analysis in looking at the comments and the entities and try to decide whether or not they were supportive. So, this is just based on our analysis, but we felt like 32% of them were supportive to some degree or another. We felt like 8 of them were not supportive. And then 19 were neutral and let me describe what neutral means in this context.

So, there were kind of two buckets in which the comments would fall into to become neutral in our categorization here, one was that they were so balanced and neutral in their comments that we couldn't tell one way or the other that if they thought the ISA was a good idea or not.

And then the other bucket was that we really actually received comments but they weren't related to the ISA at all they were commenting on Meaningful Use, they were commenting on the HIT strategic plan or the certification program or something else but they were not commenting on the ISA and so we put all of those kind of just into that category.

Of the eight that were not supportive I just want to kind of give you a flavor for those, 50% of those for of the 50% were from providers, provider organizations or individual providers and some of the feeling from was that there were a lot of federal requirements already, they didn't really understand how the ISA might be used and so they were kind of fearful of it and, you know, that was what really generated their feeling of not being supportive.

There were three of the eight that came from HIT vendors like EHR publishers and those kinds of things and they felt like the ISA might stifle innovation. So, just to kind of give you a feel for all of them.

So, in order to kind of summarize all of the comments I put together some bullets here. There was a lot of interest to expand the scope of the ISA. There weren't a lot of consistency across those comments with the exception of two areas, the biggest being security standards, you know, we heard a lot that the ISA really should have included security standards.

The other one I'll mention just briefly was that we also received some comments about administrative data within the ISA. We had specifically said that we weren't including administrative standards within the ISA and that was because CMS has responsibilities, statutory and regulatory responsibility, for administrative data and they are our sister organization. We didn't want to publish anything that may become out of sync or conflicted with what they were doing.

We do agree administrative data is very important. We will look for ways in which we direct people to the CMS standards and we'll have a dialogue with CMS over time about how we keep ourselves aligned with each other, but that was something that we weren't ready to address at that time.

We received other suggestions that included, they wanted us to provide definitions for some of the terms that were used in the ISA and in fact of all the terms that they suggested we actually have definitions for those but they are in regulation and some other documents within ONC we didn't think to include those definitions within the ISA but that was certainly something that we can do and we'll certainly consider doing.

We also had some suggestions about providing additional information about the standards. Things like providing version numbers or a level of maturity or testing tools that might be available and a lot of times that was manifest in terms of them suggesting making changes to the tables that were within the ISA.

There were a lot of comments about the criteria for best available and about the overall process of the ISA that was very helpful. Also a lot of interest about the ISA telegraphing future changes to standards and implementation specifications and what I mean by that is that it was really in the context of, you know, the ISA being annual in nature and they were worried that there would be surprises on an annual basis and so if there were standards that we were looking at into the future that weren't ready today but maybe ready in a year from now or two years from now that we go ahead and identify those and let people know that those are out there and likewise if there were standards that we're thinking out retiring that we also list those there as well or indicate on the standards which ones we feel like might be retiring.

And so anyway that is kind of an overall view of some of the comments. You'll remember within the ISA we had a section, Section 5, in which we asked a list of questions, we were hoping to get feedback on those specific questions during the public comment. The first handful were overarching questions related to the ISA, I decided to summarize some of those for you.

So, question 5-1 it was about the characteristics that should be considered when including best available and determining best available. Seventeen entities provided suggestions. There weren't a lot of consistency across those, as a matter of fact, there was very little consistency at all.

But I'm going to give you just a couple of examples of the things that we did receive. So, some of the things that they suggested we consider, we should consider whether proposed standards are compatible with other standards already in the ISA. Consider whether a standard reached a certain threshold of adoption. We should consider whether there was an active maintenance process to support the standards and also consider whether there were testing tools covering those standards.

On question 5-2 on whether there was a standard category missing. Twelve entities provided suggestions. The most common suggestion, of course, was that the security standards were missing.

And again, on the security standards I think we might have talked about this in the last meeting, I think Steve might have mentioned this, but the reason why we didn't include the security standards was that security standards are not healthcare specific and there are a lot of entities and tools and things out there to provide direction, but having said that we received a lot of comments, you know, about the importance of security and everything that we do as kind of job one for everyone in the health field or Health IT field making sure that the information is secure. And so that is certainly something that we're going to have the Task Force look at and something that we're considering.

Let me see, moving on, 5-3, what purposes were missing. Again, we received 23, twenty-three entities provided comments on purposes, there was very little consistency and, you know, almost none at all on people advocating for certain purposes but having said that there were a couple of things that we heard, one was there were a few people that suggested that ONC develop an ontology for purposes, so a logical framework in which all of the different purposes would fall under as we were working towards the learning health system.

Another theme that we saw, at least a few people talked about, was organizing the ISA around use cases so kind of the AHIC model where you identify a use case and then you list the standards and implementation specifications necessary to enable that use case.

On question 5-4 about what specific standards or implementation specifications were missing there were again not a lot of consistency but one of the things that came from that which was related was that there were some implementation specifications, well let me say it another way, some of the standards should have been listed under implementation specifications and the one that received the most comments like that were the IHE profiles. A lot of people, including IHE suggested that we had that category as wrong and we should move it over into the implementation specifications.

Let's see, moving along, so these slides were really meant just to give an overview of the public feedback that we received. Obviously, we are continuing to analyze it, we are going to have the Task Force help us to look at them in more detail as they address certain questions for us.

But I think the major takeaways from the public comments include when you look across all the public comments I think there is overall support for the ISA looking at the different organizations that commented and then the representation that they have behind them. I think there is a lot of support for the ISA and for the goals that we're trying to achieve.

The feedback was all over the map. There weren't very many cases where there was kind of a mandate by the preponderance of the comments to do certain things there were a few of those but not very many. And so there needs to be additional work through the Task Force and other means in order to understand and know what needs to go into the 2016 ISA.

But overarching themes include an ongoing interest in the transparency of the ISA process and making sure we have widespread stakeholder support. Predictability of using consistent standards balanced by the ability to innovate and make sure that we continue to improve on the technology that's being used.

Obviously, a concern for security, I've already talked about and also in the interest to expand the ISA to further support the roadmap as we work towards the learning health system.

So, in the next steps I'm going to talk about the 2016 ISA process and also about the ISA Task Force. So, we are just concluding the May/June timeframe where we obviously received the public feedback and we've been doing a lot of analysis around that feedback. I'm providing you a summary of that today and we are launching the ISA Task Force.

In August the Standards Committee can anticipate receiving recommendations from the Task Force at its August 26th meeting. You in turn will process those comments and provide recommendations to the National Coordinator.

In September ONC will update and create a draft 2016 ISA based on your recommendations and we will put that out for public comment. And then in the November/December timeframe the comment period will expire, ONC will analyze the public feedback that we received and make changes to the ISA and then we will publish the final 2016 ISA.

I provided...oh, yeah, one last thing, the Task Force, I wanted to talk about the Task Force. So, you can see the charge to the Task Force there, but the first Task Force meeting we anticipate will be on June 29th so just about 5 days from now.

We have our two chairs Robert Cothren from the California Association of Health Information Exchanges and Kim Nolen from Pfizer who is obviously a member of this committee. The confirmed members we have to date are Calvin Beebe from the Mayo Clinic, Janet Campbell from EPIC, Lisa Gallagher from HIMSS, also a member of this body, LeRoy Jones from GSI Health, Eric Heflin from Healtheway, Anne LeMaistre from Ascension Health also a member of the Standards Committee, Arien Malec who is also a member of this committee from RelayHealth Clinical Solutions, Paul Merrywell from Mountain States Health Alliance and Pete Palmer from MedAllies.

So, now I can talk about my two hyperlinks, so I've provided two hyperlinks here for your convenience, one is to the 2015 ISA and the other is to the public comments. So, we actually posted all the public comments that we received. I think it's a good idea to take a look at some of those and see what different people and organizations...what they've said to us. I think it's very instructive and very helpful and so with that I think the time is yours for a conversation and comments.

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

Great, well thanks very much. So, I think the tension that we face is some standards are suitable for purpose and mature, and should go into regulation if regulation is a way we wish to, as a policy matter, go forward with standards. Some are directionally appropriate and sub-regulatory guidance like this is very appropriate and some should never see light of day.

And I think the interesting thing you'll hear in the next set of presentations is just because there is a use case and just because there is an existing standard doesn't mean that it should be listed in sub-regulatory guidance and that's the sort of interesting tension where the Dixie Baker standards maturity model can reflect in, you know, looking at that sub-regulatory guidance like, oh, not ready for prime time, probably never will be ready for prime time, let's leave it out of the standards advisory even though you may have to leave a gap or a blank in the standards advisory for a use case.

Now David did you put up your card again? Okay, so, David, Leslie Kelly Hall, Floyd, Wes and Dixie Baker, oh, no Wes, okay. So, Dixie Baker. So, David?

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

So in continuing the role of retiring curmudgeon, first off I appreciate the transparency and the report out on the comments that's really great to hear the follow-through on stuff like that.

My concern is something flashed in my mind when I was listening to this, there was a famous letter written to one of the major computing journals in the 60s by Edgar Dijkstra, a well-known programmer, where he wrote "go to considered harmless" or "harmful, go to considered harmful." And he was criticizing a design aspect of the FORTRAN language, that was a go to statement, and he said "this is harmful to our profession." And his comment triggered a revolution in the way people design programming languages to eliminate the need for this thing "go to's" that are considered harmful.

So, I'm going to say, ISA considered harmful and the reason for that is that I think since, you know, in line with the conversation we had in the earlier session that standards should follow other drivers that listing a standard in absence of those other drivers is...creates the impression that the standard is sufficient and it leads to regulatory approaches which don't work because the regulatory approach picks a standard from the list of approved regulatory available standards and adds it and says therefore we're done.

So, you know, standards are necessary but not sufficient. That's the blog post that John mentioned, that was sort of the lead thought there.

I think standards follow business purposes but they don't drive business purposes at least not the kind of standards that were talking about here.

And I think that in healthcare if you have to go and consult a list of standards to figure out how to solve a problem you're probably in the wrong business because healthcare is so complicated you're going to have run across these standards, the ones that work, just by understanding the problems that you're trying to solve.

It seems extremely unlikely that a developer is going to go find the missing standard by consulting a list if they are a serious player in healthcare. So, I question the value in the long run of the whole notion of ISA.

Now on the other hand, something like the value set authority, where we collate the value sets, the code sets that we should reuse in exchange as part of our semantic interchange I think that on the other hand is quite valuable.

So, there's a line somewhere where listing of these things and referencing them for the industry to share is important. I just think that most of the standards in the current ISA list are, you know, probably most of them don't belong there, most of them have never been and will never be used and putting them in that list could be harmful. That's all...on the other hand I'm very encouraged by the committee, the Task Force that you guys have appointed will make good suggestions to you. You've got good leadership and good memberships so I'm encouraged by that. Thanks.

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

Thank you. So, David tells us "do no harm."

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

Do no harm.

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

Okay. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, thanks, Chris. I wanted to find out if you used the overarching comments that was received on the interoperability roadmap to somehow inform your work? Because there were large bodies of consumer groups that responded including our Consumer Workgroup and the FACAs that responded specifically to the interoperability roadmap not to the specificity in the advisory because we felt that there was opportunity to inform and lead, and guide that work without having to get to that specificity.

I'm concerned if there's a disconnect between this because consumer groups are largely going to respond to overarching themes with a level of specificity that does not get to the granular here but has important directional statements.

So could you speak to if that information was used because I'm aghast that your statement that there's been no consumer interaction or patient involvement in this.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Yeah, and well a couple of things that come to my mind when you said that. First of all, I actually am working on both the roadmap and the Interoperability Standards Advisory and when we meet in groups to talk about either one of them we also highlight the things that we heard from...so when I'm meeting with the roadmap team we highlight the things that we heard about the Standards Advisory and vice versa...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

There are those kinds of things. Certainly these efforts we're working on hand-in-hand.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

We have a lot of overlap in staff that are staffing one versus the other and so there are those kinds of things.

Also within...I should say within the ISA even though there wasn't a specific organization that could be considered a consumer group or whatever, there were a lot of comments that talked about patients and consumers and their needs and I think to a certain extent we're all consumers and we're all patients and some of those comments did come through just not necessarily from the people we had anticipated.

But to your point, yes, we definitely are looking at the comments that we received from the roadmap and concerting that we're developing and refining the ISA.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, thank you.

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

Floyd?

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

I want to thank you for the presentation and I look forward to the Task Force and recommendations. I guess what I'm a little concerned about when I see the presentation you just gave there are numbers of how many responded to what but I don't see enough analysis for me to understand what people are really saying. All I see is not consistent but what were the comments about?

If you could tell me 50% support “x” and 50% don’t and here are the reasons I have substance to listen to. I’m kind of concerned that there’s not enough information here about analysis to really understand what was stated and that’s concerning. So hopefully the Task Force can address it but I just don’t think we have enough information on the comments to really comment at all.

W

...

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

I don’t know. What are our rules of order Michelle? I don’t think we...even though Clem is the Godfather to us all...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

I was going to say, Clem, what are you going to do...

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

We can actually get a public comment from him during the public comment period.

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

Yes.

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

So, let me make a note of that. I’m sorry, Clem. It’s the Robert’s Rule of Order thing. Anyway, so, any feedback on that? I mean, maybe the answer is that the comments were so scattered and diverse they were hard to categorize and that we hope the Task Force will create more concrete conical recommendations.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

That is true but also I do have a whole slide deck that I have for the Task Force that really drills down into each of the individual things, but John really did summarize it pretty well. They were pretty scattered so there is going to be a lot of work.

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

So, I think in the Wes ontology you will get a few baboons rather than screaming monkeys. I love that Wes, we got to love him. Dixie?

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

It's my turn. First of all I'm glad to hear I wasn't only one who noticed that security was omitted from the list. And I wanted to respond to ONC's view that we have no healthcare specific standards. I would agree that most security technology standards are general technology standards as they should be because the security should be implemented low in the stack if possible, but there are exceptions like the ASTM E2147 for audit and accounting of disclosure. And HL7 has confidentiality codes and it has the act consent type value set. So, there are specific standards.

And further there are certainly implementation guides that are healthcare specific that translate standards into healthcare specific implementations. I would point out that Direct is an implementation guide of SMTP and SMIME and also the Argonaut, SMART on FHIR authorization profiles are implementation guides of standard security standards. So I don't think you need a Task Force.

I think it's obvious that there are some healthcare specific standards but there are...and will continue to be an increasing number of implementation guides that are healthcare specific.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Okay, thank you.

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

And Wes your card was up and then down, is it up again?

Wes Rishel – Independent Consultant

It's back up again.

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

Okay, yes, go ahead, Wes.

Wes Rishel – Independent Consultant

All right.

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

Oh and then Lisa.

Wes Rishel – Independent Consultant

So, I'm responding to the responses. David made a very direct and important comment about the value of the ISA and I have had occasion to work in support of government agencies where I was working directly with a government agency and it wouldn't be beyond my experience to say that sometimes these documents carry weight in the internal to the government negotiations or meetings that take up 98% of these people's time.

Suppose that's true and there is some value that as a special concern that the ISA not be promiscuous which is to say that it not contain things that pro forma meet some standard that's been published by a standards organization or something like that but doesn't meet the Dixie Baker criteria.

And responding to Leslie, the area of support for the patient in the work we do is important and has been...has resulted in some of the worst outcomes in terms of policy attempting to drive standards whereby creating regulatory incentives but not where the entities that we regulate experience business incentives not that there is a one of them, a provider anywhere, that doesn't recognize that better engagement with patients would improve their health outcomes, not that there is very many, any of importance, that don't recognize that the data belongs to the patient or at least a copy of the data belongs to the patient.

But that our work product based on those policy imperatives has not led to an actual on the ground improvement and most of the providers I talk to feel very concerned that they don't know how to get the patient's to become interested in their data other than getting their lab report online or something like that.

There is this exceptional group of people with chronic diseases who are reasonably capable in terms of dealing with esoteric information, but they don't create an economic resource and until we work with the consumer groups to create that economic driver, I think we are in danger of spending a lot of time creating specifications for patient engagement that look good, that meet all of the criteria of a good standard, but don't have that drive to implementation to get it done.

I figure by making essentially a statement that poo-poo's the importance of the consumers I can get off this committee faster.

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

Well with that Lisa Gallagher and Lorraine and then we will move on to our presentation.

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

Hi, Chris, this is Lisa Gallagher from HIMSS. I just quickly wanted to mention that following up with Dixie's comment, Dixie and I did work together to create a list of security standards that we suggest be included in the initial version and interestingly enough they're not healthcare specific they're basic security standards and I think they're applicable in widespread use in healthcare. So, they're both in the HIMSS comments and in our comments to the document from our Workgroup. So, thank you.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Thank you I saw that and it looks like a lot of the work has been done for us.

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

And Lorraine?

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

Hi, Lorraine Doo, and I think that I heard the comment right that it was...someone was proposing that a version of a standard be one of the recommendations that you all adopt a version is that right?

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Yeah, that's right and maybe that we add a column where it is specifically spelled out which version, yes.

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

Right, so I'm your sister on the administrative transaction side or administrative standards side and from our personal experience I can suggest that this might not always be the best way to go because you are then stuck with that version of the standard so that when you are ready to go with something new and adopt it then you are stuck with that. So as a new version comes out you may not be able to use that because of the regulatory process. So, it's something to consider if you are indeed looking at using versioning. Sometimes it can leave you behind.

Christopher Muir, MPA – Senior Advisor – Office of the National Coordinator for Health Information Technology

Thank you.

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

Leslie Kelly Hall. Now everybody is feeling cantankerous today I don't know if it's something in the water or it's the humidity or the thunderstorm, the barometric pressure, or the fact that they are departing and their risk is gone, but, yes go ahead.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm not departing but I want to respond to Wes. So, I think Wes the question is which standard. We are looking at bringing things like OAuth and Internet standards to healthcare. They are the most consumer friendly standards that we have and stating that standards can't apply to the consumer seems ludicrous.

Now, when we're mandated to use existing healthcare technology standards to open that up to the patient we're in a Catch-22 because we have to look at something that's mature and usable, and apply it to a totally new stakeholder who has been disenfranchised, removed, in fact, the curtain has never been lifted so there has been a void and it is impossible to manage voids.

And so we're inviting people into the void or the black hole and saying manage this with us when it hasn't been there in the past. So will it be difficult, will it be dark, you bet. So now it's how do we meet these worlds and combine these two worlds of very consumer friendly standards to very non-consumer friendly health information technology world.

I'm encouraged by the work in FHIR, I'm encouraged by the work that we're doing to try to include the stakeholder and so have we had bumps in the road, you bet, I'm still kind of shocked that we can't do secure e-mail with patients that's pretty known consumer standards and e-mail really didn't come out of healthcare it came out of the rest of the world.

So, there is a tension and a challenge of which standards are used to apply, but under the principles that you stated that every provider wants to do the right thing for the patient and aren't we just all patients, we haven't done a really good job being all patients and advocating for visibility and access, transparency and influence.

So we do have an obligation if me or others are representing patients on committee's in government to say how do we make that black hole more visible? How do we open it up? Because we actually are the stakeholders with the most at stake, it's our health, we don't understand it, we can't communicate, we can't coordinate.

A chronic care patient today is the new normal with multiple chronic conditions and no one else is helping them to coordinate care, no one else is helping them manage the potential 14 physicians an average Medicare patient in the last 10 years of life have, we've failed.

So, we either adopt the patient...adopt the healthcare standards and try and make it usable to these stakeholders or we impose consumer standards to healthcare to make it more visible.

But we have a moral obligation to include the patient as an equal participant in healthcare and where information is, that's who rules the day and so information is power. So, another rant, David, another rant. Sorry, Chris.

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

We have passion today.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We have passion today. So, and I know that Wes you are very active in contributing to patient advocacy and I don't mean to attach you personally. I just simply state that there is a tension between these two worlds and one body of thinking is use existing standards and apply them to the new patient stakeholder and that's difficult, right?

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

Okay, and so, unless this become Shana Alexander and James Kirkpatrick maybe one closing sentence and then we must move on to our presentations.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Make it a good one.

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

Mr. Kotter, Mr. Kotter.

Wes Rishel – Independent Consultant

So, first of all I agree with almost everything Leslie said, virtually everything Leslie said. Where we...and I applaud work that Leslie and folks who focus on this area do to make healthcare standards more accessible to consumer technology, I think that's the best...one of the best things that can happen.

But, in terms of going to the stage of what we've attempted, in my six years, we have tried to take on, through regulation and through proactive prospective standards development, the challenge that the healthcare industry has which is to engage the patient and every time even as in critical areas as this, when we get ahead of the business incentive we stumble so that's my one minute, thank you.

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

Well, thank you for the passionate comments and the most...of course all of the meeting today is very important and it's about celebrating everybody and thanking everybody, but we wouldn't do our duty as a Federal Advisory Committee unless we offered very specific advice and we do have for our next set of presentations that very specific advice in effect following the Dixie Baker framework of what is ready for prime time, what is not ready for prime time and what will never be ready for prime time. So, with that I think we move onto Rich Elmore and Content Standards Workgroup.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you, John. Can we advance the charts, please? So, and one more. I'd just like first to thank and recognize the members of the Workgroup. We just had an outstanding group and you've heard and seen more detailed feedback from this team in prior updates to the Standards Committee, but, so first of all thanks we're very much appreciative of all the great work that was done, and you can advance once again, we previewed for you last month those standards that we thought would be the ones that we thought would be recommended for adoption. Move forward one chart, please.

Starting with clinical quality measures, the HQMF and I'm not going to get into descriptions of the versions but just to give you the headlines, common clinical dataset using, you know, SNOMED and Consolidated CDA standards as specified below.

The Workgroup, kind of despite the relative immaturity of FHIR thought it was important to go as far as we could go in regulation to specifically call out FHIR with the idea that, you know, the ability to gain consistency in the use of APIs across various clinical systems that would be subject to the 2015 standards and beyond would be very helpful.

So, the recommendation was to kind of despite kind of the failure maybe on the maturity screen, that there were other offsetting value considerations that meant that we should try and emphasize use of FHIR as part of the API access. Quality reporting, QRDA have obviously been in standards and that is making forward progress with some new versions. SNOMED and LOINC latest versions.

Consolidated CDA, a slight change from where we were a month ago. There has been additional work that's been done that it does look as though version 2.1, which is presently being worked, will address some of the challenges related to backwards compatibility. So, we think that if that can be ready in time it is a maintenance kind of improvement on Consolidated CDA that we think will be helpful and beneficial to Health IT developers to go in that direction.

Our recommendation is to certify only one version of Consolidated CDA, no interim period with two versions and further I think you may recall that the Workgroup had recommended that we limit the set of templates to CCD discharge and referral.

We think that there is refinement still needed for the identification of food substance, reactions, intolerances, labs and medication order entry that we think is worth addressing.

And one of the things...I think to the earlier comment about versions and not getting stuck in, you know, regulation in a version...and we'll leave this really to ONC and to the regulator experts, that the recommendation from the Workgroup was to encourage a method that allowed us to specify, you know, maintenance updates to be included as those progressed kind of beyond when the regulation is published we think that we can all stipulate that each of these standards will have things which are wrong that need to be righted and we want to make sure that we've got, you know, an orderly operating mechanism for moving the industry forward not in big ways but in refined ways that will continue to improve and hone the standards. So those were the standards recommended for adoption by the Workgroup.

And then the last chart lists a set of standards where the general view of the Workgroup was that, if you could advance one more chart, please, these were not ready for adoption at this time, those included clinical decision support, data segmentation for privacy, electronic sending and medical documentation, the virtual medical record, the quality improvement and clinical knowledge data model or the QICK data model, the electronic delivery of service and the NCPDP formulary and benefit standard.

Now it's important to note that the Workgroup felt that all of these areas were important areas, important use cases, important areas to be addressed in some cases the thought was that perhaps an API approach, RESTful approach may...an innovation may allow us to have new ways to address some of these use cases and in other cases it may just be a matter of time before the standard reaches a level of maturity where we could recommend adoption. So we did not try to get to that granularity in this report out, but in any event those were the ones that the Content Standards Workgroup thought that were probably not ready for a standards recommendation. So with that I'll stop, hopefully return some time to the Standards Committee and take any questions when you're ready.

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

So, Rich, just one quick question on slide one you say QRDA is appropriate and on slide two you say QRDA is not appropriate and I just want to clarify is that because they're different use cases for the same standard?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I'm just looking for the QRDA is not a...

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

Virtual medical record you note QRDA DSTU release 2 US realm is not...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, I think it is specific...I think it was specific as it related to the virtual medical record. So, QRDA, the recommendation of the Workgroup was that it was at a level of maturity to be able to be considered for adoption.

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

I just wonder if we might want to...and Floyd may have a comment on this, look back at that because it doesn't make any sense. I don't know how the virtual medical record would be related to QRDA. So, I wonder if there was another standard? Floyd.

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

So, I was on the Workgroup and there are two issues that I have one is that on the recommended, unless my recollection is off, I thought we suggested QRDA category one release 3 which is now published on the HL7 website because that does have updates that correct some errors that were noted earlier in the release 2 with the 2014 errata.

And I thought that's what we agreed to if not please correct me, but there was nothing about QRDA relating to VMR in our discussion. I think it accidentally added in as a sub-bullet but it was not part of our discussion that I recall.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

That's correct.

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

So, thanks for that clarity and then one other question for you Floyd, which is, you and I have had a lot discussions about HQMF and just, you know, in the Dixie Baker notion of ready for prime time is HQMF one of those directional standards or is it really ready for use?

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

Interesting question currently in HL7 there is movement to move...in fact there's a ballot coming up in October for moving to a FHIR-based electronic clinical quality measure, eCQM, representation and report whether that report will be in September I don't know.

But, I am aware of commercial companies that are using work that has been done in HQMF to represent measures they create themselves to share and also to implement within their own systems the measures that come from Meaningful Use. So, there are people who are using it. Is it ready for prime time with the r2.1 release, it is still a little bit problematic, but I think it's getting closer. I guess that's a decision that folks have to make.

But a lot of this is moving quickly in HL7 the question is I don't know that folks...the reason we didn't recommend some of this in the NPRM or comment on is it's moving so quickly, things like QICK the data model and the newer FHIR work that it's just not stable yet.

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

Steve Posnack did you have a comment?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yes since there were at least identified either some oversights in the accuracy of the slides that they would be corrected before they got submitted to ONC.

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

Okay.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Just process-wise, yes.

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

Right.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

That would be helpful.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

We'll do that.

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

And in fact Michelle has noted that we actually need to, as a group, forward recommendations to ONC and therefore we need to approve these and so what I think we've seen thus far is that there is a correction on the first slide that is it's going to be release 3 not release 2 of QRDA and on the second slide there is an extra bullet point that just simply needs to be removed. And then I think we didn't really stratify, in any of our Workgroups things into ready today, probably ready tomorrow, never will be ready.

And so I think what we can see in these two slides is we have clarity of what isn't ready clearly. I mean, these are not recommended but on the ones that are recommended, as Floyd just said, there are some that are pretty ready and those that may be ready and that's going to take a differentiator. ONC will need to look at regulatory versus sub-regulatory guidance for those things that are unstable and still in flight. And I know we have comments from Dixie Baker and Arien Malec and Leslie did you have your card up?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think I got it answered.

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

Okay. So, Dixie Baker and Arien.

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

Well, this follows along with what you did, it's not clear for me what our recommendation would be but I would say that anything that is DSTU 2 including...and FHIR none of those are really ready to become national standards at this point. So, you know, I don't think we should recommend them to become, as big a fan as I might be of FHIR, it's not ready to become a national standard at this point.

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

Arien?

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

I have a question with respect to the question for the first slide of recommend for adoption. In what context is HQMF being recommended for adoption?

When I looked at the NPRM my understanding was that HQMF was sort of packaged in HeD which is not recommended for adoption. So, I'm having a hard time triangulating the first slide to what we're actually recommending.

I wonder, if Steve, if you can comment in terms of HQMF and what it would mean for us to recommend for or against adoption of HQMF with respect to recommending against adoption of HeD?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Floyd do you want to comment on that HQMF usage?

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

I mean, so would you like Rich to comment maybe first?

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

Yes.

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

Yes, so go ahead Rich and then we'll turn to Steve.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I was going to ask Floyd if he cared to respond to Arien?

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

Okay, Floyd.

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

So, from our discussion it was HQMF for expressing the measures but not HeD for expressing decision support since there was not adoption. HQMF is used to express measures today whether it's fully implementable was the question John was asking.

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

The question is, this is not a recommendation for the Standards Advisory, this is a recommendation for certification criteria. So, what would be the certification criterion that recommending HQMF would be attached to?

And my understanding is only certification criteria that it would be relevant for would be relative to HeD which we're recommending against.

So, I'm just trying to get clarity on what are we certifying? What are we asking EHRs to certify against or health information technology modules to certify against?

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

Well, I wonder if there is actually decoupling between this representation of a measure and then decision support against that measure. I mean, I think we all know that it is certainly true that in clinical practice that we would like to measure quality and have decision support so we provide good quality care but they could be decoupled.

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

Yes, and again, no objection to people wanting to use HQMF to represent clinical quality measures for whatever purpose. The question is what's the certification criterion that we're proposing inclusion of that includes HQMF as its standard or implementation specification?

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

And Steve, do you have any clarity there?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Having looked at it I believe it's integrated into the QRDA category 1 as a basis for how the measures are structured related to QRDA category 1. The write up that we have is that the September 2014 errata reflects updates to the implementation of QRDA category 1 consistent with QDM-based HQMF measures, I'm sorry, I'm repeating the acronym, release 2.1 which is the relationship between HQMF and QRDA 1. But there wasn't a separate proposal as far as I can find in a quick search of the PDF that we...

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

Yes...

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

In isolation referenced HQMF on its own.

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

Yes, so I'm just...I don't think there's a certification criteria that we detach any endorsement of or non-endorsement of HQMF to.

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

Very good, so, because I know in the interest of time we do have to hear the other presentations, but I think what we is the following notion is that is there is a slide where there are, these are standards that are ready or could be ready and there needs to be further decision-making on that. We are not specifically saying, you know, that something that is just a DSTU is going to be certification criteria requirements it's maybe too early that becomes sub-regulatory standards advisory kind of guidance.

And then there are those that we specifically recommend against and the amendments that have already been offered, release 3 and the redaction of the QRDA you mentioned on slide 2. Any objections to moving forward with those?

Okay, well very good, thanks, we will move forward with those recommendations and prepare a transmittal letter.

So, next we have Mitra who is going to tell us about semantic standards.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay. So, I'm Mitra Rocca, I work at FDA, I am a Medical Informatician at CDER Office of Translational Sciences and I am presenting today on behalf of our Co-Chairs, Becky Kush and Jamie Ferguson, who are overseas. And these are the members of our Workgroup and Stan is also here and he is one of our Workgroup members and some of them might be on the phone as well. So, these are timelines and our tasks that was assigned to us since we were established.

So we also reviewed Dixie's paper that published in JAMIA in detail and the metrics that have been adopted by your committee and so they are for the maturity criteria there are multiple criteria and then for adaptability criteria those three areas of implementation, areas of operation and intellectual property.

So after reviewing the paper our Workgroup develop guiding principles for the standards that were assigned to our Workgroup to rate. So, as Dixie also just mentioned, so one of the first principles is if the standards are in development, for example DSTU draft standards for trial use, then by definition they cannot be high in maturity. FHIR profiles, application access APIs fall into these categories.

Then if they are standards where they have shown a successful pilot then we assigned maturity and adaptability level of moderate or medium.

Then one of our colleagues from NCI he recommended we need to consider the relationship between the target desired level of adoption versus the current level and consider other barriers to adoption, for example associated infrastructure when rating adoptability.

Then there are some standards that don't meet the national standard criteria or definition but they are in regulation, ICD-10 CM and ICD-10 PCS fall into this category their transition date is October 1, 2015 but they are already specified in HIPAA regulations.

And then UCUM is not widely adopted but it is the only game in town that is the only choice to standardize units.

Then it can be good to focus on items in isolation but when considered in combination or in broader context they may be problematic. LOINC for example for labs, CPOE has been successfully isolated in instances but there are still major barriers to broad adoption.

And then using this criteria and the definition of attributes based on the paper from Dixie, so standards not listed as high and high should not qualify for designation of national standards except as noted. So, we have footnotes on some of them.

So the first one is CDT which is code on dental procedures and nomenclature and we went through the NPRM one by one and we assigned a maturity and adoptability for each one of those categories. Yes?

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

Why don't we stop here because several of us who previewed this slide...

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Yes?

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

Think that we actually might need to send these slides back to the Workgroup.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay.

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

And let me explain why. This doesn't make any sense.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Oh, okay.

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

And that is to say it is mature in this context but is not mature in that context when the only difference is the wrapper in which we are sending the package, right? If the vocabulary standard is widely adopted and familiar, who cares what package it's in?

And so Dixie, I know you had comments and Arien, David you had comments...I mean, because we're going to go through these but I have concerns about this entire presentation. And I know unfortunately Jamie and Becky aren't here so we can't get their feedback.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Yes.

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

Dixie, Arien, David any comments?

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

Yes, I just want to...I could just clarify that when the Nationwide Health Information Network Power Team put together these criteria we had a discussion about suitability for use and that is not among the criteria.

We concluded that a standards readiness in terms of implementability and maturity is orthogonal is whether it's suitable for that particular use and I think that this assessment perhaps gets those two confused and may reflect your Workgroup's assessment of its suitability for the proposed use rather than its maturity and implementability.

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

Are the other members of the committee who would comment just using this slide as an exemplar to say if CDT is a lovely vocabulary it's perfectly fine in CDA but not fine in FHIR. It makes no sense. Nancy?

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

One of the questions I get in my organization a lot is...a lot of people and software implementers get confused about are you implementing it in this format? Message format and content, they have really...they have a lot of trouble getting terminology standards separated out from where they're used to seeing it or where they want us to tell them to put it. So, that's...CDT for example, dental terminology we use. We're probably expecting to see it in the claims in an X12 format at this point.

W

It has been adopted code set.

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

And Stan did you have any comments on this?

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

Yes, yes, I can...I was a semi-active member of this committee but...and we may have been wrong but the thinking has to do with in fact the maturity which had to do with how often...you know how is it used and so terminology in a sense, you know, I understand what you're saying but, you know, you could think that if SNOMED was being used for problem list that's great but nobody in the industry was using that somewhere else, you know, so it's not so much about the terminology but if you say is it ready for adoption does it meet the maturity criteria in that context it doesn't not because the vocabulary isn't ready it's because nobody has experience or has been using that in that particular context and so that's the thinking whether that's flawed or not I don't know, but...

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

Well the context isn't ready but that doesn't mean the standard is not.

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

Right.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Yes, right.

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

That is what's gotten confused here is you're really rating the context is not ready.

W

Not that a lot of them are ready.

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

Right.

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

Right.

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

Well, yeah, but that...I mean, that's what...the criteria of whether it's ready isn't talking about...does talk...implies adoption and if it's adopted one place and it's not adopted the other you're right it doesn't change the technical quality but it does change whether the industry is ready to use it and that's part of the maturity criteria.

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

Not of the standard.

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

So, what I wonder here is that, in the interest of providing good guidance to ONC, that we can conclude, based on this slide, that as a vocabulary CDT is appropriate. Now again, we've probably already directionally said that we actually think FHIR is lovely it just it's one of those that isn't quite ready to put in regulatory guidance, it's more sub-regulatory. So if you want to evaluate the context the use of a vocabulary in something that isn't quite ready for prime time is that some of that is it's not quite ready for prime time, I mean, something like that.

Our advice to you and maybe again, Jamie and Becky could say, CDT is fine to put in regulatory guidance as a standalone semantic vocabulary and not so much judge whether the context is appropriately ready but Arien, Wes?

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

This is Arien, I do think understanding the context in which it is used is important. There is a clear sense in which CDT is appropriate for use in a claims transaction. I would look at the context not just in the...not as specifically as potentially this chart is looking at it, looking at the context of clinical system to clinical system interoperability and whether there is wide use of CDT for the purpose of expressing dental terminology and transmitting the semantics of that dental terminology from one system to the other.

I mean, there is a sense in which if you've done it for Consolidated CDA and you've done it in transition of care that the extension of doing that to APIs and FHIR is fairly small whereas if you haven't done it in the context of system to system interoperability the lift is large the first time you do it and smaller the second and third times you do it.

I do wonder whether CDT is widely infrequently used for the purpose of clinical system to clinical system interoperability for preserving common semantics of dental procedures.

W

...

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

Right, so that's I think the...that's I think the more interesting and broader context is how well do we have practice in using terminology to exchange common semantics between two different clinical systems?

And I question both the high and the discrepancy between the high and low in pretty much all of these with the most maturity being in medication standards because we've got a fair amount of practice in the context of electronic prescribing translating to and from a variety of representations.

So, I'd encourage this...I'd encourage the Semantics Standards Group to look at the broader context of use of comparing semantics across clinical systems and looking at the maturity of a standard for that purpose and that really should be the dominance for the assessment of the maturity of the standard.

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

Now, I see there are a couple of cards up. Dixie, did you want to make additional comments?

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

I think to really clarify this to make it crystal clear, if you think about the regulation itself, for those of us who have them memorized, Steve and me, there is a section called the certification criteria and there's a section called the standards. And the metrics that we developed were intended to figure out whether that specification is mature and adoptable enough to be in that section that says standards.

What is being assessed here I think is whether that context pointing, you know, that certification criterion pointing to that standard is ready to become in the national regulation.

So I think that we need to look at...it's useful because these, as you've pointed out John, many of these standards are quite mature and fully ready to be in the standards section of the regulation, but may not be ready to be pointed to from the application access certification criterion.

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

And so I know we're running very short on time Michelle and so what I wonder is, I mean, we can flip through these slides just to see because I think the same problem exists on every slide, and is it possible to push this slide stack back to the working group just to get them to come out with...sort of as Dixie said, you know, either the semantic standard is ready to be included in the standards section or it isn't.

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

Well I...I mean, it might go back, but I mean, I think the other thing is that especially when you're talking about terminologies you could argue for instance that LOINC is robust and beautiful for all things that have to do with lab data but in the evolving area of genetics you would say well, there are still things that need to be done there.

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

Yes.

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

So, I don't think it's irrelevant, I don't think it's all or none. I think you have to talk about, you know, if you're talking about, you know, is the standard ready for use for genetic data and I'm using LOINC as an example because I think LOINC is beautiful everywhere, but...

M

...

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

But, especially when you're talking about terminologies they can have content that's in use and robust in some areas and not in others and so I think that has to be considered in whether you say, this standards is "ready for adoption." I think it's not all...

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

And Stan...

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

I don't think it's an all or nothing circumstance.

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

Right, but, Stan's comment is very good, which is to say, it's within a sphere of semantics that it's good. The thing about these slides that's funny is it's mixing semantics, content and context.

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

Well, I would argue that's a perfect example of what I said though, if you're certification criterion has to do with genetics...

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

Right.

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

And that criterion points to LOINC then I would say that this criterion is wrong. I would not say that the standard is less mature.

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

Yes, so that is sort of the confusing admixture here. And so, I know, Michelle, what are our options if any?

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

Steve seems to have a thought.

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

Yes, Steve?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Well, I mean, in the interest of time, I think perhaps with the transmittal letter this additional context that was discussed by the committee could be reflected so that the Workgroup doesn't have to go back to revisit all of this just to simply address the context that I think has been made abundantly clear from all the members.

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

Okay.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay.

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

So, let us just see if we could just flip through these because I know we have two other presentations.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay...

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

And we have a hard stop because of the lunch. So, please go ahead.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay, so I don't need to go through each one, like through every row.

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

Yes.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay, so this is CPT and it is all high and application access to common clinical dataset low, that is, as Stan mentioned, we looked at the context of where that standards is being used or team knowledge.

ICD-10 PCS we gave it low because, I guess the transition date is October 1, 2015. On LOINC for CPOE the maturity and adoptability low. And some other context like vital signs, body mass index, growth chart high and medium.

For social, physiological and behavioral health data medium, adoptability low because at the time the NPRM was published there were four pending LOINC codes from the 15 survey questionnaire which later LOINC, I guess it was due to the copyright issue of those questionnaires, but now even those four pending LOINC there are LOINC codes for them. So, that we need to revise here.

Transition of care high on both criteria, incorporate lab tests and value results as Stan mentioned is high in both categories. Transmission of lab tests reports high and medium. And then it continues data portability high in both categories criteria of view, download and transmit to third-party high. I don't know, do I need to read all of them or just move on?

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

I don't think so.

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

So, this is our again, perfect example of what Dixie and Stan were saying which is, here we have an issue where LOINC is actually wonderful for a result but it's too specific for an order because if I want to place an order for, and Clem always used an example, but this is probably wrong, but for a serum sodium that must be run on a Roche analyzer that is too specific for an order, but it's completely fine for a result to tell me that it was a serum sodium on a Roche analyzer.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

...

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

Yeah, okay, but so the idea that, at least is what I heard from this report in the committee was that there was a question of granularity or specificity in a particular use case I think. It wasn't exactly saying whether it was C-CDA or FHIR, or something like that. So, please when it comes to public comment I'd love your input on that.

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

Yes.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

I actually invited Clem today to come.

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

Okay, so next.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Okay, so the next one is the race and ethnicity that is the CDC code from their PHIN VADS system and then that OMB race and ethnicity, which FDA actually uses for many of their standards, this is administrative gender code from HL7 male, female, unknown and it is medium in all the categories but the last one.

This is HL7 version 3, this is other NullFlavor, other as but unknown, this is for social, physiological and behavioral health data focusing on sexual orientation and their responses to the HL7 code.

Then UCUM, which is, we assign need and maturity high and adoptability medium, but that is not the last category. Then HL7 version 3 implementation guide, this is family history, pedigree, interoperability, this is HL7 version 3 and we didn't find implementation of this standard beside the US Surgeon General Office that has used it. So, that's why we gave it low.

And then we moved to SNOMED CT and that for problem list high, for smoking status high, for adoptability medium, family health, high. So, all the others are high. Clinical information reconciliation and incorporation high for maturity, adoptability low.

Data portability high in both criteria. Then it continues to clinical quality measures medium for both maturity and adoptability. View, download and transmit to third-party high in both categories. Transmission to public health agency medium this is focusing on reportable lab tests and value sets.

Transmission to cancer registries medium in both categories. Consolidated CDA high for both and access low just like the others.

And this is actually NDC, oh, no NCPDP for drug formulary and preferred drug lists, this is maturity high, adoptability medium. Then the Consolidated CDA, and these are the different templates that are in the NPRM and those are there, maturity and adoptability level for each one of those templates.

And ICD-10 CM we gave them low because they haven't...we haven't transitioned to that. Then SCRIPT standards implementation guides version 10.6 we gave it high for ePrescribing in both criteria. Then RxNorm is for transition of care medium in both criteria, clinical information reconciliation and incorporation medium and low, ePrescribing medium, adoptability, high.

For the next three, data portability, view, download and transmit to third-party, Consolidated CDA medium in both categories. Application access to common clinical datasets low.

Then HL7 standard code set CVX this is developed by CDC and that for transition of care, high actually all those are high. Transmission to immunization registry for adoptability medium. For Consolidated CDA creation performance medium and application access to common clinical datasets low.

This one is NDC developed by FDA and one of the Workgroup members mentioned this is like a 35-year-old child living in your basement, so this one is for all the categories medium but the last one. And NDC is incorporated into RxNorm and therefore in most of the First DataBank and all the other third-party systems use.

Then this one is from CDC PHIN messaging guide for syndromic surveillance and transmission to public health agency for this and those are medium in both categories. And then there is HL7 version 2.5.1 implementation guide for electronic lab reporting to public health agency and that is medium in both categories.

And implementation guide for CDA release 2 reporting to public health cancer registries this is also medium. And IHE quality research and public health technical framework supplement structured data captured trial implementation both medium. This is transmission to public health agencies for case reporting. I think maybe that is the last one, yes, I am finished, that's it, thank you.

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

Very good. Well, so again, we're short on time but I think, you know, Arien you had a comment if you could make that quick, I just wonder again, process step here is this is...I mean a lot of this work is very good it's just I think the transmittal letter, as you said Steve, really just needs a lot of qualifiers because as Stan has said, I mean, some of these slides actually have use cases or domains where a standard may be appropriate or not appropriate and that's great but some of the slides then mix the semantics, the content and the context in a way that seems just a little confusing. But, Arien, please?

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

Yes, just a comment on the notion of medium maturity. The intent in our work in the NwHIN Power Team was that you should be able to achieve medium maturity by limited scale production use and I note that you've...so, you know, medium level of maturity generally would be associated with something that is in some level of production use and I think some of the standards where you point to medium level maturity, to my knowledge, are in connect-a-thon type use or early preproduction use and I don't think would rate medium, so I don't know if there is...Dixie if you feel the same?

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

...

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

Yeah.

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

And David did you have...

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

The question on the one that we're struggling with, 315(g)(7) application access to common clinical datasets, Steve, does that requirement specify the vocabulary? You're not specifying the API definition. I'm wondering if this...we should just rate these as not yet relevant or something and just basically say...this question will eventually come up but we're not there yet.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, I mean, I think it's a context mixing paradox issue because from a consistency perspective it's analogous and mirrors transitions of care...

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

Right.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Or any of the other criteria that reference our shorthand common clinical dataset definition so from a consistency perspective it would be odd...

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

Right, but let me just hypothetical then, so let's say since an existing vendor API is allowed under the current rule with the clear intent in the long run to make it FHIR, it's conceivable that a vendor might expose internal non-mapped value sets for some of these fields simply because you didn't specify otherwise and that is the path of least resistance and that's what current users of those APIs are dealing with.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

To meet the criteria though...

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

Right.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

I'd propose they'd have to meet required vocabulary.

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

Okay, so...

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Standards.

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

So than this is a relevant rating.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

If you're looking at it from the context in which those vocabularies may be deployed.

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

Right.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

But, you know, part of the context of the proposed criterion was to...for a request for a full document the response be a C-CDA.

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

Right.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

So, there's really no difference in implementation, context.

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

But that would get a low by this rubric because FHIR for API access to a CDA, C-CDA is an unproven and a undeployed technology...I'm just...what's the meaning of double L's here? It's really sort of irrelevant based on any use that you're going to put it to. So we should either remove it or start in some way to say not really relevant.

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

Can I suggest that we try and rework this with the chairs and see if there's a way that we could reformat this and share it back with the committee for approval. It will be an e-mail approval but I think we need to rework it before we vote on it today.

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

So, I think...because I know we have two more presentations that we've got to move onto but...so, I think again we thank Jamie, Becky and the committee for their very thoughtful work and I think we are going to use as much of it as possible and there's going to be some refinement and that refinement will be circulated to the committee for review, a transmittal letter taking all this input into account will then be prepared.

Mitra Rocca, PhD – Medical Informatician – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences – Food & Drug Administration

Thank you.

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

Thanks so much and I can assure you that David and Arien's slides are short, sweet and noncontroversial. Liz and Cris, well maybe yours are a little controversial but they're short.

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

We'll surely get a lot less questions with them presenting.

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

So, first of all we did put together a transmittal letter last time and I believe these slides simply summarize the previous transmittal that we put together so there shouldn't be anything controversial here. There's the Workgroup. Standards readiness.

As we previously noted we do not believe HL7 FHIR is ready to be endorsed as a certification criterion because we don't have enough experience in production for what that certification criterion would look like.

We put in our transmittal letter some advice back to ONC with respect to putting regulatory winks and nods to encourage folks to implement the API certification criteria in terms of HL7 FHIR using public/private consortia such as Argonaut as their enabling organization.

HPD, not ready for prime time. XDM, we pointed out one particular subsection of the XDM section and provided more specific guidance and with respect to that believe it was ready for prime time.

With respect to data portability we made a whole set of recommendations with respect to that but we, in particular the standards readiness, suggested that data portability be confined to the CCD profile or the CCD sub implementation guide of the Consolidated CDA implementation guide.

With respect to CAQH CORE we noted that it's neither ready, nor not ready for prime time. It is not applicable for the purpose to which it was intended.

And we...so that was our comment on standards readiness. David anything else you want to comment on the comment?

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

No not on the standard readiness.

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

Okay, and then we also had a final farewell meeting of the API's Service or the Architecture APIs...Architecture Services and APIs Workgroup where we had been doing what we thought was highly important work with respect to orchestration patterns and we made some recommendations back to ONC with respect to future potential Task Forces.

We believe that peer-to-peer and peer-to-peer delegated auth are already covered by the Argonaut Project as are the Stage 2 of the Argonaut Project but believe that with respect to publish/subscribe and what we called the clinical decision support as a service that we have examples of more generalizable orchestration patterns where having a Task Force that could review art, review practice in these areas and make some foundational recommendations with respect to work over the next couple of years to formalize these orchestration patterns with broad applicability to the standards roadmap and other policy outcomes that ONC wishes to achieve we thought might well be a good idea and I think David you probably have some comments there.

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

Yeah, I'll just comment on that last one, the clinical decision support as a service, as a project, that's an informal project that I've been undergoing or working on with Josh Mandel and some others, reviewing the number of companies that are approaching the vendor community with services that would be embedded in the workflow and what's striking about them is how similar they are and also what's striking is that every one of them would require custom code when with just a little bit of a swizzle to a common orchestration pattern they could all be accommodated with almost the same code from the vendor point-of-view.

So, on our Task Force with four vendor representatives there was a lot of interest in saying can't we find a way to orchestrate this just a little bit so as to reduce the workload for the vendors and conversely to increase the options that our clients have to integrate third-party components?

And since that conversation IHE has come out with their proposal around radiology procedure authorization that's, you know, close but not quite right. Health eDecisions has advanced forward and likewise it's close but not quite right.

And then I've talked to five different vendors all whom are very interested in doing this but none of whom fit either of the above patterns even though they're all very close but not quite right.

So we think there is some very important low hanging fruit here to attack through some channel that can bring some harmony to what is already a pretty fragmented unnecessarily fragmented space.

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

Any comments? Wow.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I have one.

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

Okay, yes, please?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I just would echo David's comments on the Health eDecisions work and clinical decision support as a service especially as you include patients in shared decision-making it will be even more important to have this as an external service without such an emphasis on internal workings, internal artifacts, which the Health eDecision Group was going down a path of very, very highly prescriptive internal workings and shared decision-making.

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

That's a great point.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And it needs to not go forward with any sort of internal oversight, that's one that shouldn't reach prime time at all because decision-making as a service will be prevalent, it's already prevalent in the ecosystem outside of healthcare as services that we use all the time and it's really content that has to be managed day-to-day by organizations that look at the research, look at the services, look at the evidence.

So, we would advocate from a consumer point-of-view it needs to stay as a service external. This is...the little InfoButton standard is used over a billion times since we brought that up. We can get to content as a service using minimal artifacts, no PHI and get to good decision-making criteria. So I would just echo and support your...

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

Yeah, I mean, to be...to take that specific example, I would see InfoButton would be just a use case...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

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

Of the general orchestration and that would free up InfoButton from the artificial constraints that it has now.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

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

So the general model is that if you need to communicate back-and-forth you use FHIR.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And if you need to interrupt the physician to converse with them you use SMART App. If you need to authenticate you use the OAuth protocols that we've worked out.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

I mean, we've covered almost all of the use cases with these very generic APIs and that's what we should be orchestrating is these generic APIs, not highly specific custom FHIR operations where somebody makes up a use case that's only good for one thing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct and then I would further state if there's a need to have some sort of certification for content providers or today many are under FDA control and provide their own regulation as a content or decision-support tool, great, but that is outside the boundaries of the standard specifications that I think the artifact approach under Health eDecisions was attempting to do but ill placed.

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

I just want to double underscore your point that establishing this as a general orchestration pattern makes these decisions support services applicable to a much wider range of actors...

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

Right.

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

Including and maybe most especially the person him or herself. So, again double down on the recommendation to ONC that this is a useful Task Force that could usefully be convened to make progress.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'd love to help too.

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

Yeah, thanks.

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

Great.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Do I have the triple...there?

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

Yes, so I believe there are no objections Michelle to forwarding these recommendations and we will double down on them. Okay, so let us now conclude our presentations from the committee with the Implementation Certification and Testing Workgroup. Liz and Cris?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

All right and Cris is joining us and he's on the phone so I'm going to kind of give you some overall themes. You will certainly find more recommendations for non-inclusion than you will for inclusion. Let me preface it by telling you that we have provided to ONC in significant detail great examples and reasons for our recommendations we are happy to share that with the Standards Committee given the amount of time allocated for today we're going to go through overall general perceptions.

Again, I think we've heard it over and over but we wanted to preface our presentation with saying, where you a lack of recommendation it is really...comes in just a few categories, first of all there is not a standard even available for use today or the promulgation of the standard is very limited in its use in implementation world. There is too much prescription within the NPRM which doesn't allow us innovation or other options that were not listed because the box is too tight and so you're going to see those kinds of themes repeatedly.

Also there were a number standards...and we're in complete agreement with many of the things we've heard today about the readiness of standards, we were clearly assigned specific standards those are the ones that we look at, so our failure to not include a standard that we may or may not agree with has nothing to do with the fact that we don't agree with the other recommendations. They were not in our body of work.

So, moving forward, as always, Cris and I want to say thank you, this Implementation Group has met virtually weekly for hours and Michelle will attribute that and we'll certainly recognize the amount of work that has gone in, so thank you very much for all these volunteer hours.

I will pause at the end of each slide to give Cris an opportunity to speak since he's not in the room with us. But as you can see, we did make some general recommendations for adoptions around the gap certification eligibility table.

We'd like to see a little bit of variation eliminated between ACBs and ATLS. We're generally supportive of the common data set definitions with the exception of the UDI, the unique device identifier, we think that it should be clearly articulated around field surveillance of a deployed system and what that entails. We were having a difficult time to understand what ONC might be envisioning for getting it out in the field. We think it's a good idea but what does that really mean?

And then again, you can see we're generally in support of several other concepts, you know, retesting and certification and certainly around the removal of any requirements that have already been clearly met and will continue to be met by the providers regardless of what's the MU requirement. And with that I'll pause before we go on to those that recommend not adopting at this time and allow Cris to speak.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Thanks, Liz, I think you got most of it the only piece I would maybe add is on this slide there is, in addition to some standards items there are also process and approach methods and we spent a fair amount of time talking about the process by which implementation certification and testing occurs in addition to the specific standards to go through that process. So, I just want to note that some of this has to do with the workings of the groups that are associated with these standards.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Right, and again, you're going to see towards the end of our presentation we're already working on the testing criteria and that really does call into play how would you test for something. Often we are given the greatest amount of purview into what is expected when we actually look at the testing methodologies.

So, moving onto the do not recommend for adoption at this time, we'll start with the first slide and, again we tried to add a little color to the slides so you would have some idea of what we were thinking but we've provide detail to ONC.

We are on the unique device identifier, we have concerns particularly in the ambulatory space. Immunizations are not mapped currently to NDC and as we move forward with that we believe that immunizations are a critical part of care but we don't have the standards that are necessary yet.

We like the C-CDA concept-wise, but we think there needs to be more content and constraint, coming from us asking for constraint around a recommendation is unusual, however, what we found was because there's so many if, ands or buts it makes it very difficult to actually test and then implement it universally so that we could actually do exchange of data.

Again, we gave you very specific recommendation around the EHR definitions around security. We do not think that involving clinical end-users in terms of the safety enhanced design makes sense yet. And then when we looked at the web content accessibility, we don't think the compliance tools are ready to make a change in the actual standard required so that's where our recommendation came from. Again, Cris, additional comments on this slide?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

In the interest of time I would say Liz I think you covered it well.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Okay.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

And we should just complete the next slide.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Great. So, again...these are again ones that we recommend non-adoption at this time and again I really don't want to read this slide to you but I think, you know, we think for example summative testing is a good option but it shouldn't be required. We were confused around what billing diagnosis might mean and so we need further clarification on that one. Medication dosing, again, it's about the wording, it's not about the concept.

I'm going to move on and talk a little bit about portability and then talk about the fact that we need to...we clearly recognize that this is critical and if we're going to move into a world of interoperability our data has to become more portable. No argument there whatsoever, but, we are, against specific standards and we really think that we need to look at those standards carefully as they're adopted to make sure they're actually applicable in an implementation world.

What we find frequently is, again, as we pick on Dixie one more time, it's really about the effectiveness and the usability and the penetration in the market today and how they're being used and how effective they are not against the concept in general.

And then, again, coming from the Workgroup they would really like to make sure that there's not requirements for automated numerator recording if it would not...if it requires additional clinical documentation, in other words, let's make sure that when we ask our clinicians to do additional documentation that it's for the benefit of patient care not for capturing a measure. And Cris?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I guess I would say in general on these last two slides our Workgroup had broad representation, Liz and I represent provider groups obviously, but there was also strong representation from the testing organizations, from vendors across the board.

And you'll see in all of our comments most of these are simply a case of, these are decent ideas in most instances where trying to accomplish them at this time is either burdensome, those standards are immature and unready or that there is lack of clarity that would allow us to move forward to go back to John's comments about the existence of a standard and the use case does not necessarily imply a solution.

So, in some sense it looks like our report is a negative about many of these recommendations. I think our overall comments that we reported last time that there is lots of good ideas but the accretion of lots of good ideas does not necessarily make a coherent whole still holds. And, you know, we look forward to comments from members of the committee. But in general it seems as though our recommendations are highly congruent with the reports that came before us.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

And then just a follow-up, good point on the membership of the committee. I think what we have brought forward before over the last several years is as we look at the implementability, the ability to actually implement in the real world of all the things that we talk about we want the concepts but as we work with vendors and other providers we recognize that we have a timing issue and a readiness issue, and so we always go back to the timeline of when are we going to make up our minds what we want? When is that code going to be ready? How long will it take us to implement it and design the processes?

I mean, we've been through that timeline over and over. So, again recognize long-term there is very little we don't agree with but when we are asked to say can you do this in a year or two years from now, we're not going to be able to so it's our job to come back to the Standards Committee and say support the standards, please recognize that if we go with them the way they're currently written we won't be able to implement them effectively and with that John we turn it back to you.

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

Okay, well...

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup – The National Quality Forum

I have one last comment, excuse me, I'm sorry I cannot be there to thank all of my colleagues in person for everything I have learned from all of you and to my Co-Chair, Liz, who has been a pleasure to serve with.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Thank you.

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

Thanks, very much Cris. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Just one quick question, on the UDI example, Liz, I know that the FDA has mandated the new UDI labeling structure and all of our revenue cycle systems will begin to have that very quickly and so the idea was then how do we capture the UDI in the EHR so that we be consistent and we avoid a mess of un-reconcilable data.

We anticipate that claims will be asked to have unique device IDs for payment in the future although CMS has not yet done that.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, how do you balance that? Did that question come up, that issue come up in your discussions?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

I would say and I certainly will defer to Cris, but I would say that you're correct and that we've been collecting information in central supply and other places for a long time, but it's a very different thing to get it into our clinical system.

So what we...particularly in the ambulatory area I think it requires further research. We have to close that gap you're right. But...particularly in the ambulatory services what we heard from our colleagues both in that provider service as well as the vendors for that provide service they're not ready.

So I think, you know, as the Standards Committee moves forward and as Task Forces are formed one of the things we'll need to look at is reconciliation for UDI.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Especially because people want to know what's in them, the implantable device issue is a big deal.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Well, and I would have to say to you for years and years, and I know you know this as many of us do, we've been notifying...when FDA notifies us...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I know.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

We've been notifying patients for as long as I can remember, which is a very long time, that there was a problem so that we don't rely on some kind of a public announcement that we've implanted something in you and it's no longer functioning or there is a recall or whatever the information may be we have shared it. Now there is...I'm not going to go into some of the obvious problems that we have finding people sometimes, but we make every effort so that's not a new concern for us.

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

Very good. Well in the interest of time, because I know Michelle, you guys have an announcement about Task Forces and we have the lunch schedule. Were there any objections to forwarding these recommendations as written to ONC? I see none. So, let us now turn our agenda back to you guys. We have public comment and your comment, I think Steve and Michelle, about Task Forces. It takes five minutes to give a three minutes.

Public Comment

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

If there is anyone in the room that would like to make a public comment please come up to the table. As a reminder public comment is limited to three minutes and I'll turn it to Alan to open up the lines as well.

Alan Merritt – Interactive Specialist, Digital Communications Services – Altarum Institute

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

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

Go ahead, Clem.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Can I do that now?

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

Yes.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, three minutes is too short. But, I mean, there's a general tension about things coming out of ONC that collide with other things. So, HL7 does standards and there's S&I Framework and I think the same with the roadmap. I mean, who decides what? It would be nice to kind of simplify and have one thing to trump all.

The thing I'm probably most interested in is the last...the slides that Mitra presented and I've a couple of issues with them. One of them is it sort of says, if they're not using it we're not going to get them to use it, which is sort of...and the ones that they said they are using it is one that you mandated two years ago or the last round. So, there is sort of a catch-22 in that. Granted it's good to be critical, so I don't know how that should really play out.

I was particularly concerned about the order entry one, I'm interested in LOINC, as you all know, because if we don't do that what are we going to do? What's the point of doing...requiring them to order entry if doctors can't send the same order to three commercial labs, which they have to do because they may have three different insurance companies, and if you knock out both the eDOS and the use of LOINC and order entry you've kind of destroyed the facility to know what an order is. So, I think you ought to really think about that again.

And in terms of the social, psychosocial variables there is a huge contradiction I think based on some errors or lack of knowledge. So, LOINC was knocked down because it had four of them that were pending, the reason they were pending was because neither IOM nor ONC checked on the copyright requirements on them and we spent months doing it.

We actually had two of them in the system at the time of the NPRM but couldn't release them because we didn't have permission. We have all of them but one now. Now one of them is the one for stress from Finland. No one in the US has ever gotten permission to use that. We think we can get it, but it's taking a little negotiation. So, we've got to worry about copyright.

The contradiction is that on the other side it said SNOMED is ready for them high/high, these codes are not in SNOMED, not in the CT or not in the US extension. I don't know where they are but they are somewhere maybe but they're not in any formally available one, so these are rated high/high and it couldn't have gotten copyrighted because we know that the Finnish one has given no copyright to anyone in the US.

So, you've got to worry about your...maybe do a little more homework on them and I think John your idea of reconsidering is a good one because you get these codes that are really good for everything except when you're going to use them in clinical use. My point is that's what we need them for most. If they're sitting in a record we should be able to query them and pull them out to use them. So, maybe...I don't know if I've got any minutes left, but, let's see roadmap...

W

...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I guess that probably covers it. Mitra did a nice job. Okay, all right. Thank you.

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

Thanks very much Clem, of course as Clem is the Godfather to us all we listen to him very seriously. Thank you.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I've got a lot of gifts to give every Christmas.

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

Michelle, do we have any comments on the phone?

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

We have no public comment.

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

Well, again, certainly, thank you everybody.

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

Oh, no, sorry, wait we do...

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

And let us go back...

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

I'm sorry, Linda, please go ahead, Linda. As a reminder, you have three minutes for public comment. Linda are you there?

Lindsey Hoggle, MS, RD, PMP – Director of Informatics – Academy of Nutrition & Dietetics

Lindsey.

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

Yes, please go ahead.

Lindsey Hoggle, MS, RD, PMP – Director of Informatics – Academy of Nutrition & Dietetics

Hello, my name is Lindsey Hoggle and I serve as the Director of Nutrition Informatics at the Academy of Nutrition and Dietetics. I have participated in the Health IT Standards and Policy Committee meetings and comments on proposed rules for the past six years and appreciate the continued ability, availability to comment.

In particular, I have two points. First we have worked during the past six years to ensure that content for nutrition care process be included across all patient care settings. This is more than simple creation of a diet plan for each patient but considers patient condition, nutritional risk, ability to eat and metabolize nutrients, nutrition focused labs and physical findings to name a few.

Patients who are challenged by infections, chronic diseases, pressure ulcers, diabetes, renal disease, inborn errors of metabolism and yes even malnutrition often create challenging care scenarios for patients. Nutrition care including oral intake, enteral and parenteral infusions, and/or alterations to nutrient composition should be considered a critical necessary component of patient care.

In our Stage 2 comments to ONC and CMS we included a table that identified 11 of the top 15 causes of death as conditions which can be positively impacted by appropriate nutrition care. The overall financial burden from these conditions based on 2010 data is \$1.2 trillion.

Secondly, early on we recognized the requirement for medication allergies, omitted references for food and environmental allergies. Since 2009 we have supported the development of the HL7 allergies and intolerances, the Mayo Analysis Model under the direction of Dr. Russell Leftwich and Elaine Ayers from NIH.

This Workgroup has initiated conversations with others who have worked in the area of...while the terminology to support the draft standard has not been formally agreed to the significant work has been completed to include food concepts, substance concepts in SNOMED CT. This work has been consistently improved during the past six years and we have to challenge the consensus on terminologies and value sets as certainly attainable by 2017.

This standard considers a patient centric approach which includes creation of a list that then includes necessary clarity such the severity and criticality. We continue to assert that failure to guide in our required food allergy documentation in a consistent manner is patient safety risk.

A child who is critically allergic to peanuts has the same potential reaction as a life-threatening medication allergy. We recommend an iterative approach which adopts HL7 allergy and intolerance standards with SNOMED and possibly UNII with improvements over the next two years. Thank you for this opportunity to comment.

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

Thank you very much.

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

Thank you, Lindsey and we have no more public comment.

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

Okay, comments on Task Forces and then we celebrate our departing members.

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

Yes. In addition to our appreciation for all of our departing members we also want to thank the current Workgroup members who are participating in all of our Workgroups. Just as you saw today there has been so much work and time and effort put into all of the Workgroup activities and we want them to know how much we appreciate all that they've dedicated to us.

And although the Workgroups will be sunset after today's meeting for the most part with a few caveats based upon the discussion today we are hopeful that the current Workgroup members will continue to participate in future Task Forces and we encourage them to go into the ONC database and identify Task Force that they may be interested in participating in. Most of them also have my current e-mail address and they can certainly just send me an e-mail as well. So, just want to say thank you to all of them.

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

And July meeting?

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

Yes, and we didn't want to confuse people, but we have decided to cancel the July meeting. So, following today's meeting you'll get that cancellation and so we won't meet again until August which will be a virtual meeting just based upon where we are in the committee we're picking up a few Task Force activities and so there won't be much to discuss next month, it's summertime people will be vacationing so we thought we'd give you a break after all of your hard work working on the interoperability road, the certification NPRM. So, we'll meet back in August, hopefully everyone will be refreshed and ready to go.

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

Very good. Well, again, I'm going to echo Karen's earlier remarks that you guys have done remarkable work. We've fundamentally changed the trajectory of standards making for the country. There is more work to do but our trajectory is very positive and Dr. White we'll give you the final word.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Let's eat.

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

Okay. Thank you and see you at the reception.

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

Yes, so, just outside there will be some food if people want to take maybe 10 minutes to get food, maybe check e-mail and do a few things and then come back in we would appreciate it.

Meeting Attendance								
Name	06/24/15	05/20/15	04/22/15	03/18/15	01/27/15	12/10/14	11/18/14	10/15/14
Andrew Wiesenthal		X	X	X	X	X		X
Anne Castro	X	X		X	X	X	X	X
Anne LeMaistre	X	X	X	X	X	X	X	X
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris	X		X	X	X	X	X	
Charles H. Romine		X	X	X	X			X
Christopher Ross	X	X	X	X	X			X
David McCallie, Jr.	X	X	X	X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson	X		X	X	X	X	X	X
Eric Rose		X	X	X	X	X	X	X
Floyd Eisenberg	X	X		X	X	X	X	X
James		X	X	X	X	X		X

Ferguson								
John Halamka	X	X	X	X	X	X	X	X
John F. Derr	X		X	X	X	X	X	X
Jon White	X	X	X	X	X	X		
Jonathan B. Perlin				X				
Keith J. Figlioli	X	X		X		X		X
Kim Nolen	X	X	X	X	X	X	X	X
Leslie Kelly Hall	X	X	X	X	X	X	X	X
Lisa Gallagher	X	X	X	X	X	X	X	X
Lorraine Doo	X		X	X	X	X	X	
Nancy J. Orvis	X		X	X	X			X
Rebecca D. Kush		X			X		X	X
Sharon F. Terry			X					X
Stanley M. Huff	X	X		X	X	X	X	X
Steve Brown	X		X			X		
Wes Rishel	X	X	X	X	X	X	X	X
Total Attendees	21	21	22	26	25	22	20	25