



## HIT Standards Committee

### Final Transcript

August 26, 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 call and there will be time for public comment at the end of the call.

As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Jon White?

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

Present.

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

Hi, Jon. John Halamka?

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

I'm here.

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

Hi, John.

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

Hello.

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

Andy Wiesenthal? Ann Castro?

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

I'm here. I'm here. I'm here.

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

Hi, Andy.

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

I couldn't get it off mute, hi.

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

Anne LeMaistre?

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

I'm here.

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

Hi, Anne. Arien Malec? Charles Romine? Cris Ross? David McCallie?

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

Here.

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

Hi, David, thanks for joining. Dixie Baker?

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

I'm here.

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

Liz. Hi, Dixie. Liz Johnson? Eric Rose?

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

Eris is here.

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

Hi, Eric. Floyd Eisenberg?

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

Here.

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

Hi, Floyd. Jamie Ferguson?

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

Good morning.

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

Hi, Jamie. John Derr?

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

Here.

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

Hi, John. Jon Perlin? I'm sorry, he is not going to join. Keith Figlioli?

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

Here.

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

Hi, Keith. Kim Nolen?

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

Hi, Michelle, I'm here.

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

Hi, Kim. Leslie Kelly Hall?

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

Here.

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

Hi, Leslie. Lisa Gallagher?

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

Here.

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

Hi, Lisa. Lorraine Doo? Nancy Orvis? Becky Kush?

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

Here, I'm here.

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

Hi, Becky. Sharon Terry? Stan Huff?

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

Here.

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

Hi, Stan.

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

Hi.

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

Steve Brown? And Wes Rishel? I think that he is on. Okay, with that I will turn it over to you Jon White.

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

Michelle, this is Kim, sorry, can we make sure Kim is on and he can be heard?

**Robert Cothren, PhD, MS, SB – Executive Director – A Cunniff Plan, California Association of Health Information Exchanges**

I am here.

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

Okay, thank you.

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

Okay, very good, can I go ahead?

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

Yes, go ahead, Jon.

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

Okay, fantastic. Well, listen, good morning everybody, it is morning everywhere unless you're way over on the other side of the globe. Thank you all so much for joining us here online. I hope you've had a good summer. It's been in some ways a quiet summer. We haven't been convening, you know, as a group that much but in other ways it's been an extraordinary busy summer.

There's been some really exciting activities that have been happening in terms of our interoperability Task Force and our Precision Medicine Task Force that I think you're going to hear about today so I won't talk too much about it. But I think it bodes well for a really exciting fall for us and a lot of good activities that I think we're going to find are building on a lot of things that have happened over the committee over the past six years and through Health IT generally speaking.

I am extremely grateful for our colleagues whose terms are kind of easing out but have agreed to continue participating in the committee while we get new committee members through the clearance process and bringing them up-to-speed. So, delighted to have some of our established members continue to participate with us while we go through that process, thank you, I look forward to your always trenchant comments.

And, you know, I would also just offer you general comments from the Office of the National Coordinator which is that it has been a fairly busy summer for us. We got a lot of great input from you, the Standards Committee, from the Policy Committee, from all of our comments, public comments on our proposed rules. Those rules are in terms of our certification rule and incentive program rule. Those rules are of course still in clearance so we won't be able to say a whole lot more about, you know, them and where they are and, you know, when they'll be published but I just want to acknowledge that we're grateful for all the wonderful, thoughtful, detailed input that we got from you and we've been chewing on it long and hard within HHS and across the administration.

It's also been a busy time for clearance of a number of other things in terms of we continue to work internally on the Health IT Strategic Plan and the Interoperability Roadmap. We've gotten a lot of great feedback and we feel like it's really advanced our thinking and our insight to months and years ahead in terms of where we're going for a lot of these things.

So, I'm excited for what's been happening over the summer and pretty eager to hear about that. And I'm excited for the fall coming up there's going to be a lot of great things that are, you know, kind of coming out to the public and I think a lot of significant progress that we're going to see and frankly, you know, what's become completely obvious to me is the work of this committee and the stuff that we do in terms of recommending standards and implementation specifications to support the various things that we do are really foundational and fundamental to achieving the goals that a lot of people have for health and the healthcare system.

So, thank you very much for your attendance and for your attention and your efforts and I turn the floor over to my esteemed Co-Chair Dr. Halamka.

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

Well, Jon, thanks very much. And as Jon just said it has been a busy summer at ONC and of course as all of the Meaningful Use Stage 2 and Stage 3 ONC rules and modifications and enhancements happen behind the scenes, you know, they're in regulatory period, approval period, etcetera, so we aren't involved, but as Jon said, you'll see that over the course of the next several months there will be a ramp up of activity for us all, they'll be the transition as the new members go through their clearances and so we will have a new quorum of folks to deal with new challenges.

And today is really introducing those new challenges. We know that the Precision Medicine Initiative is very much a priority of the Obama Administration and in some ways it provides a catalyst for our next level of work as we think about what is the learning healthcare system, we think about the incorporation of phenotype and genotype, and microbiome, and protocols, and standards, and cloud-based decision support and all the things that will deliver that optimized care with lower cost and higher quality that we want for us and our families. So precision medicine really gives us that catalyst to discuss all of that and so we will hear and introduction from Leslie Kelly Hall and Jon White today on their Task Force.

We also are going to discuss the Interoperability Standards Advisory. Now remember that ONC did two things. On one hand they had the Stage 2 rule which is more of a formal certification of what standards must be incorporated and how they should function but there's also a very helpful Interoperability Standards Advisory, which is a bit more forward looking, that says, well we won't require this in certification, but boy if you need a standard to represent this kind of content or this kind of vocabulary, or this type of architecture for transport these seem to be the most mature standards per the Dixie Baker maturity criteria that are out there for those purposes today, you know, it may not be perfect, it may not be, in fact, ready for prime time but directionally they seem right.

So you could say, and this is of course John the private citizen and I have no comment as I'm sure ONC will not make any official comment, but let's say Stage 3 for whatever reason is delayed. Well we still want interoperability. We still need clarity on standards to use for innovation. So, this is where I think this Interoperability Standard Advisory, which is sub-regulatory, is something that can be updated and the Standards Committee can have a lot of influence on it outside of actual formal rules and it could really catalyze industry innovation, because the private sector, as we know, is really ramping up right now with FHIR and other kinds of interoperability activity.

So we'll hear from Robert and Kim about their Task Force activities on digesting all the public comments on interoperability standards advisory and making general recommendations for a framework going forward.

And Steve will tell us a bit about Task Forces that are going to be formed and then of course we'll have important public comment. So it is August, I recognize many folks have probably had to sacrifice free time on vacation and family for time to be here so as Jon said, thanks very much and look forward to the meeting.

So, Michelle, shall we convene the first topic?

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

We first need to approve the minutes from the last meeting.

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

So, see, now what folks should know, Michelle is somewhat compromised right now because of an IT related issue, she is not able to access the domain and e-mail so of course she would have normally reminded me virtually about seven times about that. So if folks had a chance to review the minutes if there are any edits, revisions or comments?

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

Hi, John, this is Jamie, so unfortunately, as you know the Co-Chairs and the discussion leads from the Semantics Standards Workgroup were not able to be in the last meeting and so I was actually very surprised to see the nature of the discussion on our recommendations. I just want to focus on one particular thing and then I think others, Eric or Becky, may also have comments on the call.

One comment that I saw in the minutes was a reference to FHIR as being a wrapper for LOINC and this is absolutely an incorrect view. While it's true that FHIR can be used as a wrapper, FHIR, in fact, also can include a full semantic information model that can constrain the coding system or terminology system within in potentially inappropriate or unsafe ways and so without, you know, real evidence of the testing and use of FHIR in the API model or in other architecture models there is absolutely no way to know whether the use of the semantics standards is correct.

So I think it was your comment, John Halamka, that, you know, that the semantic standard within it shouldn't be deemed unready just because the wrapper wasn't ready. That's completely an incorrect view because FHIR is not just a wrapper. So, I wanted to have open a discussion on that point and I think, Eric, you may have something else to say about that.

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

This is Eric, I don't have anything to add at this point.

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

And to Jamie, what we had agreed at the last meeting, because it was very unfortunate that the folks who did the work weren't there to actually discuss the work, as Michelle my recollection was is that the content that they had produced was going to be reformatted to be consistent with the other presentations.

Jamie, it wasn't so much an argument about whether what you guys said was factual or not, it was that the way it was presented was actually quite different from the way that the other presentations had been ordered and I think ONC said, actually, yeah, you know, we should have ordered them in a similar fashion so that the recommendations were just clearer to everybody.

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

Yeah, that's correct, John. We had followed up with the Workgroup and shared updated slides that we gave everyone in the Workgroup an opportunity to respond to. I actually had an email ready to share to refresh everyone's memory, but I can't send it. So, as soon as today's meeting is over I will share that with everyone or hopefully as soon as my e-mail is up I should say I will send it.

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

So, Jamie, would it be appropriate to amend the minutes to say that the presentation was made and that the next step was to reformat that presentation to be consistent with the other presentations so that the recommendations were clearer and then the committee will have a chance to approve those, something to that effect?

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

Well, I mean, I...you know, you certainly can do that. I think that it would be appropriate to actually revisit the presentation with the Workgroup leads and the discussion leads rather than just reformat it because I don't think that the content was appropriately discussed in the last meeting.

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

And, you know, I defer to Michelle is that...

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

This is Michelle, yeah, I'm sorry, so Jamie we actually tried to get you to engage and we couldn't get a response from you so we moved forward without that, but we can follow-up off-line and figure out how to...

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

This is Becky and I did engage and I came back and apparently some of the committee members still feel like there's some places where we're not adequately reflecting their view. So, I do think it might be worth getting the committee together one more time to review that. I think there is...

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

So, it sound like that there is still lack of consensus on this point. So, I wonder, Michelle, is there an opportunity for the committee to get together, have a discussion and then for us to, you know, at a future meeting take a look at what they have come up with. I mean is that possible?

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

Sure.

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

I think that would be great. Thank you.

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

Because this is again...it's one of those vagaries of the timing of everybody's schedule so don't worry Jamie, I don't...I don't think there is substantial disagreement here it's just making sure there is chance, as you say, for re-presentation and discussion and we'll all be fine.

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

Okay. Thank you.

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

Other comments on the agenda or at least on the minutes? So, none being heard I think with that amendment we will approve the minutes and then move forward to our agenda. And so Michelle we have Leslie and Jon on precision medicine unless you had other administrative items?

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

No, thank you, John.

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

Turn it over to Leslie and Jon.

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

All righty. Well thank you everybody look forward to this discussion. This will be Leslie and Jon of course discussing this. The flow of this is that I'm going to give you all a little bit about the Precision Medicine Initiative more broadly and kind of the opening slides and then Leslie is going to tell you about all the great work that's been happening with the Task Force and the really kind of amazing presentations and testimony we've heard from a pretty broad...for the standards and implementation specifications for Health IT that are needed to support it. So, look forward to your attention to this and some good dialogue if you've got it. Next slide.

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

Hey, Jon, this is Michelle, it's really hard to hear you.

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

Oh, dear, okay, hang on one second. Lonnie and I had this discussion earlier let me just tweak a setting. Is that better?

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

No.

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

Is that better?

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

Not really.

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

No, really? Okay, hang on.

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

I mean, we can hear you before you were stuttering so at least we can hear you now.

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

Okay. Let me make one more tweak. All right how's that?

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

Oh, good.

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

Better.

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

Okay, at last, got you, okay. I just switched to a different microphone, okay. All right, so what you see listed up here on the screen is the membership of the Task Force and in addition to Leslie and myself, we had a lot of great interest from the committee, thank you all so much, you know, broadly for your interest and participating on the Task Force. The members are listed up here.

In addition, because the Precision Medicine Initiative covers a broad array of parts of the administration we've got a number of Federal Ex-Officio members that participated and invited guests that participated in this Task Force from, as you can see, the Veterans Administration, the National Institutes of Health, Office of Civil Rights, the FDA and from the White House the Office of Science and Technology Policy and the US Digital Service, and of course our perspicacious ONC staff who are helping us pull it all together. Next slide.

So this is a kind of broad overview. So in the State of the Union this year the President described the Precision Medicine Initiative and then in our 2016 budget proposal, the President's Budget Proposal, more details were laid out of the Precision Medicine Initiative.

It really is a sweeping initiative and to my very pleasant surprise has been enthusiastically supported not just by a broad swath of the administration but by one of the other branches of congress, it's gotten pretty robust support in congress both in the senate and the house.

So, there's a lot of enthusiasm both in Washington as well as in significant stakeholders in the healthcare delivery system and in the scientific community. So, it's really been exciting to be part of this. Within ONC I've been working with our team to more forward ONC's part of this but as I mentioned there's a lot of other folks that have been working with it and it's been a lot of fun.

The mission statement of precision medicine is here for you and I normally don't like to read slides but I'll read you this one, to enable a new era of medicine through research, technology and policies that empower patients, researchers and providers to work together towards development of individualized treatments.

And the reason it's written that way is because this is not just some new and interesting funding opportunities from NIH, although that certainly is a significant part of it. What we're finding is that this is really...this initiative is the intersection of a lot of different streams of work that's happening both in the public and private sectors and it's been a really fruitful and dynamic demonstration of how the intersection of policy and technology, and science, and participant engagement, and, you know, just a whole sort of other things really that can give us, you know, tremendous hope for the future. So, next slide.

So, across the Precision Medicine Initiative as it's laid out in the 2016 budget \$200 million is requested in appropriations for the National Institutes for Health of which \$130 million would be appropriated to the National Human Genome Research Institute to establish a million person cohort or a million or more person cohort, as Francis has recently been saying, and \$70 million would be appropriated for the National Cancer Institute to augment and establish new clinical trials that incorporate precision medicine aspects into current cancer treatment research.

In addition to the NIH component there is an FDA component, \$10 million in the 2016 budget, to investigate new regulatory approaches for next generation sequencing testing and the data that comes from that testing.

And then finally \$5 million is requested to be appropriated for ONC to advance data standards needed to support precision medicine and to address privacy policy that enables precision medicine and the Precision Medicine Initiative.

So, obviously that is our wheelhouse is data standards here at the Health IT Standards Committee and in particular this is what we're looking for in precision medicine around data standards. We're looking to advance data standards to support precision medicine, address relevant privacy policies and advance innovation.

The initiative will work with the ONC's Federal Advisory Committee Task Force on precision medicine to recommend existing standards that they are ready to use now to support precision medicine, existing standards that may be able to support precision medicine but require further pilot testing and to identify gaps in available data standards to support precision medicine.

The initiative is going to recommend standards to support privacy and security of participant data as well as standards that support a participant-driven approach to data contribution. And then finally, to identify opportunities for innovative collaboration around pilots and testing of standards that support Health IT interoperability for research.

So, you know, kind of what I want you to take away from this is that, you know, this committee has been, you know, kind of working in the salt mines of standards and implementation specifications for a while and this infrastructure has been built in the healthcare delivery system, you know, for our eligible providers and our eligible hospitals and that's a broad swath of, you know, the health care continuum in this country.

And, you know, there is tremendous excitement and interest in the Precision Medicine Initiative to tap into that infrastructure that we have spent, you know, your blood, sweat and tears helping to build. So, you know, I think, you know, as these opportunities become much more concrete, you know, they need these specific recommendations from this committee and that's what this committee does for the data standards to help them move these things forward. So, again, really it's a showcase opportunity for us to help drive something forward using, you know, the hard work that we all know that these are the ends...one of the types of ends that we're trying to achieve with the work that we've been doing. So, next slide.

So, I've talked for a while here, I'm going to stop and I'm going to gladly turn it over to Leslie. She is going to talk a lot more specifically about the Task Force and some of the presentations that we've been hearing where we think we're going in the near future. So Leslie, Co-Chair, take it away.

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

Thanks, Jon. This has been really exciting work a lot of it over my paygrade but certainly exciting to see the emphasis on the contributions that patient generated health data through family health history and other kinds of phenotypic data can contribute. So, I think there is a groundswell of opportunity here for us.

So, our Task Force charge was really to identify those opportunities for collaboration and pilot testing and to recommend existing standards that are currently ready, emerging standards and gaps. Next slide.

So, we have a very aggressive timeline and we have heard really varied presentations from consumer focused organizations like 23andMe to the Institutes of Medicine Genomics Roundtable to Sage Bionetworks, a variety of charges and interests that have presented to us. And this timeline is quite aggressive.

So, the preliminary recommendations will probably or will include further work going forward, but there is a lot to do, there is a tremendous amount of interest and there is a lot of collaboration already going on in the industry to try to make sure that standards can play a part in providing accelerated use and adoption of precision medicine. Next slide, please.

So, we asked the group how will we work to be the most effective and really our emphasis is to have the exchange of information of both the genomic data and the phenotypic data for the patients and participants into EHRs, for researchers and testing labs. And reminded always, by David McCallie, what is the problem organizations are trying to solve. We've asked them to answer that question to give us the minimal interoperable data exchange recommendations, what the standards are that support that movement today and the gaps in the future.

We've collected both written testimony as well as verbal testimony to help us to create some initial recommendations and staff has been very supportive and helpful in this effort. Next slide.

So, the presentations, as I mentioned earlier, all the way from the White House, 23andMe, Duke, Sage and others, and these were fascinating presentations. Duke presented this from a primary care point-of-view and it was a really great and insightful presentation about how precision medicine can help in the primary care setting.

23andMe presented how they're doing their work to support both the research and helping the consumers find out their own family pedigree. So, really vastly interesting and different points-of-view. Next slide.

So, the challenges and topics that we discussed were the patient access and return of the study results, electronic consent, privacy and security and how do we de-identify information, the minimum set of EHR requirements and the representation of both the genomic and family history data in the EHR for primary care and how to implement clinical decision support and pharmacogenomics.

So, we have also heard and had a great article that was presented to us about the FHIR and the use of FHIR with genomics and we discussed a little bit about data storage and transportation. Next slide.

So, our hearings are complete and now we're developing recommendations. We will align with the other workgroup recommendations and then present our findings at the face-to-face meeting in September. So, we will have more detailed recommendations later this winter as we have identified there is a considerable amount of work to be done and we've only begun to scratch the surface on this work.

We are ever mindful that this is an accelerated program, there is funding being announced very quickly and so in order for us to support this effort we need to be mindful, we need to be directional and to provide some opportunity to really accelerate this work. So, it is that balance of, as we saw earlier, standards that exist, as John Halamka mentioned earlier, what's directionally appropriate and what are the gaps. All of those things will be important to identify as we go forward.

This is exciting stuff and there is a lot of not only opportunities in precision medicine but also to advance the standards we have in place for new use cases which just helps standards adoption overall. I think that's it. Next slide. Yes, are there any Q&A?

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

Hey, Leslie...

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

Any questions for the group?

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

Oh, hey, it's Jon, I just wanted to highlight one thing that Leslie said, so those of you who have been following the Precision Medicine Initiative may know that NIH has held a series of workshops under the guidance of a working group, which is part of NIH's FACA the Advisory Committee to the Director, well it's not a FACA it's a Federal Advisory Committee, FACA is the actual act, but so NIH has held a series of workshops to help better understand kind of the dimensions of precision medicine, the Precision Medicine Initiative and creating a cohort really with the intent of informing NIH in the investments that they're going to be making.

Our work is happening in parallel to that work, so two Advisory Committees are kind of, you know, two horses pulling the chariot here, and right now that working group has been pulling...since the end of July has been pulling together their recommendations broadly for NIH and it's investments. They are well aware of this Task Force and the goals of this Task Force.

So, the recommendations that we're looking to bring to you all in September are number one going to be complementary and hopefully dovetail well with the recommendations that this Task Force, that working group is pulling together.

Number two the timing is important because if you think about the 2016 budget, right, so we've requested, you know, funding or appropriations to support the Precision Medicine Initiative. In order for this to be...those funds to be, you know, appropriately awarded in Fiscal Year 2016 those funding opportunities have got to be published pretty soon so folks who are interested in that funding can apply for it.

So really for our recommendations to be incorporated into the implementation of the Precision Medicine Initiative we've got to get at least initial ones out here in September, which is in roughly mid-September is the timeframe that the NIH Advisory Committee is going to be presenting their recommendations to the Director of NIH. So, that's the reason for the aggressive timeline.

As Leslie correctly observed I think what we've done in the testimony we've heard today in the discussion we've had...

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

It sounds like we just lost Jon.

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

Oh, no, am I here?

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

You're back.

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

Can you hear me?

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

Yes, we can hear you now.

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

Oh, sorry, gang, sorry, this is...the excitement of VoIP, sorry. Where did you lose me?

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

I'm not sure now Jon.

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

Jon, I heard you, this is Andy, I heard you throughout.

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

I heard you throughout.

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

So, I think that was more on...

*Multiple voices*

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

It was more on Michelle's end.

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

Maybe it was me, okay, sorry.

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

The old "it's not you it's me" applies, right? So...

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

It's the access, as Rosana Rosana Adana would say "never mind."

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

I love Rosana Rosana Adana. So, I just wanted to try to explain the reason for the aggressiveness in trying to get an initial set of recommendations out and why that's important but also just, you know, as Leslie correctly observed, I think we've unearthed a lot of opportunities to dig into this further.

So, after we get this initial set of recommendations to you for consideration I think we're going to look at, you know, a next phase for the Task Force. So, I just wanted to provide a little detail underneath the excellent frame that Leslie laid out. So, thanks.

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

And Michelle let the minutes reflect that was Emily Litella not Rosana who said that.

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

Same actress, okay, sorry.

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

Are there questions?

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

I have a comment.

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

So, this is David. This is David can you hear me?

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

Yes, David.

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

Just to segue on Jon's, the last comment there, as a member of the workgroup I've been cautioning us to be careful not to prematurely close on standards in such a rapidly evolving space and I'm focusing or thinking mostly about the intersection of what goes on in the genomics research world with the EHR that intersection is relatively unexplored and the movement of genomic derived data back into the EHR to influence physician decision making is a really fairly unexplored space.

We don't have much experience with biomarkers with lots of structure behind them coming back into the EHR and being incorporated in decision support tools. Lots of people have done early work in that space but it's still publication worthy events when you do it.

So, I'm just, you know, raise the caution flag that we be sure not to prematurely close on a particular set of standards in such a young space. Giving guidance on which direction to go or which looks promising, or scoping out the points of intersection so that people can focus on those and find the best standards in those spaces that makes sense, but I don't think we're going to be able to come up with a specific answer in a field that is as young as this.

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

This is Leslie and I would add that we've heard a lot of information about family health history as an earlier opportunity where there is a bit more maturity. So, we still have lots of work to do before we come back in September with recommendations.

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

Yeah, this is David, I agree with that, that's probably the lowest hanging fruit although the current standards in use from the v3, HL7 v3 world are inadequate to capture a full pedigree and so we already have an issue there of whether to endorse a standard that is not quite adequate or to go through a process of improving it, perhaps at the same time that it's migrated to FHIR or some other transport mechanism. But, yeah, that's a good place to start.

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

This is Arien, if I could be put in the queue.

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

Yeah, I'm trying to get through as well, how do...is that how you do it?

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

Well, so, Michelle I trust you have no access to queue management or do you?

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

No, I can see it I just...I think I heard Dixie first then we'll go to Arien.

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

Okay.

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

But, yes in the future if we could use the hand raising feature that would be awesome.

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

Okay, so you said Dixie was up next?

**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**

Dixie?

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

Okay, thank you. Jon mentioned that this infrastructure has been built within the healthcare delivery system. So, I wanted to point out that...well first of all Sharon Terry and I have been engaged in this since PMI...heavily engaged, she more so than I, since the beginning and I wanted to tell you...make sure that this group knows that at the kickoff for the PMI there was a very strong emphasis on three things genomic data, consumer engagement not just consumer donating their data, but ongoing consumer engagement and personal health technology and the integration of data collected through things like the Fitbit with the EHR as well as genomic data integration with the EHR.

In fact, at that kickoff there was an entire session of presentations that were focused exclusively on personal health devices and how the PMI might collect that data and integrate them with genomic data and with EHR data.

I also wanted to point out that CMS, and I know we don't have any influence over CMS, but they made the decision to soften measures, as we all know, for Stage 2 and part of that softening was related to the consumer engagement and reducing the consumer engagement threshold from 5% to one patient and this change will undoubtedly have a detrimental effect on PMI. So I think it would be...it would be good for this Task Force to point that out. So, anything we could do to counter that direction that things are going I think would be helpful.

I wanted to mention that the Institute of Medicine has an EHR action collaborative that is finalizing recommendations regarding standards for integrating genomic data with the EHR. The initial focus of that is on the integration of data that, you know, pharmacogenomics data that could change how one...the treatment protocol.

And then finally, I wanted to recommend that the Task Force capitalizes on Sharon Terry's very deep involvement in this, you know, maybe even reach out to her as an expert consultant. She is a very busy person but I have no doubt that she'd be happy to answer questions or help out however she could.

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

So, that was a...this is Jon; that was a great series of comments. Michelle can I offer a couple of quick responses?

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

Sure.

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

Okay. So, number one, have been grateful to have Dixie and Sharon involved with the, you know, the rollouts of the NIH activities and being involved in those meetings. There were four workshops and one focused specifically on participant engagement and I'll just, you know, side comment here, Dixie used the phrase consumer engagement, you know, in the research world, you know, it starts off as subjects, right, research subjects. We really didn't feel like that struck the right tone so we've been calling them participants and participant engagement because rather than being people and their data being subjects of research we wanted them to be participants in this. So, you're absolutely correct to highlight that as a unique aspect in my mind of the Precision Medicine Initiative in a real kind of fundamental foundational difference for other things.

There was a workshop on participant engagement that was actually at the end of July, a separate workshop on mHealth and personal health technology, you're absolutely correct to call those out. And those I think are things that are key in there.

I think, you know, closer along the lines that David was saying, I think that those...things like mHealth and data that comes from, you know, personal health technology we're going to look at those and say, wow, those are promising areas and either there aren't data standards right now or there are ones that are kind of out there promising but we really need to come to better consensus before we can settle on one. So, I think that's going to be a useful thread of discussion for the recommendations.

I will also say that I believe...I know we had Sharon and I believe we had the IOM as one of the testifiers...

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

Brent.

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

Yes, over the past couple of weeks to our Task Force. So, they are a great resource and I absolutely anticipate that they'll be continued. I will take as much of Sharon Terry's time as we can get. As you mentioned, she's busy.

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

Yes.

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

You know the final piece, I think it bears further discussion about the changes that CMS has proposed in consumer engagement, that's probably all I'll say about that, is that I think it's a good issue to raise and I think that what we ultimately present as recommendations we'll discuss out. So, thanks.

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

So, Michelle, next person in queue? Arien?

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

Arien.

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

Hey, thank you. Yeah, this is a fascinating time in the history of medicine. David's...I've got a lot potentially to say but I'll confine my comments to one area. David's comments I think hit home and in an area where the practice is evolving as rapidly as it is in this area I worry about a focus on standards setting activities as opposed to a focus on practice convening activities where, you know, sometimes in healthcare we think we set the standard then make everybody use it and we get interoperability as opposed to a focus on working to achieve interoperability and then standardizing what works.

The other comment I'll have is I'm sure the group has seen the SMART Task Force or the SMART group's article in a journal affiliated with Cell on the use of substitutable medical Apps. In some aspects of precision medicine, in particular some of the decision support activities that David's mentioning, although I'd also mention that if the underlying data that's being used for precision medicine isn't itself collected and standardized in an interoperable way it's sometimes difficult to have interoperability standards so in some cases we're dealing with practice of medicine issues and not interoperability issues, which again brings me back to my meta-recommendation that says rather than, to the extent possible, rather than setting standards it may be better to define a process for convening for example providers and vendors together to solve practical problems, achieve interoperability and then standardize what works.

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

Arien, all good comments, it is Jon, all good comments. If you do have more to say I think Leslie and I would be delighted to have an off-line conversation with you. Would you be interested in that?

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

Yeah, of course.

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

Okay cool. Thanks.

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

So, Michelle, others in queue on this topic?

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

No, nobody else in the queue.

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

Well, very good, as I think all have said it's a very exciting area and I look forward to the day where all patients can receive the same kind of treatment my wife did for her breast cancer where we were able to comb the phenotypes and genotypes of many other patients like her and then make wise treatment decisions.

So, I think next up we have our Interoperability Standards discussion and as I said it's going to very important for that sub-regulatory guidance of the direction and trajectory of emerging standards especially. And Dixie, yes, your article keeps getting focused on, it's very impactful. So, are Robert and Kim on the line?

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

Yes, I'm here.

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

And I'm here also.

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

Great, well, let us go ahead.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

Can you hear me all right?

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

We can.

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

We can.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

All right, thank you, well, I am Rim Cothren and on behalf of myself and my Co-Chair Kim Nolen and the entire Interoperability Standards Advisory Task Force I want to thank you for this opportunity to present some of our findings and a summary of some of our discussions over the past several weeks. If we could go onto the first slide, please.

Dr. Halamka gave us a good introduction to the purpose of the ISA earlier in today's committee meeting and I won't revisit that but I think it is useful to just touch briefly on the charge to the Task Force that was provided by the committee really to meet and make recommendations regarding ONC's consideration in the Interoperability Standards Advisory or ISA moving forward. If we go onto the next slide please.

In addition to that charge the committee gave us a number of different questions to consider during our discussions and we will come back to those questions at the end of today's presentation just to make sure that we covered them all.

Just to give you a little bit of foreshadowing of today's presentation I will be talking some about some of the overall overarching recommendations that came out of our discussion in Task Force and then we'll touch briefly on each of the four sections in the ISA itself and Kim will help especially in Sections I and II to discuss that and then, as I said, at the end we will come back to these questions and make sure that they were actually covered. Let's move onto the next slide, please.

This lists the members of the Task Force. We had a good representation across a number of different stakeholders, a lot of different experiences and I will say that we had a very engaged Task Force, a lot of good discussion in our meetings, a lot of good discussion out of band as well to research separate topics and it was a delight to be part of this Task Force to discuss this important document. Can we move onto the next slide, please?

Just a little bit about the process that we followed. The Task Force as a group met 10 different times via teleconference for an hour and a half each. It was a very active discussion during those meetings. We reviewed the public comments largely organized our discussion around the four different Sections that are found in...but I will say that the discussion often went to more general items and you'll see a lot of more general recommendations as we move forward.

We also reviewed other work of the FACA bodies, Task Force, the S&I Framework, other federal agencies, etcetera as that had bearing on our discussions. We did supplement our meetings with some out of band e-mail conversations to make sure that we researched items or topics in more depth and then brought those back to the meeting so that they became part of the record and did conduct some additional research out of band as part of that. In addition to drawing from experience from the Task Force members we also got a fair amount of public comment some of that also makes it into our notes and was discussed during the meetings.

Today's presentation and this slide deck largely serves as a summary of some of the higher-level recommendations and higher-level points that came out of our discussion but it is accompanied by a relatively detailed summary of the discussion in our notes that also was sent as handouts. I would certainly recommend and encourage the committee to look through those notes for more detail.

For example, one of the things that the Task Force did do is discuss every single standard or interoperability specification that's found in the ISA and all of the public comments. We're not going to go through those all today. In particular there are some that the Task Force recommended be accepted as they were that there were alternatives suggested and we won't go through all that litany of standards today but they do appear to be within the notes. Let's go onto the next slide, please.

Just as quick reminder, there was quite a bit of public comment on the ISA that we considered as part of the Task Force meetings. I believe that the committee's already seen a presentation on the public comment so I'm not going to go into that in any detail here other than to remark that there was quite a bit of variety in the public comments that we reviewed. There were a number of stakeholders engaged, there were a lot of differing opinions on how to proceed and I will point out that there was little payer engagement and there were no comments from any consumers or groups that represented consumers and one of the recommendations that the Task Force thought was important is for ONC to continue to seek some input from consumers or consumer representatives as the discussion of the ISA and future versions of the ISA are considered. Let's move onto the next slide, please.

As part of our discussions we saw emerging some overall guiding principles that we thought were important both for our own discussions and would be important for ONC to consider in future work on the ISA. And I think it's worthwhile to touch base on each of them just very briefly here.

First of all that the ISA when it discusses a standard or interoperability specification needs to qualify it in terms of maturity of where it is in its lifecycle for testing, how widely it's adopted, etcetera. There are a few characteristics that are really important beyond just identify a standard as best available.

We thought that it was very important that the purposes for the standards accompanied the standards themselves, in particular we thought that it was important that the ISA discuss a set of outcomes and clinical functionality that was important to address in order to achieve interoperability and then standards should be identified that meet those objectives.

It's tempting, in our field, to discuss standards that we believe are good standards and select them without identifying the functions that they actually fulfill and the goals that they actually fulfill and we found it very difficult to assess the appropriateness of standards or whether they really address a best available without a stated goal, a stated function and the outcome associated with them and we really encourage ONC to take that on. We'll discuss that a little bit more in the coming slides.

We should also make sure that each standard identifies what it is best for whether it is an emerging innovation and therefore should be explored, whether it is a tried and true standard that addresses a particular use case or functionality, etcetera. Many of the standards are building blocks rather than overarching specifications for services or particular outcomes and therefore should be identified as such.

When discussing maturity it's very tempting to focus on only very mature standards we want to make sure that the ISA does not stifle but instead promotes innovation and therefore believe it's important to continue to list emerging standards.

Just a quick recommendation that standards that are part of regulation should be identified as such and as we move forward we think that it's also important for us to reach out to vendors and understand which of the standards, especially emerging standards, appear on vendor roadmaps so we can get a better feeling about what adoption may look like in the future. Let's move onto the next slide, please.

Just some general recommendations on the ISA purpose and scope. The ISA needs to cover a broader set of stakeholders it focuses primarily on clinical use cases right now and there is a need, as we move forward, to have a larger stakeholder representation in its recommendations.

There was quite a bit of discussion in the workgroup concerning highly constrained standards versus standards that included optionality. There has been a lot of discussion on that in the industry as well and we recommend, at least early on, that highly constrained standards be selected whenever appropriate and there may be an appropriate move to more flexibility in the future. That the ISA should make sure that...of the interoperability roadmap, we'll talk more about functions and outcomes in a minute.

We need to make sure that pre-conditions, dependencies and other characteristics of the standards are included. We will talk many times about emerging standards and we do believe that it's important that the ISA reflect emerging standards and also needs to reflect how orchestration patterns, functionalities and use cases can be layered to meet the needs of the healthcare marketplace. Let's move onto the next slide, please.

Some general recommendations that apply to the entire document and the tables that are listed, in each one of the sections we believe that it's important to again talk about maturity of each standard and reference the work of the Nationwide Health Information Network Power Team and its recommendations on evaluation criteria.

Also needs to map standards to outcomes and clinical or business functions and reference the work of the S&I Task Force and its recommendations, we'll talk on those just very briefly.

And again, point out that innovation should be promoted and that stability and maturity...it needs to be considered but should not be a hindrance to innovation. Let's move onto the next slide, please.

I just want to refer back to the work of the NWHIN Power Team, again, this is reproduced from those materials outlining maturity criteria and adoptability criteria and we believe that this work should be considered in describing standards. I will remind everyone that we should not use the move towards national standards as a means to hinder innovation. We need to make sure that emerging standards are still considered.

Let's move onto the next slide, please, which defines within that document an emerging pilot and national standards and just point out that in some of the discussions that we had within the Task Force a pilot often is taken, within the industry, to identify standards that may have been tried by only a few organizations and that may not be what the best description of a standard that is intermediate in its maturity and therefore there may be a better term that's used there but that it is important to understand where a standard fits within the lifecycle of standards development. Let's move onto the next slide, please.

And just a few recommendations from the Task Force as part of our discussions concerning the maturity model is that we should make sure we're not just considering national but also international standards, that it's always important for us to be considering international interoperability as well. We need to identify where a standard is in its maturity model but not exclude emerging standards because they're still valuable.

And the absence of a mature standard should not be a reason not to call a standard out within the ISA. That if an emerging standard does exist it simply needs to be identified as an emerging standard so there are cautions in the maturity for its implementation but that it is still valuable to identify the direction that industry is taking. Let's move onto the next slide, please.

A little bit on outcomes and functions. As I said before, the Task Force believed it was very important to identify the primary drivers for identifying standards as national outcomes or clinical functionality, or use cases that needed to be addressed.

We did talk quite a bit about use cases and are concerned about a focus strictly on use cases as perhaps being too limiting as use cases often deliver on very limited or very detailed requirements whereas overarching functionality or outcomes may be a better descriptor of the requirements that should be delivered. Again, I'll just reference the S&I Framework Task Force recommendations that have already been presented and approved here by the committee as underlying some of the deliberations here. Let's move onto the next slide, please.

A little bit on structure and we'll touch on these items a little bit further as we move forward. In general we do recommend that we remove the section on transport standards and we'll discuss the reasoning for that a little bit more as we move forward but it did produce some confusion that we noted during the public comment and although transport standards are incredibly important or critical to us being able to move forward they provided very little value we felt in the ISA itself and identification of transport standards in this services section was more appropriate.

The ISA did not include a section on security and we do have recommendations on how security standards might be incorporated into the ISA and we'll talk about that a little bit more later on in the presentation as well. Let's move onto the next slide, please.

As the next few slides in the presentation here presents some more detailed discussion organized by each of the sections. The ISA beginning with Section I on vocabulary and Kim if you're on if you want to walk us through the next two sections. Thank you.

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

Thank you, Rim. Can everybody hear me okay?

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

We can.

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

Yes.

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

Okay, perfect. And I just want to go back to Rim's point, our first bullet we have the Word document which has a lot more detail in it. We had probably over 150 hours of conversation and it's being condensed down into a little over an hour so we tried to pull out the high-levels, but there are more details in the Word summary so please take a chance to look at those.

The next couple of bullets go over allergies and we had a lot of discussion from our group both in the beginning when we went over the vocabulary and code sets and even towards the end at the summary. And how we came up with looking at allergies is that we should divide it into three groups like an overarching high-level about allergies and what needs to be done and then substances that caused allergies and that should be broken into two sections with medications and food, and environmental substances, and then the actual reaction that happens from a substance.

And so when you look at our recommendations we felt that for medications there was a complex cascade of vocabularies that were needed and that we needed more consistencies and constraints in that vocabulary so that it could be implemented better and articulated more clearly and that there is currently no regulatory vocabulary for food and environmental allergens.

And the group kind of referred back or we did refer back to what the Content Standard Groups had presented in May and thought that a good starting place for food and environmental allergies were the top eight and not that it should be limited to that if more people wanted to do that but that this was a good starting place, but we really needed to define vocabularies for the food and environmental allergens.

The next couple of bullets talk about the care team members and we had a lot of discussion about this and one of the things that came up is we didn't know what the care team member was being used for. Was it just to identify the person or was it to identify the role the person was playing in the care setting?

And so we really felt that it was important to be able to separate the person and their role because potentially a person could play a different role within an organization than their license may say or they may work at two different places. So like when it refers to that patient what role are they playing and there is a code set out, the National Provider Identifier, that we felt has already been established and billable providers have to sign up and have an NPI. It does allow non-billable care team members to apply also but that's not widely known. So that could be a starting point but we still thought it was important to define what are you using this for and is it just for the person or is it for the person and the role?

The next couple of bullets go over talking about sexual orientation and gender identity. The group really leaned on the Fenway Institute approach who has done a lot of research around this and we did feel that it was important to start capturing this information electronically in the electronic health record and the Fenway approach actually takes and breaks down gender identity to how you identify yourself and how you were born so that way you can capture both of those pieces of information and then it also has a question on sexual orientation. And we felt like the language or the vocabulary set for sexual orientation could be updated to the more modern terms that are used for sexual orientation. If we could go to the next slide.

The first bullet talks about industry and occupation, international classification for functioning and disability this was where the functioning and disability question. And the ISA Task Force did not feel there was a best available standard for this. We felt that the one that was listed was more of a clinical classification that maybe could set up your data model for it but we did not feel it was an appropriate technical standard. And we also didn't feel like there was a good vocabulary for this.

So we would recommend figuring out the vocabulary for this and then also figuring out what you want to represent in this. The group also was in consensus that we didn't feel like this should be a requirement for everybody to fill out but only if it was needed.

The next topic was on the preferred language. We felt like there should be a smaller value set for language codes and that was really all the comments that we had on that one.

For the dental codes, and this kind of applied across the board it wasn't just for dental codes, but it brought up the conversation, it was...the CDT, the code on dental procedures and nomenclature, is a proprietary code set and we felt that if it was possible to convene a group to have more of an open code set that this would be optimal.

And then for smoking status, we do have qualifiers for smoking status. We thought there might be a gap in the vocabulary and I think that was mentioned actually on the last slide, one of the top bullets, if there is a time where there is a gap in a vocabulary we felt like the ONC would be a nice convenor to help remediate that gap and we found one in smoking. We didn't feel like there was good representation for e-cigarettes or vaping and that's kind of a new trend that's happening.

And we also...there was a lot of discussion that it's not just smoking status that we need to capture but some of the qualifiers around the smoking status like how quickly do you have your first cigarette to kind of determine nicotine dependency and quit attempts and lifetime exposure.

We also have a separate section because there was a specific question on immunizations that we're going to cover later so that one we will discuss more a little bit later in the presentation. If we could go to the next slide.

Okay, this starts with Section II which was our content and structure. We thought the C-CDA release 2 was an emerging standard and should be labeled that way. We also felt that the ISA Task Force felt that the Consolidated CDA release 2.1 is the version to recommend moving forward since it's backwards compatible with Consolidated CDA release 1.1 and that one...and 1.1 has been widely implemented by the 2014 certification criteria and 2.0 really has not been implemented so if we're going to move forward let's move forward with a version that is backwards compatible with what people have already implemented.

There were several sections that addressed standards for public health reporting and a lot of our discussion revolved around the fact that there's a lot of different processes in public health reporting and there's a lot of different capabilities about what they can accept and not accept. So we thought it was more important for maybe the ONC to convene those stakeholders to define that process better and then you could work on the standard around that process.

There are standards that could be used but, again, it goes back to a capability issue. If that public health entity can't accept that information you have a standard but it's not delivering everything that it should and it's not a standard's issue but a process issue. So, we thought it was important to work on that process first.

Several standards in this section we considered as emerging and it's labeled as such in the Word document and really this goes back to our guiding principle one that the standards should be qualified on maturity, implementation, adoption, pre-condition, dependencies and its ability to meet its goal and if all of that is labeled with a standard we felt that would make it more appropriate to be listed in the ISA guidance document.

And there was some discussion that FHIR was considered both content and services and it would probably be best described in Section IV. And then if we could go to the next slide.

The first two are on formulary and benefit and ePrescribing. The first one there was discussion around the NCPDP formulary and benefits standard and the group did not feel that this standard would meet the goal of getting real-time patient benefit information to the point of care and instead of going with a standard that would not meet that objective we recommended waiting on the real-time prescription benefit inquiry standard which is in development right now at NCPDP. And this is also in alignment with the Content Standards recommendation back in May for Meaningful Use 3.

We also, for the second bullet, for ePrescribing, we were in agreement with the NCPDP SCRIPT standard 10.6, however, there were a lot of public comments around the different message transactions within the NCPDP SCRIPT standards and we felt like those needed to be looked at a little more closely in how they fit in with workflows and system capabilities. We didn't feel like that had been vetted out well enough and that should be looked at.

There were two that we felt probably you could move forward with and that's the cancel Rx so that a physician could cancel a prescription or the refill Rx where the pharmacy could send a message to refill that prescription but the other ones we felt like it should wait and there is actually...we referred back to the Standards Committee, back in May, with the Content Standards recommendations and they tiered these out so we would refer back to that.

The next one was on genomics. We felt like this was an emerging standard and I know we just had a lot of conversation in the first hour of the meeting around this and we felt like it should be pushed more by market demands and a lot of the comments that I heard afterwards I think kind of supported that, you know, figure out what the practice setting process is and then fit the standard in with that. And it is a young space, as David mentioned, and so we should let the market help define that a little better before we push the standards into that.

There was one section, it was called healthcare survey information to public health, and it was for a very specific well-defined survey that is widely used in healthcare and we were fine with that as an emerging standard, however, it did bring up a lot of discussion around it would be nice if you could have a standard that could handle general survey capabilities and that data capture so a more generalized survey instrument. So it kind of...we were fine with this specific one, but it would be nice if there were a standard that could handle different types of surveys that you could build on your own.

We had a lot of discussion around imaging and it wasn't only the exchange of the actual image but the reports that go with the image. And there was a great need from the Task Force or a lot of passion, I guess I could say, that the reporting function has been missed in current regulations and that it was critical and it should be considered more strongly.

We listed a couple of emerging standards, DICOM had a standard that is being published and then there was some discussions around MDM v2, which is currently out in practice to exchange those reports and so we felt like there needed to be more around the reports and how to get those reports out as the clinician typically looks at the report first.

The next one was around computable patient consent or patient consent and we felt it would be good to have a way to do computable patient consent, but we didn't feel like there was a good standard and we also felt like there needed to be a better value set that defined the information that was exchanged in that area so you could be able to do it. There is a standard that is used and is mature but it hasn't been used in healthcare a lot.

And then the last bullet on this side was around data segments for privacy. And we felt like the ONC should really align with other federal organizations like SAMHSA to understand what needed to be exchanged and what could be exchanged and not exchanged and that would help the process a lot better than just with a standard and some of the policies that go around it. And I believe that is the last part of that section and I'm going to turn it back over to Kim.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

Thank you, Kim. The discussions on Section I and Section II during the Task Force meetings was well over half of the time that we spent and probably three quarters of the Word document. Kim has covered a lot of things very rapidly and again, I'd refer you back to the Word document for more details on that, there was a great deal of discussion on the part of the Task Force in those sections. Thank you, Kim. Let's move onto the next slide, please which is on Section III.

And first I will say that if you do turn to the Word document and the notes there you will find discussion about specific transport standards, but none of that discussion is summarized here and it was because we ultimately found, believed and will recommend to ONC, that this section be eliminated from the ISA and I think that it's probably worthwhile to discuss just very briefly why that is.

First of all, obviously transport standards are critical to interoperability and this is not a statement that should diminish the need for transport standards in any way. However, there are a large number of very mature transport standards that are the building blocks of other things that actually achieve goals for within healthcare.

And in both the public comments and in our own deliberations we found it very difficult for instance to discuss the utility of SMTP without also discussing the other standards that bundled together with SMTP actually provide direct messaging or it was difficult to discuss the utility of HTTP without discussing the profiles that form FHIR, RESTful API or SOAP web services that ultimately result in IHE profiles or in eHealth Exchange interoperability specifications.

And therefore our recommendation would be that this section can be eliminated from the document and the specification of specific transport standards should be included among the services section, Section IV, in the document instead.

Let's move onto the next slide, please and that's on Section IV. There was quite a bit of discussion on services as well. First I will start by saying that we did have quite a bit of discussion about the data access framework which provides some very good guidance on how to accomplish, how to harmonize standards to accomplish querying for information in healthcare and although that is still an emerging framework it provides some very useful information that should be considered as part of the ISA.

We do recommend that ONC consider separating patient matching from queries. They're often grouped together in both discussion and in lists and specifications and while patient matching is an important part of querying for documents or querying for individual healthcare information, patient matching has its own utility outside of that context and therefore should probably be separated out.

What we did not find as particularly useful is separating out intra and inter-domain patient matching or query exchange. And in the document today they're currently separated out, IHE profiles used for inter-domain patient matching and querying and IHE profiles used for intra-domain patient matching and querying and therefore the document would be better organized if inter an intra-domain profiles were gathered together.

We do need to include more complete standards associated with authorization and there are some recommendations you'll find this in the Word document for some profiles there. However, there is some caution associated with it that many of those profiles may not be widely adopted yet.

In particular, it's also important to think about ensuring that authorization standards can cross across networks that maybe using different services to provide exchange and therefore authorization needs to be interoperable across different networks.

Kim already mentioned FHIR, we do recommend that FHIR be included in this section and be identified as an emerging standard, it is not strictly just transport it has content considerations as well but it's probably best housed within this section rather than within the content section.

We do recommend that ONC convene stakeholders to discuss requirements for image transport in more detail before selecting a best available standard. It was difficult for the Task Force to identify a real recommendation there without understanding the underlying function or need that is trying to be addressed.

Kim has already touched base on a number of discussions, the lengthy discussion we had on imaging, on DICOM, on MDM that's used for reports and in general there are a number of different standards associated with images and especially radiology reports but the Task Force didn't have within its own membership sufficient experience to make a specific recommendation there and recommends that ONC reach out to the imaging industry to collect more information in regards to that.

Just in general, there was a section on resource location within the ISA and a number of standards that are listed there. They may well be the best available standards today but should all be identified as emerging without a widespread adoption yet or implementation. Not to say that this is a reason not to move that section forward and continue to include it.

In particular though FHIR has discussed provider directories and some other profiles that touch upon resource location as part of the Argonaut Project but has not currently identified it in any of the near-term sprints as part of the work that's going to be conducted there. And the Task Force recommends that ONC should convene a stakeholder group to explore the use of FHIR should the Argonaut Project not identify a near-term work product so that we can just move that topic forward.

And then in general we do believe that there is a need for a publish and subscribe information exchange pattern and there are some standards that are identified both in the ISA and elsewhere that you'll find within the Word document to describe how publish and subscribe might be achieved. However, it is an area that needs more exploration and we recommend that ONC convene a workgroup or a group of stakeholders to address the potential solutions in this area. Let's move onto the next slide, please.

I wanted to touch a little bit more on recommendations associated with security. As I said before, the ISA does not currently include a section on security explicitly and just like with transport standards the Task Force didn't believe that a section on security standards best served the ISA.

In particular it may just lead to confusion if we tried to reiterate the recommendations of other organizations that have already performed work and made recommendations concerning security standards. Therefore it's better to point to these organizations and then to list a maintained and curated standards that they reference, let those organizations maintain those lists instead.

What we do recommend instead though is that the ISA identify a section on security patterns that are useful within healthcare. As an example, it may be important to identify standards to identify how a disclosing party has adequate information before making a decision on whether to provide access to health information or make a disclosure and that pattern and the standards associated with it like the services section would provide some utility and something specific to the healthcare environment.

We do believe that there needs to be statements specific within the ISA that standards are important and that reproducible standards be part of the national standards and therefore there needs to be some representation within the ISA. Let's move onto the next slide, please.

There was a specific question in the call for public comment to the ISA. You'll find a number of comments on specific questions in our discussion within the Word document, but one that we did find...we thought was worthwhile to pull out today was one on HL7 messaging and whether message types should be listed. And our thoughts on that was the answer should be "yes" and the public comments seemed to be that we should call out message types for specific transaction patterns as that is an important and mature area for exchanging information today, but that we should call out a specific version of HL7, that optionality is not our friend in this area and that we'd be better off in being very specific and to the extent that it is possible to call out specific implementation guides whenever they are available because the HL7 messages themselves will only get us so far. Let's move onto the next slide, please.

Just in summary, I think Dr. Halamka provided us a good summary of why the ISA is an important document and we spent a great deal of time talking about it through the Task Force and at the committee meeting today. Just in some summary here we think that it can continue to be a good guidance document moving forward but there are some things that can help make it more effective.

Just in summary, again, including a maturity model and how mature each of the standards listed are, to discussed national outcomes and the common functional requirements that the standards are meeting to show how they fulfill requirements for the healthcare industry, that we relate best available standards to clear outcomes and goals, that we recognize implementation guidance whenever possible that enables interoperability and tighten constraints early on potentially loosening constraints and providing more flexibility as we move forward over the coming years.

We need to make sure that we recognize common vocabularies whenever possible because vocabulary standardization is an important part of interoperability. I think that that's at least somewhat reflected in the volume of discussion that we had on the topic and the volume of notes that you'll find within your packet, that we do need to curate emerging standards and list them in the ISA but critically consider them as they may form an important part of interoperability moving forward and in some cases it even maybe important to identify that emerging standards are good candidates for replacing mature standards that don't fully meet the goals for which they were intended.

We do believe that it's important because things mature to include a broader stakeholder functional representation and that we should...that ONC should work with industry to remediate all of the identified gaps through SDO or Workgroup activities whenever that's possible.

And then just finally think it's very important to make sure that the ISA continues to promote innovation. Let's move onto the next slide, please.

I believe this begins to take us through the specific questions that the committee posed to the Task Force. I won't cover these in any great detail because I think we've covered them mostly so far but think it's worthwhile to touch base on them just very quickly.

What additional information about the standards and implementation specifications would be helpful to represent in the ISA?

We've talked about this in some detail that rather than just calling out best available standards it's important to reflect their maturity and to make sure that there is good separation between standards and the implementation guidance within the tables that reflect standards just to make it clearer what role each of the identified documents plays and to include implementation guidance whenever it is available.

Are there other suggestions for additional characteristics?

And we've talked about the characteristics in some length now both in the maturity model, the need to include information on pre-conditions, dependencies, etcetera and especially in outcomes and functionality, clinical and business functionality, that it's important that each of the standards or implementation guides fulfils. Let's move onto the next slide, please.

As Kim had said there's a detailed question on immunization code and terminology standards. Kim do you want to touch on our answer to that question briefly?

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

Sure. So, what the group came up with is that we did feel like there was still a need for CVX codes both in the historical and the administered immunizations because this is a maintained and curated list that could promote interoperability whereas NDC codes should really be used for inventory management, packaging and that type of stuff, and maybe it's something that is kept on the local system but it should not be a code system that is used for interoperability because that list is not maintained, the codes can be repurposed and so you could actually have a conflict with the coding system.

So we felt that the CVX code was the better coding system to be able to define what immunization was either administered or historical and then if they had a need for the NDC code that it would just be for local organizational management.

There was also some discussion around the MVX code and we felt like if that was available you could use it but it shouldn't be a requirement whereas the CVX should be a requirement. Kim, did you have any other additional comments there?

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

No, I think that covers our discussion well, thank you.

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

Okay.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

Let's go through the rest of the questions just very briefly. Should security standards be represented?

We've discussed that in some length and we believe that they should but in the context of security patterns that are useful within healthcare as opposed to reiterating the work products of other organizations that are considering security standards already should probably occupy a section within the ISA and we need to make sure that security is identified as an important part of interoperability. Let's move onto the next slide, please.

The next question was how to ensure that the ISA is relevant?

And I think that this comes back again to our discussion of the outcomes and functionality that standards occupy. I think that it will help and the Task Force believed that it would help ensure relevance if it was clear what standards, what requirement standards we're delivering on.

There is a great deal of information that you've heard today and I will admit that I found it somewhat difficult to prioritize all of the recommendations here what should occupy near-term versus longer-term focus but there are at least a few recommendations here.

In the near term for 2016 we would recommend to consider recommendations on reorganization of the implementation guide concerning security and transport in particular, try to characterize best available standards in terms of maturity, testing, adoption, pre-conditions, dependencies and the ability to meet specific goals which will require at least an initial assessment of what those goals are in terms of outcomes and business functions. So, that's a fair amount of work to try to accomplish for the next iteration.

We do caution towards rushing forward to identify best available standards when one is not evident and that ONC should make sure to identify emerging standards that do make sense but to make not to identify as best available standards that are not yet mature, not yet widely adopted without identifying them as such.

Longer-term then, beyond 2016, obviously it will be important to continuously update maturity models for each of the standards as they become more widely adopted and to adjust outcomes and function requirements as necessary as we move forward towards a learning healthcare system.

We do hope that it will be possible to start including more information about adoption or especially commitment to emerging standards perhaps by surveying vendor roadmaps, to the extent that they'll make them available, so we can understand where vendors are starting to put some of their focus.

WE do recommend broadening to include a more complete spectrum of stakeholders and therefore healthcare needs and then point ONC and the committee back to the guiding principles, the recommendations on scope and purpose and document structure that were in the early slides in this slide deck as continuing themes as ONC would move forward. I believe that is our last slide and that we are now ready for any questions or discussions.

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

Rim?

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

Well, that was a remarkable presentation. So Michelle, I would imagine your queue is filled with folks who have comments and discussion.

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

Michelle, this is Kim, could I clarify one point?

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

Sure.

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

Okay, on slide 21, Kim, and I'm sorry, I just noticed there was a conflict between our slide and the Word document so I wanted to point that out. We had listing the version number but in the Word document in some of the discussion so I'll open this up for the comments that are in the queue for how we should correct this. We felt that the constraints and the limiting of the optionality was more important than listing a certain version and here we said both, so I just wanted to point that out and then we'll open it up for discussion about how y'all feel it should move forward.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

Thank you Kim.

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

You're welcome.

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

And just to remind the group that Dixie's article about how to assess standards maturity is published in JAMIA now and Michelle we'll make sure you have that URL if folks need to reference it. And so, questions from the queue?

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

David McCallie is up first.

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

Well, David?

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

Hey, thanks. First to the Task Force congratulations on an immense amount of work organized very clearly I'm totally impressed that you got all that done in the summer. So, anything I say in criticism please interpret in the context of tremendous admiration and respect for what you've done.

And mostly I'm really quite comfortable, particularly with the guiding principles. The one that jumps out at me was way back on your slide six, the ISA should recommend standards and interoperability specifications that are subordinate to achieving a set of real world value added outcomes and business functions to better achieve our state of the world in healthcare.

That role of standards being subservient to is the one, to specific settings, is the one that I want to just call out as being to me so important, the lesson learned from six years that we've been doing this so far is that if you don't have the well-defined business function with clearly defined value added outcomes, the standards just don't get used or don't work very well, or are never implemented properly. Standards need to follow. So just to reinforce that point about which I totally agree.

But my question and it may be really is more a question for ONC is, and I'm wondering if this came up in the discussion at all, is would the Standards Advisory take on some official role with respect to the regulatory process? In other words, is there some notion that unless a standard is listed on the Standards Advisory it could not participate in a regulatory apparatus or are those two completely decoupled from each other? Did that come up?

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

I think that's a very good question and I think that early on in the Task Force deliberations we did talk about that. I think that our impression was that they were decoupled and that the Standards Advisory was a forward-looking document as Dr. Halamka had identified earlier that might be separate from regulation and that there wasn't a needed progression, but I don't know that that received a great deal of pointed discussion within the Task Force deliberations. Kim, do you remember more discussion than that?

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

Yeah, we did not discuss that a lot but David I think it might be a good point maybe to put in our guiding principles to define that out.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cuning Plan, California Association of Health Information Exchanges**

It...

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

David, its Jon White do you want us to pointedly discuss that now?

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

Well, I'd be happy to just, you know, put my two bits in, which is that I'm still a little unclear on what the role of the Standards Advisory is and my argument goes as follows.

The people that have the well-defined process oriented business outcome value statement, etcetera that you call out are going to be so deep into...the people that are going to work on achieving some value added outcomes are going to be so deep into the space they're going to either understand the existing standards or they're going to create a new one if there isn't a good standard available and, you know, we see that over and over again and the focus that the Task Force has called out on in innovation I think reinforces that point.

So if standards can emerge as a side-effect of innovative business practices they might not make it onto the Standards Advisory for whatever reason. So decoupling the Standards Advisory from any notion that the standard is appropriate for widespread use and eventually for inclusion in regulatory framework seems like a good idea to me.

In other words I'm not sure we want to create a bureaucratic step that says you've got to get onto the Standards Advisory first. I don't know what that would mean. I don't know who curates it. It almost becomes a subcommittee of the Standards Committee and that seems to be even more complicated than our current real world.

So listing the standards that we have today to kind of catch people up makes good sense but I'm not sure what happens going forward as innovation continues to occur.

You know I'll particularly point out within this space with FHIR there's likely to be quite a bit of dynamic innovation around FHIR resources, this is not FHIR as transport, but FHIR defining resources and that innovation is going to happen much faster than the Standards Advisory is going to get updated and one would hope not to suppress innovation simply because it wasn't on the Standards Advisory.

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

Hey, this is Steve Posnack from ONC. And I'm glad you kind of answered your own question David in terms of what your preference would be.

So, you know, we first approached the Interoperability Standards Advisory as both a transparency mechanism for the industry at large as well as a coordination mechanism for everyone to represent what all is going on and where, you know, this concept that we had included in, in terms of, you know, best availability in reflection of both the interoperability roadmaps work leading up to its publication as well as just our own past experience that, you know, a number of the interactions that we've had with the community at large has resulted in, you know, debates or dialogue associated with, you know, what should we be using for X.

And I don't think that there is a necessary kind of precursor to your point that things need to be on the Advisory in order to be referenced in regulation, but, as, you know, when we first introduced this we saw that as something's inclusion in the Interoperability Standards Advisory as an indication or at least additional vetting before we would, you know, be able, I shouldn't say be able, before we would look to considering something for regulation or regulatory purposes.

And so it had some additional value added at least from an initial perspective that, you know, its maturity and its testability, and other such factors as identified by the Task Force would be articulated transparently in public and that this would serve to guide initial decisions if a use case or an outcome, or goal from a policy perspective was identified and was trying to be pursued via regulation.

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

So, this is David again, yeah that's good and I mean, I'm in general, obviously, in favor of being extremely cautious about something getting into regulation because once it's there, you know, it's really hard to refine it or correct mistakes. So the degree to which the Standards Advisory adds additional scrutiny to the process of something landing in regulation I think that's a useful goal and maybe something I underestimated in terms of thinking about it.

But the converse of that or the unintended consequence associated with that is if there are groups out trying to solve problems in the context of a real world business case and they're inhibited from trying something new because of the process going through a Standards Advisory is thought to be cumbersome or complex, or expensive, or unpredictable that would be an unintended consequence.

So I like the focus on innovation that the Task Force called out we just need to make sure that doesn't get lost in whatever processes grow up around the way the Advisory listing is curated.

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

Yeah, and I...you know, my own personal hope just would be that as folks, you know, pursue that approach for, you know, new innovative purposes and etcetera that they would see this potentially as an opportunity to report that in so that others would know, you know, hey, we're pursuing, you know, approaching FHIR this way and, you know, that could be referenced not as a limitation but as a way to communicate to the entire community like we're trying out this thing.

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

So, then that begs the question of report into whom under what framework. I mean, is this another S&I? Is this an S&I replacement? Is this a...in other words let's say I want to share insights into how to use FHIR to move biomarkers around between genomic testing labs and EHRs, how would I do that vis-à-vis the Standards Advisory?

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

I think it's a really important topic and I can see us having, you know, a half hour of discussion about it that I don't want to belabor folks on, but I don't think it's an S&I, you know, replacement oriented thing. I think this is, you know, where that could be an evolution of just the general engagement and availability, and, you know, if it's, you know, tactically speaking, if it's a, you know, wiki or something else that is, you know, more industry value added, you know, contributions than, you know, that would be great. If there's some other things or, you know, we don't take it on at all and we stay out of people's hair then, you know, I don't think we're prejudging, you know, what it would be.

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

So, the way I think about this...

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

Okay, thanks, I'll let others go.

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

Yeah, but David, the way I think about this document is it's sub-regulatory guidance which is intended to be helpful to stakeholders who are trying to make a decision for what standards they may want to work on in pilot mode or forecast for the future. And in effect the Standards Committee is supposed to be the nation's experts and advisors trying to do a public service. Well, thanks for the comments and so Michelle who is next in queue?

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

Leslie Kelly Hall.

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

Leslie?

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

Hi, guys, great presentation, thank you and early on you mentioned that the group lacked consumer feedback and I hoped that you had recommendations of how to include that kind of consumer representation that's one comment and I'd volunteer myself if there is any opportunity.

And then the other comment is specifically, as you discussed, stakeholders it didn't appear that patients were included in that stakeholder group and so how do we make sure that there is a broader idea of stakeholders throughout your recommendations, so that's a second point.

And then the third point is we have mature standards in the consumer world that can inform Health IT and so perhaps...one of your slides talked about the maturity should not prevent the ability to be included in an advisory and I would also like to see that, if it's agreeable, that we have maturity evaluated not just based upon its use in Health IT but it's based...it's use based in other places, you touched on that a bit with comments around devices and Dixie made those earlier. It's just very important.

We will have an onslaught of consumer types of standards, devices, patient generated health data, phenotypic data coming into this environment from a very mature, often a mature base. So could you comment on those three things? Thank you.

**Robert Cothren, PhD, MS, SB – Executive Director – A Cunning Plan, California Association of Health Information Exchanges**

Well, I'll go ahead and get us started here. I think the lack of specificity on how to engage consumers only reflected the organization of the document as it stands now and the stakeholders that were primarily identified and the lack of comments from consumer representatives but not the intent of the Task Force at all and I apologize for the oversight and not including consumers in the list of stakeholders, it absolutely should be there and I think that the Task Force would agree with me on that point that this is the feeling of the Task Force and not myself.

We did not discuss in any detail a better way to identify or encourage better involvement by consumers so I don't know that there were recommendations that came out of the Task Force in that regard. Kim may recall some conversations that I do not.

But I do think that the Task Force would agree with your last point that drawing on standards from that environment will be important and one thing that was clear through our deliberations is that there is a great deal to be learned and incorporated from other industries within Health IT and therefore we do need to learn from other things that work.

I'd go back to a comment that Arien made in the previous presentation concerning focusing on interoperability and then standardizing on what works. I think that this applies here as well.

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

Thank you.

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

So, other comments Michelle?

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

Stan Huff.

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

Stan?

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

Yes, this is Stan. I'm impressed as others have been by the report and I like the way that the value of the Advisory has been positioned. I see it as a place where people could come if they're contemplating making a new interface or trying to progress they can go there and say "oh, these are sort of the starting assumptions around this" you know whether that might be a use case for movement of lab data from labs to EHRs or service interfaces to allow applications to interoperate across the EHRs. So, I like that.

I think the thing that became clear is that it is a starting point and just to make a statement that I hope people would understand is that the Advisory won't get you to interoperability. So saying that, you know, we're going to use version 2.x, HL7 and LOINC, and SNOMED doesn't get you to interoperability you still have to get to details that would be either in implementation guides or information models that would say, but what's your policy about whether you pre-coordinate method with the LOINC code or you don't, how do I make the connection of specific value sets for coded data elements. There are a whole bunch of things that would have to end up in more specific guidance to get from what's in the Advisory to truly interoperable software. And so in a way I think I'm saying something that's obvious to everyone.

And then the second part I think is just to say...and when you think and contemplate that it's a message that we need to get out broadly to legislators and others that this is hard work. If you're going to get to real interoperability it's a lot more than just saying I'm going to use this version of this syntax and I'm going to use LOINC codes and SNOMED codes.

There's a lot more work that needs to be done there to get to interoperability and so I guess it's a plea that people understand the complexity of what we're trying to accomplish and don't set arbitrary unrealistic timeframes for accomplishment of what we're trying to do and I'll stop there.

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

Well, Stan to your point, I was testifying in front of a group recently and I described the need for core datasets and agreed-upon pre-coordinated vocabularies and they said, no, interoperability is the exchange of all data in the EHR with everyone for every purpose. Okay then.

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

What could be clearer huh?

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

Right. So, Michelle other comments?

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

Jamie Ferguson.

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

Jamie?

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

Hi, thanks. So, first of all I really want to thank both the presenters but also the members of this group and really recognize the tremendous work and appreciate both the clear presentation but also just the sheer volume of good work that was done here.

I do have a couple of comments, one is, I know you went through the PowerPoint slides, you also distributed a Word document summary of the workgroup discussions and I'm looking at the very end of that document the statement that the maturity of standards should be based on the standards development organization's own objective metrics that define the maturity of the technology within its lifecycle.

And so this comment really is that...I think that, you know, in order to ensure not only full transparency and trustworthiness of the process but also the validity and reliability of the assessments of each of the standards I think it would be advisable to more fully describe the metrics that were used to assess each of the standards against the characteristics and factors and so I just think...so taking nothing away from the recommendations or the work that was done I think it would be helpful to be more descriptive about sort of the measurement process against those characteristics. So, that's one part or part one.

I guess my second comment, I want to support the question that David McCallie raised about the purpose of the Advisory and I'm thinking back to...I had to look up the letter to the ONC from the Federal Trade Commission on the subject of this Advisory which was back on April 3<sup>rd</sup> and they had more than 10 pages talking about the effect of the Advisory on competition, on innovation, on lock-in and switching costs and one of the key recommendations from the Federal Trade Commission was that ONC should consider allowing both standardized and non-standardized approaches in order to better achieve interoperability and so in line with considering the purpose and the use of the Advisory I wanted to support that comment from the FTC.

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

Well, very good advice. Michelle, any other comments?

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

Arien Malec.

**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**

Thanks, I just wanted to follow on Stan's excellent comments that actually recapitulated a lot of the discussion that we had on the Task Force that it's very important that the Standards Advisory list all of the preconditions for interoperability and also provide any of the caveats in terms of what to expect when you're interoperating, that in many cases interoperability is not a case of picking a standard and you're done, it is a case of picking a standard, carefully defining what you're actually solving for, defining the subset vocabulary that you're interoperating, defining the subset of data that you're interoperating and listing a standard on a Standards Advisory with a broad use case without listing all of those preconditions will have the unfortunate side-effect of providing unrealistic expectations. So, Stan's comments really are important and reflect a lot of the deliberation and discussion of the group.

I guess the last comment that I'd have is that in the enumeration of standards and vocabularies that we put together it really puts to lie the notion that we don't have standards in healthcare or that we haven't picked and named standards in healthcare and I think it should be a somewhat cautionary tale for those policymakers who believe that interoperability is simply a matter of picking standards.

We have many standards, we have some interoperability, but, you know, we should re-recognize and double down again that interoperability is not simply a matter of picking and naming a standard and everything is good. Thanks.

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

Well said. I think all of us who testify say this over and over, its politics, its policy, its process and not just an enumeration of standards. Michelle, other comments?

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

No that's it.

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

Wow, less controversy than I thought. I think this was such a remarkably well done document, very comprehensive and included all the usual caveats that we've had over the years with regard to maturity and the standards being necessary but not sufficient for true interoperability. So, I think next we hear from Steve Posnack and he is going to tell us about a Task Force to be found.

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

All right, yes, as soon as we discover it we'll let everyone know. So...and thanks to the...I want to first pause and acknowledge Kim and Rim as well as much as everyone they did a tremendous job taking on this work and maybe we'll recruit you the next time we have to do an update to the Advisory again. So, that's your reward for doing such a good job.

So, in terms of Task Forces, a little bit of history for those of you that may have joined the Standards Committee after this time. In 2011 the Standards Committee issued recommendations on the assignment of code sets to clinical content for use in quality measures and in that set of recommendations vocabularies and code sets were named, terminologies were named and identified for particular representations of data and where there wasn't a kind of single or exclusive standard identified there is a transition period or transitional vocabularies that were identified and some considerations in timing that I think reflected folks estimates of timing related to what the world looked like in 2011.

And as we've discussed those recommendation with our colleagues at CMS there was an interest in getting updated recommendations from the Standards Committee since you all were the ones that originated these recommendations and thoughts and our hope would be that we could kick off a short term Task Force of which some of you were part of the Standards Committee process at the time in 2011 and we'd seek to recruit you to do this again to really answer the question about should some of the transitional terminologies that were referenced be eliminated as alternatives in reporting to federal quality measure programs, and, you know, if so, which ones and by when. So, that's a pretty simple, yet, complicated question in terms of the amount of...I think there are 26 clinical domains that were looked at previously as part of that set of recommendations.

So, we'd like to have that Task Force kicked off pretty soon and have recommendations later this year in terms of a revision and analysis of the 2011 recommendations and I'll stop there, at least on this one.

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

And the process for the formation of the Task Force, selection of its members, etcetera, anything the group should know about?

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

Interested Standards Committee members should contact Michelle via e-mail as soon as she has that ability again. And members of the public can apply through the ONC FACA database if you haven't already. For those of you that we've predetermined as potentially likely suspects we'll reach out to you to solicit your interest and availability, and other than that I think that kind of wraps it up for your awareness of the initiation of this Task Force.

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

Great, any comments on the Task Force formation? Well, Michelle I think it would be useful, just we have a couple of minutes, then of course we have public comment, just to remind folks of our upcoming meetings, virtual versus in person.

At the moment my understanding is that September will be virtual, October 6<sup>th</sup> will be in person that's the joint meeting of the Standards and the Policy Committee, November will be in person, December will be virtual and then January will be in person, and I think important to note in the January meeting is that I think we do have some transitions of additional members occurring at that time, including my own transition from the committee. So, I think January will be a bittersweet meeting for several of us.

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

Thank you for noting that.

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

Did I get the schedule correct?

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

You did and on that note we did announce a few positions that will be available in January, yours being one of them. So if people are interested in joining the committee we also are accepting applications through the FACA database which can be found through healthit.gov the same database that you can apply to workgroups through as well, I should say Task Force.

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

Very good and I hear Donald Trump is applying for my position so I wish you all well. So, with that I think Michelle unless there are other administrative matters we have public comment.

**Public Comment**

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

Lonnie?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

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

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

We do have a public comment from Eric Heflin. Eric, as a reminder, public comment is limited to three minutes. Please go ahead.

**Eric Heflin – Chief Technology Officer – HealtheWay, Inc.; Chief Technology Officer – Texas Health Services Authority**

I...

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

I can't hear Eric can others?

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

I cannot hear him.

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

No.

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

Okay.

**Eric Heflin – Chief Technology Officer – HealtheWay, Inc.; Chief Technology Officer – Texas Health Services Authority**

Hello?

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

Eric, do you want to start over?

**Eric Heflin – Chief Technology Officer – HealtheWay, Inc.; Chief Technology Officer – Texas Health Services Authority**

Can you hear me now?

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

We can hear you, yes, go ahead.

**Eric Heflin – Chief Technology Officer – HealtheWay, Inc.; Chief Technology Officer – Texas Health Services Authority**

Okay, great. I guess I hit \*1 prematurely. So, I just want to say thank you for the opportunity to provide comment and I also was really honored to be part of the Interoperability Standards Advisory Task Force and found that to be a very enjoyable process, one I thought was very valuable, we had a chance to triage and disposition a large number of public comments and try to interpret those and provide concrete feedback to the ONC.

I just had just a few brief comments, regarding Leslie Kelly Hall's comment about consumer representation, I just wanted to point out at the bottom of the ISA, slide number five, which I believe is physical slide 37 in this deck, there is actually a specific recommendations that the Task Force came up with which is that given that there were no public comments or no comments received from that very important segment that we recommend that the ONC specifically reach out and solicit proactively feedback from that group.

Regarding the comment about determining the process that standards bodies use to assess the maturity of their standards, I just wanted to point out that most, if not all, standards bodies as part of their charter, under the ISO or ANSI or other charter organizations actually are required to do that.

And so for example the IHE, which I'm a member of and very familiar with, they actually specifically publish their assessment criteria to determine whether or not a standard is actually ready to move from say a draft standards to final tech standard and that includes factors such as adoption by multiple organizations showing essentially vendor neutrality, successful testing at test events that exist of the test cases and similar criteria and those are actually all documented and available to my knowledge by probably all standards bodies that we're referencing.

And then my final comment, I just want to echo what I think several have said on this call which is that the Standards, Interoperability Standards Advisory Task Force repeatedly, almost every conversation, came up with the same issue which is it was hard for us to recommend specific standards in the absence of a use case or an outcome to drive that. So I just want to reiterate that one point that a use case-driven approach, I believe, is very critical because then we can judge a standard as being sufficient or overkill or insufficient but without a use case or an outcome to drive that that's very difficult and that concludes my comments. Thank you.

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

Thanks, Eric. Eric also submitted his comments via the public chat so we will distribute those to the group. We also got a comment from Gary Dickinson through the public chat that we'll distribute to the group. And we have another public comment from Afton Wagner.

**Afton Wagner – Manager Federal Affairs - HIMSS**

Hi, Michelle, can you hear me?

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

We can hear you.

**Afton Wagner – Manager Federal Affairs - HIMSS**

Great, thank you. Thank you so much for the opportunity to provide comments today and for the great discussion. I'm with HIMSS; my name is Afton Wagner, just wanted to provide comments that are consistent with this rule as a leading subject matter expert in security. HIMSS commented on the ONC ISA document during the public comment period stating that the document should contain a list of security standards in a separate section and we provided a list of standards.

We are supportive of the final Task Force's recommendation in this regard that the ISA document should discuss explicitly the need to leverage security standards to facilitate interoperability and then point to external resources such as NIST to publish a list that are curated and maintained in a timely manner.

During the Task Force discussions the point has been made that purpose of use is a very important constraining factor for security standards that can be leveraged in terms of permission constraints providing...across...information resources and supporting security system...policy.

We agree that security standards in the use in healthcare should be constrained by a purpose of use and work should continue in this area.

We also concur with the Task Force's assertion that security standards are very important but there needs to be sound and clearly articulated information showing policies that are promulgated and agreed upon so that optimal technology solutions can be leveraged.

We thank the Task Force and previous workgroups for the time and energy they have contributed to making the ISA document a very valuable resource for the healthcare industry and that concludes my comments. Thank you very much.

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

Thank you, Afton. It looks like we have no further public comment so thank you everyone and thank you for the great participation from the public via the public comment.

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

Well, hey, and Jon White, and so we are near the end of our time. Do you have any closing benediction for us all as a close out our summer vacations and look to the fall?

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

Yeah, so, just, you know, everybody's already said it before, it's tremendous work, I too wanted to thank Kim and Rim.

You know I'm excited, I'm really excited about the future of the work that we've got tee'd up here, you know, the rules are always changing, right, but it feels like there has been a lot of swirl and a lot of, dare I say it, drama over the past several months and it feels like there's some real substantive stuff that's lined up in front of us.

And, you know, I'm grateful for the head's down work that's been happening over the past couple of months and I'm really excited to see what's going to be happening over the fall and the months ahead. So, thank you, everybody for your hard work. Dr. Halamka the final word is yours.

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

Well, very good, I think you've summarized it well. Let us all hope that the next tranche of work is productive without drama that's all we could ask. So everybody you have a wonderful rest of the summer and we will reconvene on our call post Labor Day in September. Have a great day.

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

Thank you.

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

Ciao.

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

Thank you.

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

Thank you.

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

Thank you.

## Public Comment Received During the Meeting

1. Gary Dickinson, CentriHealth, gary.dickinson@ehr-standards.com Start with Guiding Principles (Slide 6, Item 3): “3) ISA should define what the standard is best for – innovation, tried and true use cases, and/or functionalities... Cross walking between use cases and functionalities and explore the ability to tie functionality to use cases”. Then consider Outcomes and Functions (Slide 12, Bullets 1-2): “1) The ISA should include a description of outcomes and clinical functions that standards and interoperability specifications must support in order to identify Best Available. 2) Should focus on functionality...”. ISO/HL7 EHR/PHR
2. Gary Dickinson, CentriHealth: Also note need for “functional requirements” in Summary (Slide 22, Bullets 2.2-2.3): “[2.2] Discuss national outcomes and common functional requirements. [2.3] Relate best-available standards to clear, real-world outcome goals and functional requirements.” ISO/HL7 10781 and ISO/HL7 16527 are primarily focused on EHR/PHR functional requirements.
3. Eric Heflin: On the Task Force, I specifically mentioned and recommended to the ONC that they specific solicit feedback from consumers and consumer representatives. See the bottom of the ISA slide 5, which is the bottom of physical slide 37 (Which has the recommendation documented).
4. Eric Heflin: Regarding the comment of the SDO maturity assessment, SDOs such as the IHE, transparently publish the standards maturity assessment process. Factors include adoption by multiple organizations, rate of change of the standard under consideration, success in testing at test events, and similar criteria.
5. Eric Heflin: Final comment was the Use Case driven approaches are critical. Otherwise it is impossible to determine if a given standard is appropriate, sufficient, or insufficient.

Meeting Attendance								
Name	08/26/15	06/24/15	05/20/15	04/22/15	03/18/15	01/27/15	12/10/14	11/18/14
Andrew Wiesenthal	X		X	X	X	X	X	
Anne Castro		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
Charles H. Romine			X	X	X	X		
Christopher Ross		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

Eric Rose	X		X	X	X	X	X	X
Floyd Eisenberg	X	X	X		X	X	X	X
James Ferguson	X		X	X	X	X	X	
John Halamka	X	X	X	X	X	X	X	X
John F. Derr		X		X	X	X	X	X
Jon White		X	X	X	X	X	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		
Rebecca D. Kush	X		X			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
<b>Total Attendees</b>	<b>15</b>	<b>21</b>	<b>21</b>	<b>22</b>	<b>26</b>	<b>25</b>	<b>22</b>	<b>20</b>