



HIT Standards Committee Final Transcript September 22, 2015

Presentation

Operator

All lines are now bridged.

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. As I take roll there will be some new names and some old names so just bear with me if you can. So, Jon White?

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

Here. John Halamka?

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

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?

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

Here.

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

Hi, Andy. Angela Kennedy?

Angela Kennedy, EdD, MBA, RHIA – Head & Professor Health information Management – Louisiana Tech University

Here.

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

Anne Castro? Hi, Angela.

Angela Kennedy, EdD, MBA, RHIA – Head & Professor Health information Management – Louisiana Tech University

Thanks.

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

Anne Castro? Anne LeMaistre?

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

Present.

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

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

Hi, Dixie.

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

Hi.

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

Liz Johnson?

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

Here.

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

Hi, Liz. Eric Rose?

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

Here.

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

Hi, Eric. Floyd Eisenberg?

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

Here.

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

Hi, Jamie. Jitin Asnaani?

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Here.

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

Hi, Jitin. 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. Josh Mandel?

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children’s Hospital

I’m here, hello.

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

Hi, Josh. Keith Figlioli? 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?

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

Present.

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

Hi, Lorraine.

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

Hello.

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

Nancy Orvis?

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

I'm here how are you?

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

Patty Sengstack?

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Hi, I'm here.

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

Hi, Patty.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Hi.

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

Becky Kush? Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Good morning, Michelle.

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

Hi, Rich. Steve Brown?

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

Here.

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

Hi, Steve. And Wes Rishel?

Wes Rishel – Independent Consultant

Here.

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

David McCallie? I know he was here. And Stan Huff?

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

Can you hear me? Hello?

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

Hi, David, yes we can hear you.

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

All right.

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

Is Stan Huff on the line as well? Okay, with that I'm going to turn it over to Jon. And Jon let me know if you need help explaining the new members and what's going on.

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

Thank you, actually I will lean on you for that but first I want to say welcome everybody on the phone. Thank you so much for getting on what I think promises to be a really thoughtful, substantive and hopefully fruitful discussion today. It is my really actually distinct and great pleasure to be able to introduce several new members of the Standards Committee to you all today.

As you know we've been having some of the normal cycle of turnover of membership in the committee, that membership is kind of dictated to us by the law and we've been, you know, working with it as, you know, as best we can. And we're really grateful for the standing members of the committee who have agreed to extend their service as we've gone through the clearance process and we're partway through that process.

But we've got some really outstanding new members and I'm going to tell you a little bit about them now and then I'm going to ask Michelle to explain kind of the context in which they join us today and for future meetings.

So, first I'd to introduce everybody to Jitin Asnaani who is the Executive Director of...hello...who is the Executive Director of the CommonWell Health Alliance. Jitin is on a mission to make nationwide health information exchange a reality. He comes to the CommonWell Health Alliance with experience in both the public and private sector. Public sector notably being his time at ONC previously equipping him with the tools and knowledge to effectively collaborate with government, vendors, providers and other interoperability stakeholders across the care continuum.

His diverse work history includes product innovation and interoperability at athenahealth, technical standards development at the Office of the National Coordinator, product management at Health IT startup and strategy consulting at Deloitte. So, Jitin we're delighted to have you.

Next up is Dr. Josh Mandel of Boston Children's Hospital. Josh is a physician and software engineer with a special interest in building tools that support App developers new to the health domain. After earning an SB in Computer Science, I didn't even know they awarded those, at the Massachusetts Institute of Technology, and an MD at the Tufts University School of Medicine he joined the Faculty of the Children's Hospital Informatics Program at Harvard Medical School where he serves as the Lead Architect for the SMART platform's team. With SMART he's helping to foster an ecosystem of substitutable medical applications that can run in multiple EMRs, PHRs and data mining platforms.

So, our third new member to announce is Rich Elmore from Allscripts. Rich is responsible for Corporate Development and Strategy at Allscripts. His areas of expertise include healthcare standards and healthcare information exchange. He is presently Co-Chair of ONC's Content Standards Workgroup and serves on the Board of Director for the CommonWell Health Alliance.

During 2011 to 2012 on leave from Allscripts he worked as standards coordinator for the Office of the National Coordinator, meaning us at ONC, ONC's initial foray into standards for a learning health system, the Query Health Initiative, is now being used by PCORI and many others. Prior to this engagement he had served as a Workgroup leader for ONC's Direct Project. Prior to his time at ONC Rich ran the Allscripts Provider Analytics Business and prior to Allscripts he had a long career at IDX during which he ran the Flowcast Hospital Business, served on the IDX Corporate Strategy Board and was Vice President for Product Development for IDX Flowcast.

Our fourth new member is Doctor Angela Kennedy. Dr. Kennedy is a strong advocate for health information where and when you need it and we're glad to have that. A consumer advocacy information governance interoperability and ICD-10 top the list of presentations she has given recently. Dr. Kennedy is the Department Chair and Professor at Health Informatics and Information Management at Louisiana Tech University and serves as past President of the American Health Information Management Association or AHIMA.

Dr. Kennedy was the 2010 Chair of the Commission on Health Informatics and Information Management. She has served as State President for the Louisiana Health Information Management Association and the Louisiana Health Information Systems Society. Dr. Kennedy has received both the LHIMA Distinguished member award and the Career Achievement Award. Additionally, Dr. Kennedy has received an AHIMA Triumph Award for Mentoring and Diamond Recognition for leadership.

And then rounding out the parade of wonderfuls today our fifth member is Dr. Patty Sengstack. Dr. Sengstack is the Chief Nursing Information Officer at the Bon Secours Health System and is the former Deputy CIO and Chief of Clinical Informatics at the National Institutes of Health Clinical Center in Bethesda. She has her DNP from Vanderbilt University and a Master's in Nursing Informatics from the University of Maryland.

She is currently serving as the President of the American Nursing Informatics Association until April, oh, actually, sorry that is past, but she did that recently. She has multiple informatics publications and most recently has published a Sigma Theta Tau book titled Mastering Informatics a Healthcare Handbook for Success.

She is currently on the Faculty at Vanderbilt University and teaches Informatics at the Master's and Doctoral Level. Her focus over the last several years has been health information technology's impact on patient safety as well as building a program to improve the evaluation process of IT systems. And her many other publications can be found in her resume which we will make available.

So, you know, we've spent the several meetings talking about the wonderful folks who have finished their time serving on the Standards Committee and I'm really delighted to be able to welcome a new tranche of amazing talent and colleagues with whom we're looking forward to being engaged over the coming years. So, thank each and every one of you. So, Michelle, if you don't mind can you explain to folks the context in which they're here?

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

Sure, so both Josh Mandel and Patty Sengstack are provider representatives. Rich Elmore is our new technology vendor representative and Jitin is our health exchange representative and Angela Kennedy is our consumer patient representative.

And just so other folks know we're going to wait until the October meeting for the new folks to be up and running and be voting members because there is a presentation today that does require a vote by the committee, you heard David McCallie is on the line, and I believe Stan was going to try and join as well, of our former members because they are up-to-speed with the content, so that is why we have both members on the phone today.

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

And Michelle maybe you want to clarify for folks there are five additional replacements of which probably there will be three more that are announced in the relative short-term and then two in more of a long-term.

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

That's correct and so that's why there is also some of the older...not older, our beloved folks on the phone Dixie Baker, Liz Johnson, those are the two that came to mind off the top of my head, there are a few, Wes, no not Wes, a few others that are still giving us their time so we greatly appreciate that until we can identify new folks, John Derr. Thank you to the three of you we really appreciate it.

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

And then I believe that Jamie Ferguson, Wes and I roll off in January. I don't know there may be others?

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

Yes and Cris Ross.

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

Okay. So, there you go, there is transparency as to the comings and goings of the Standards Committee. Well, certainly welcome to everybody who has just joined. I think it's a great group of folks and very diverse, Jon White, as you've said.

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

Thanks, so I appreciate the additional comments. I don't have anything further to say at this point. John if you have additional comments the floor is yours.

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

Thanks, so a couple of things. Of course, we'll walk the agenda, but Michelle always reminds me that we need to approve the minutes of the last meeting and so just ask the floor if there are any comments, revisions or edits to the meeting minutes from our last get together?

Okay, well none being heard I trust there are no objections to approving those minutes. So, there you go Michelle our administrative duties are done.

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

Thank you, John.

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

So, today we are going to have two presentations. The Precision Medicine Task Force and the Interoperability Standards Advisory update. I think what you'll find very good about those two PowerPoint presentations is they really illustrate that ONC has listened to us quite well in that, Dixie you'd be proud, both presentations are based on the Dixie Baker maturity model analysis that is we have constantly told ONC if you are to make recommendations, if you are to create Task Forces and Workgroups that suggest a path forward it's always important to understand the level of adoption of a standard and its maturity. Has it really been used in production? Is it a fully balloted standard or is it a draft that's been piloted? Where is it?

And so what you'll see in the Precision Medicine Task Force recommendations they've really graded things as green, yellow, red. Things that are absolutely ready for prime time or will very soon be ready for prime time. Things that are clearly going to be prime time, things that are a bit more risky but seem directionally correct.

And so what Jon and Kelly are going to do is of course discuss what they recommend to support precision medicine and as a committee the question for us is can we endorse their classification? And then recognizing that we're not today specifically stating there is a regulation that will appear that includes a particular standard, but, you know, do we feel comfortable that their statement of, you know, C-CDA is mature but needs some additional work or needs some additional pilots or something of that nature. Is that okay?

And when they make a statement such as, gee, you know, there are certain genomic representations that are directionally interesting not quite yet there yet, and, you know, that's really the question. So, they're going to ask as, we heard from Michelle, for our general approval of what line items in that presentation we think are reasonable to include as green, yellow, red and the actions they have for fostering further maturity and adoption.

Now in the Interoperability Standards Advisory update, remember that's the non-regulatory guidance as to where if an individual wanted to implement something what standard might they choose? It may not be totally balloted or totally mature but it's kind of the best we have.

Steve Posnack will also show you an artifact where he is grading the standards recommendations based on their level of maturity and adoption. And for example, David McCallie, he said that if you were to develop a implementation guide for the FHIR provider directory query response he would be more than happy to include that in the Interoperability Standards Advisory with the notion that it seems very directionally appropriate it is just not yet deployed and therefore it is worthy of further investigation and pilots. So, if you create it, it will become a national artifact.

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

So, basically I followed the existing specifications on the FHIR website. So, I think it's kind of already there.

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

So, there you go, create a one-pager, point to the FHIR website your good. And so, I just hope that folks as they look at these PowerPoints recognize our job is to validate whether or not the standards maturity and adoption rankings are reasonable and the next steps to accelerate maturity are reasonable.

And I really applaud ONC for having adopted that Dixie Baker methodology and doing their work and then asking for feedback of their initial strawman grades. I think this is going to be a very fruitful discussion.

And then of course remember we get together on October 6th as a joint group with the Policy Committee and so that will be a really great opportunity for us to get together in person and just administratively I hear from ONC November might be virtual, December will be virtual, January will be in person. So, hopefully that helps you plan.

And so, Michelle, any other administrative comments before we dive into the agenda?

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

I think you covered everything, thank you, John.

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

Okay, well, one last thing to say, at this meeting we will not be talking about Meaningful Use Stage 2 final revisions, Meaningful Use Stage 3 timing and publication or the Principle Deputy National Coordinator position. I really tried to get answers yesterday, but the answer is there are no answers.

So, we of course, as a community will all await those things, they're very important and one of the things that Jon White can tell you is, he may not know what tomorrow will bring but directionally I think we all know what 18 months will bring, appropriate standards to enhance interoperability to keep congress and our stakeholders happy and to support the sustainable growth rate fix and various movements to what I'll call global risk and capitation as we move from fee-for-service medicine.

The exact steps in those 18 months haven't been declared, but directionally I think we know where we're headed. And before we move into the agenda, Jon White do you want to amend that statement in any way?

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

The only two things I would add is that there are no answers to your questions that we can share at this time not that there are no answers just nothing we can share right now. We appreciate the concern and interest and we will keep you updated as quickly as we can.

You know I neglected to mention, and I probably should have, ONC released the final version of the Federal Health IT Strategic Plan yesterday that is out with its four long-term goals and strategic options for achieving that. We're very pleased with it, we're very proud of it. We've had good reception for it. The main thing that I would...I would commend it to your reading it's not that long, it's a couple dozen pages as opposed to hundreds of pages, you know, the main thing I think I'd to emphasis to you all is that, you know, we really want to put the focus squarely on individuals and patients and their role at the center of their health and their health care and how health information systems support that.

So, it's tremendous work by our colleagues within ONC and in particular Gretchen Wyatt and Matt Swain, you'll hear more about it at the October 6th meeting but also tremendous work from all of our federal colleagues who are working with us in coordination and we're grateful for their support. And for the record that is not my dog. So, it's been exciting times, it will continue to be exciting times here ahead.

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

Well, thanks and Jon White, at this time do we want to say anything about Jodi Daniel or are we going to refer to the October 6th meeting to celebrate her 10 years of service at ONC?

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

I will briefly say that we are both tremendously excited...so for those of you...you should have seen an e-mail we sent out to the whole Standards Committee but, Jodi, after a long tenure at ONC will be departing on October 9th for a new opportunity in the private sector. We are both tremendously excited for new horizons ahead for her. As somebody who recently left the place where he was for the last 10 years to join ONC I am totally in sympathy with this.

We are also, of course, you know, tremendously, I won't say sad but I'll say definitely nostalgic about the, you know, amazing contributions that Jodi has made over the past decade both to ONC and to the federal family and to the world of Health IT generally speaking. Fortunately, she is staying on until October 9th so you will have a chance to fete her in person when you come join us there. So, we're looking forward to a blowout there.

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

Thank you, Jon.

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

Of course.

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

We wanted to get in the thank you Jodi before you left at 10:30, so thank you.

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

Thanks a lot Jon and John.

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

Okay, well, Michelle, with that why don't we move forward to our Precision Medicine Task Force recommendations turning the floor back to Leslie Kelly Hall and Jon White.

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

So, Michelle, can we launch into it?

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

Do it Jon.

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

All right, Leslie are you here with us?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I sure am.

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

Awesome, okay. Well, listen, members of the Standards Committee I'm tremendously excited with Leslie to be bringing forward some really good substantive discussion to you today. So, I'm going to take the first couple of slides that really kind of cover the background of what we're doing and why we're doing it and then Leslie will take us through the draft recommendations and then Dr. Halamka will guide us through the discussion.

So, here's what we're going to talk about, we're going to talk about the Precision Medicine Initiative, the Task Force, why we brought it together, I can't believe it was two months ago, and what we've done and who has been involved and then talk about the recommendations and then look for your feedback please. Next slide.

So, we've discussed this briefly before but I just want to recap for you, in January at the State of the Union and then in the 2016 budget proposal, the President unveiled the Precision Medicine Initiative, it's been tremendously exciting to be part of that. The mission of precision medicine is here for you and I think it's worth reading through, I hate reading slides, as many of you know, but I'll just read it to you here just so you can hear it.

To enable a new era of medicine through research, technology and policies that empower patients, researchers and providers to work together toward development of individualized treatments.

So, this is something that in many ways began in the brain of Francis Collins once he and his colleagues were done sequencing the human genome in 2004 it was like, okay, what do we do next, well we turn that into better health and better healthcare and we understand where people are individually.

You know the vision has expanded over that time, certainly genomic information is a critical piece of the Precision Medicine Initiative, but folks have come to appreciate that there are so many factors that contribute to our health care that we're in a place in time right now in our technological development, thanks, you know, by the way, in no small part, to the really significant efforts of our colleagues in the Health IT community to make a really broad swath of health and healthcare data available for analysis to try to understand things that are affecting and contributing to the health and better health care of all of us whether it's individualized treatments for better conditions or, you know, predictive analytics to be able to say, you know, kind of what's potentially in somebody's probabilistic future.

So, you know, being involved with this for the last several months I will say that it has been a really exciting initiative to be part of. I don't want to, you know, dwell on it too long, but we've been working very closely in partnership with the National Institutes of Health, the Food and Drug Administration, our colleagues at the Executive Office of the President, the Office of the Science and Technology Policy with our partners at the VA and the DoD, and many folks in the private sector as well. So, next slide, please.

Okay, so, the charge to the Task Force here and this is kind of the piece that ONC has in precision medicine, is to identify...that we're seeking this committee input on, is to identify opportunities for innovative collaboration around pilots and testing of standards that support Health IT interoperability for precision medicine, to recommend existing standards that are currently ready to support the Precision Medicine Initiative, to identify emerging standards and reference implementations that may require further pilot testing or to support precision medicine and then finally to identify gaps in available data standards related to precision medicine.

So, as John correctly observed, Dixie, I have internalized your guidance and I think that it's a, you know, wise model and I think that we're looking forward to inculcate it into the work as we move ahead and I hope you see it reflected here in the Task Force.

You know Leslie had...as we were going through the discussion, I would add that Leslie had the really brilliant idea of saying, in addition to, you know, ready for use, ready for testing and gaps, what are accelerators that we can identify and try to lean on that can help us move forward with achieving these goals. So, I'm grateful for Leslie's, you know, brilliant contribution there. Next slide.

So, what you see before you our work plan, it was very aggressive. We pulled together for the first time on July 17th, which was a month ago, the reason...and you can see the work plan kind of laid out here as well. You know the reason for such an aggressive timeline is because...those of you who have been paying attention to the overall initiative know that in parallel the National Institutes of Health has been working with their advisory committee to get recommendations on how to construct the cohort of individuals who will...who's information will be analyzed for the Precision Medicine Initiative.

NIH has had a series of really robust workshops across the country. My colleagues and I have been participating in all of those. And this past week the Advisory Committee to the Director submitted to Dr. Collins a really outstanding report with recommendations about how to construct the cohort.

And as I promised you at the beginning our work has been coordinated, ah, there's that word again, with the work of that advisory committee. They steered clear of some of the standards work recognizing that this was going on and we've actually had good overlap too in staffing between that advisory process and this advisory process. We've had a number of ex-officio invited guests from the federal side including myself, Josh Denny, Betsy Humphreys, Maya Uppaluru, Claudia Williams, BJ Patel and a number of others, so we've had good coordination with that group and that's been working through us.

The other thing that I'd mention is that working through this work plan what you see in some of the very small print, but that stands out more in my mind, was amazing presentations from a number of folks who have done substantive work in the field in the area of precision medicine. And I'm not going to go through them all with you because I really want to be able to discuss the recommendations, but I'm really grateful to the folks who took the time to come talk with us about the work that they are doing and how standards and driving interoperability plays a really significant role in trying to achieve the goal of precision medicine. So, thank you, next slide.

And finally, if I had a giant hat I would be tipping it right now. These are the members of the Task Force as well as the ex-officio and invited guests from the Feds. I won't read through your names but every one of you I am so grateful for the really, you know, deep commitment of time and, you know, brain power and expertise. It's been an amazing two-month discussion both from our private sector colleagues as well as federal colleagues.

Finally, I would love to offer a very special thank you to Maya Uppaluru who is our precision medicine staff lead at ONC and whose work you see displayed before you. I would love to claim credit for the recommendations that are coming out here but really with support of the Task Force Maya and Mazen Yacoub have pulled together these recommendations for our discussion and so thank you for your, Maya, for your both specific contributions and the work that you're going to be doing ahead because there is a lot more yet to come, so thank you. Okay, next slide.

All right and with that I will stop, that's kind of the where we've come from piece of this and Leslie who has been my partner in crime on all of this, and an amazing partner to boot, is going to walk us through where the discussions led us and our draft recommendations. So, Leslie, the floor is yours.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Jon. This has been a very fascinating workgroup to be part of and certainly something I've never been exposed to before so I appreciate all my colleague's patience with me and also the continued guidance from Jon and I think a punctuated calls often with David reminding us of our charge and the work ahead. So, let's go onto the slides.

So, really we looked at how will information come to EHRs? We wanted to get both data from the phenotypic data like the problems, the medications, allergies that could be patient generated health data. Also we had problems identified that we don't have standard data models for EMR and categorical standard responses for many basic types of information.

So, we knew we had challenges going forward but we also wanted to make sure that we recognized existing work and existing standards that could be put forward. So, you'll see in the slides ahead different information in the following ways.

So, the green section is applicable standards that could be put to use to support the particular cohort. And the next area is the, can you go back, the next area is the promising which is yellow, gaps are red and accelerators are blue. And accelerators are actions that ONC can take to move and advance standards so that we can be timely in our response and recommendations to meet this cohort. And then we also have recommended actions to advance needed or actions needed to be assigned with each standard. Next slide, please.

So, let's orient you to these slides. Under the green section you'll see recommendations and then you'll see actions to advance. And actions to advance are A, B and C.

A is to form a Task Force to advance this for this particular initiative or cohort.

B is to apply accelerators. This could be existing things like the S&I Initiatives or a pilot project or some policy guidance to existing standards by ONC.

And then C is really, follow the existing standards process to see these things through.

So, in this initial recommendation we acknowledge the existing interoperability standards that have been in place through existing regulation and certification rules. And we recommend that we follow existing standards process where those standards are used.

Standards to capture and represent family health history such as SNOMED CT and HL7 family history and pedigree model for familial relationships need to be pre-coordinated and also for care and post care and there's a lot of work being done and some overlaps so we see that there's an opportunity to apply some accelerators perhaps an S&I Initiative, something to convene multiple groups and come to coordination and resolution.

And then also we felt that the existing HL7 Clinical Genomics Workgroup standards could also be used to accelerate where there are overlaps. We heard a good deal of information about LOINC being used particularly to come from the lab to the EMR. And there is existing overlap where SNOMED and LOINC exist and we do not want to replace existing standards or replace existing recommendations but look to see how we can coordinate where there are gaps or opportunities. Next slide, please.

So, in the yellow section, which we believe is opportunities for use in the future, but needs further work it could be pilots again or it could be policy recommendations, or other things like S&I Initiatives. So, FHIR was brought up over and over again and hat's off to Josh on the work he's done there. And we felt that the Argonaut Project may provide opportunities to advance these things like authorization, family health history and to build on SMART on FHIR for genomics that has already started. OpenID Connect, OAuth we've heard about this in other standards committee meetings we feel that this also has an opportunity to be coordinated in this effort.

We heard the need for computable patient consent and we think there's great promise there. However, today the cohort that we're specifically interested in is a group of people who will provide consent to use their EHR information, consent to use their genomic information and so there's some pre-existing constraints that make the need for the computable consent for this cohort not as urgent as it might be for others. So we felt there was an opportunity to follow the existing standards process.

We also felt that including more complete authorization standards could help be more compatible across disparate systems because remember we're now adding not just the current EHR technology but also researchers and patients into this cohort and new laboratories. So, there are new stakeholders. There is more work to be done.

We also felt we had some great information from the genomics round table and the GA4GH work and felt that could be accelerated to provide very specific help to this cohort. Next slide.

So, there are definitely some standards here, gaps here and we felt that there are opportunities to provide some direction in the future. And although I mentioned earlier the computable consent model, we do feel there is some immediate need for guidance or more immediate need with regard to how we add these new stakeholders.

And then race and ethnicity, family history, pedigree this information continues to come up. We think that there are opportunities to advance and coordinate this care.

So, the minimum dataset is something that we all strive to achieve and when we talk about what that might be, reminded of Betty Humphreys, that although on an EHR we may need a reduced amount of information than what the lab might have in order for us to achieve and received that information there has to be standards back at the originating system to have very concise and consistent information sent to the EHR.

We also considered that there is new information and recommendations coming out of the Interoperability Advisory including the sexual orientation and gender identity and so there are opportunities there to convene and to coordinate those efforts. Next slide, please.

So, our accelerators we continue to hope that...there is a lot of work here that needs to be done. This is still very emerging but we felt there are opportunities to advance health and standards for these cohorts by providing these accelerators. So, an investment in pilots, FHIR for particular PMI research and individual data donation use case could be something that could be dramatically helpful right away.

We also felt that using the existing standards process for incorporation of HPO and more alignment with SNOMED and UMLS could be done. And also that OMIM for codes in genotypes and links between those two there still needs to be work. So, in each area where we feel the existing standards process can inform the work we do encourage more inter-cooperation across standards organizations so that we have consistent and concise information. So, Jon, do you have...I'm sure something to add to all of this, I went through this quite quickly so we could have discussion?

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

No you did fantastically, you know, the only thing I guess I would add is that on the first screen slide where we talk about, you know, publish standards that, you know, if, you know, again, there's no news to report at this point, but if we get to a point where, you know, future guidance is published that we would certainly be interested in pointing to standards or implementation specifications that are included in that guidance should that happen in the relatively near future, but otherwise I think that's a great outlay of, you know, everything that's out there. So, thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great, so John Halamka I think you want to lead the discussion on this.

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

Well, I am happy to do so because, you know, from a process stand-point Jon White thought it would be awkward for him to lead a discussion of his own work. So, let us go through the recommendations and of course Leslie's work.

The green, yellow, red designations and so let us go back to the green slide. And so when we look at these recommendations to suggest that such things as SNOMED CT, HL7 family health history, the HL7 Clinical Genomics Workgroup, the Interoperability Standards Advisory let's open it up to discussion on this particular slide as to whether or not you feel these merit this designation of green sort of reasonably mature to put forward into use?

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

John, its David I'll get in line.

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

Please, go ahead. In fact, Michelle, do we have the hand raising feature?

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

We do.

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

It didn't seem to be working.

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

There's nobody right now with their hand raised, but...

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

So, David, please go ahead. See this is I was trusting in you to make comment.

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

Yeah, so I like the way Leslie and Jon have laid out the recommendations. I missed the last meeting of the Task Force when all this work was done so I'm actually not commenting on my own work. So, I'll take advantage of the fact that I missed that meeting.

My only concern is on the green slide anyway is the phrase leverage HL7 Clinical Genomics Workgroups suite of standards. That's a huge space and many of the things contained within it are probably not very relevant to the specific goals of the Precision Medicine Initiative. Many of them are focused on sort of behind the scenes genomic issues that are probably better dealt with within the work done by the Global Alliance for Health.

So, I think there's a lot of devil in the details of what it means to "leverage" the CG Workgroup's suite of standards. So, I'll just add that caveat that it may not be completely clear what that means when you dive in and actually start looking at specific standards.

What I take it to mean, in the positive sense, is that you can leverage existing models like v2 to move data from genomic testing labs back to EHRs but I think we know that we'd like to do better and have a more robust biomarker model than is currently accounted for in the common use of the HL7 standards referenced there.

So, the ongoing work, the accelerator work around the models that are starting with FHIR, simply because it's an easier domain to work with, I think are the ones that will capture the most attention in the coming couple of years simply because they're more robust.

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

Very good. Other comments folks would make on the green designations?

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

This is Jamie...

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

John there are a couple of people in the queue.

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

Okay, well, Michelle, go for the queue.

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

Okay, Steve Brown.

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

Thank you. I'm interested in the family history in HL7 versus SNOMED CT or some combination thereof and I think this is a wonderful opportunity to do post coordination to enhance content coverage.

But I'm wondering how you would advocate or what the group thought about post coordination using SNOMED family relationships or some other approach in a post coordinated fashion with SNOMED and if you're advocating for that, how would you make up for the overlap perhaps between family relationships in different terminologies involved in the same post coordination? I mean, it's starting to sound complicated.

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

Thank you, Steve. Leslie its Jon would you like me to respond or would you prefer?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead.

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

Okay and I assume that was my colleague Steve Brown from the VA?

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

Yes.

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

Excellent, hey, Steve. So, it's a great question and here's what I'll say recognizing that this was a two-month Task Force process, okay, and recognizing that there are recommendations that we can make now to try to help precision medicine along as well as...we can totally...along the way is that there is more discussion that's needed. So, we think that there's stuff that could probably go in a parking lot for later.

So, for this if you look at the actions to advance for this particular standard, okay, what we say is, you know, it says use standards to represent, capture and represent family health history such as, but then the action to advance is B and what that...you know if you go down to the key below it says apply accelerators for example S&I Initiative, pilot projects or policy guidance to existing standards by ONC.

I think, what to me that means, and I'm happy to, you know, talk about it, is that, you know, we recognize that these are sources of, you know, information about familial history that we haven't quite put the pieces of the puzzle together but that we really ought to go as far down the rabbit hole of coordinating amongst those either in a pre or post fashion and then try to feed that back into...and then, you know, again, with the use case here being the Precision Medicine Initiative that we're pulling data from a number of different places about a cohort of people to try to analyze that data and, you know, develop at least correlations if not findings, research findings from that, and then return that back into the care delivery system. That with this use case in mind what's the best way to try to pre or post coordinate amongst those different sources of information.

So, I think what's being recommended here is that these are the standards we ought to be using but we've got to figure out how to make it all come together. So, that's that.

I also just, as long as I've got the floor, jump quickly back to David McCallie, David your great recommendation, if there are any amendments that you would suggest to any of these recommendations, you know, you don't have to, but would love to hear them. Sorry that the schedules did not coordinate exactly to be able to get your always valued input. So, with that back to Steve, did that answer your question?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

May I add something Jon? This is Les.

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

Absolutely.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, one of the things that we heard over and over again is that the patient generated health data or phenotypic data is valuable and so one of the reasons that we really need to coordinate this for pre and post coordinated care is information we might typically have gotten post coordinated care in the research environment by querying the patient directly we might actually have opportunities to query the patient directly in care. So, we want to make sure that this is a continuum of information independent of the source so that we have really good and rich robust data sources for continuing use.

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

And Jon, it's David, on your notion of a friendly amendment, what I see in your yellow slide around the IOM genomics roundtable, which gets a B action to me that is the way to pursue at least in the near term the usage of the HL7 Clinical Genomics Workgroups suite of standards, that's exactly what that group is starting with and it already includes multiple labs and multiple EHR vendors and experts from both HL7 and other domains.

So, it seems like until that group is superseded with a broader focus or one that jumps ahead to focus on FHIR that this group is caring the torch for sort of how to use the existing HL7 standards in a consistent way.

So, I would maybe suggest that your yellow IOM genomics roundtable point be moved up to your green since they both get a B action.

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

Gotcha and I'm perfectly amenable to that. Leslie are you?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's a great suggestion. Thank you.

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

I mean, they're already doing most of that stuff and they do have a pretty good representative base as best I can tell.

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

In fact they've got a 12 p.m. call today that, you know, I don't think we may or may not be done in time for that today, but...

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

Yeah.

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

Looking forward to continuing to engage with them, yes.

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

Yes.

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

Okay, well, in the queue who else do we have?

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

Dixie Baker.

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

I...

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

Thank you. Thank you for this presentation it obviously, as you know, something near and dear to my heart. I wanted to agree with a lot of what David McCallie has said about the HL7 Genomics work. In fact I would suggest changing what's on slide eight where it actually says...has it categorized as green. I would categorize that whole suite as yellow. I think, you know, part of it might be green but the whole thing there is a lot of active work in that area. So, I would not consider that green at this time. But I would support...I would recommend that ONC support the work of that workgroup through HL7 and through the GA4GH data working group.

For the green category, on slide eight, I suggest you look at the HL7 draft that is just coming out of the Institute of Medicine Digitized Action Collaboration which focuses on pharmacogenomics HL7 standards that are much more readily integrated with the EHR particularly since they're...those kinds of tests and treatments are supported by insurance companies. So, I think that this work definitely would merit a green. I think the rest is still evolving.

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

Okay that's helpful. So, since you...Dixie, since you brought it up let me ask, so there's...on slide eight here, which we have displayed on the screen, there's three recommendations, I think I get what you're saying about the second and the third rows.

The first row, okay, says precision medicine efforts should align the standards currently referenced in the 2015 ISA where they're including current regulation. Are you saying that should move to yellow or are you saying that this is still green but the other two should be in the yellowish category?

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

Well, I don't know exactly what's in the advisory about clinical genomics. I think the rest is fine. I don't know what's in...is the whole HL7 suite, clinical genomics suite, in the advisory?

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

I can go back to it and get the very, you know, specific details probably while we're on. I'll try to do it while we're on the phone.

So, I guess what you're saying is that with the exception of clinical genomics in the Interoperability Standards Advisory everything else should be...that can be pointed to as a non-regulatory form of guidance, however, clinical genomics information should fall in the yellow category? Is that a fair representation?

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

Except for I would definitely look at the draft it's just now coming out, I can even send you a copy maybe, of the draft HL7 standard that's coming out of the Institute of Medicine Workgroup, it's called the digitized...well, you know you're familiar with it. And you know that is built on existing HL7 mature standards so it's not as extensive as what the whole clinical genomics suite that HL7 is going toward.

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

Gotcha.

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

And this is David, that's exactly what I was suggesting.

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

Okay.

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

I didn't use the name digitized medicine but that's the output that I was describing. So, I agree with Dixie's suggestion.

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

So, it sounds like we have consensus that the last bullet point might be more yellowish than greenish.

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

With the caveat that the Digitized Medicine Workgroup from the IOM is probably greenish.

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

Okay.

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

Because it's a subset, it's a pretty narrow subset on pharmacogenomics and it's got a fair amount of vendor engagement already. So, it's being, you know, discussed by people that are actually building systems that do things. So, it's I won't say pilot stage but it's certainly passed just paper.

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

Great. Well, who else do we have in the queue?

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

Anne LeMaistre.

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

Anne?

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

Thanks, John. Jon and Leslie I'm going to change the direction just a little bit. I was curious if the workgroup had time to talk about security and maybe clarifying strong security standards for the transmission and storage, and maintenance of this data?

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

Leslie, would you like to cover?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We had some discussion on that as well. We also acknowledged work being done in other areas. There was some public comment that we heard about this as well and the...here's what I took away from it, and Jon correct me if I'm wrong, but that when we get to genomics data and phenotypic data combined this isn't data that's just observations about you or a test result in the traditional way. This data defines who you are and there is a sense of responsibility that must come with that beyond what may be our current constructs look at.

And one discussion that was brought up was making sure that even if aggregate data was coming in an identifiable way that somehow the key fields for identity management would be separate and I harken back to the NIST presentation we received about how not to put all of your eggs in one basket. And so there was some discussion about this with mindfulness around the topic but no specific recommendations coming out of the group because we felt there was additional work being done. Jon, do you have comments?

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

I think that's a great capture of the discussion. You know I think that where we identify standards and implementation specs to support the security of this information I think we want to point to those. You know Leslie is right this is kind of a unique case, you know, it may not totally define you but it's definitely a part of a definition of who you are in terms of this information. So, you know, it plays a pretty significant role.

I would add that a fairly unique and prominent feature of the Precision Medicine Initiative is the engagement of participants, you know, we've deliberately chosen not to call them, folks involved with this, you know, research subjects but participants because, you know, it's a new day and we think that this is a new time to define the way people engage, you know, with this sort of effort.

Of course, you know, there is a proposed update of the conical out there that factor into this discussion. There are a lot of cybersecurity discussions that are going on at the same time. So, you know, I would simply add that it's an incredibly important focus for us as the federal leaders of the initiative and we totally get its significance and are pretty keenly focused on it.

I think in terms of specific recommendations from the Standards Committee, I think, you know, at this point where we are is we think we want to point to, you know, the standards that we already recommended and just recognize that it's pretty important and we'll be paying very close attention to it.

You know in terms of...I mentioned ONC's role, we have two roles described in the 2016 budget, the first is to advance data standards that support the Precision Medicine Initiative and the second is to address privacy policies. Lucia Savage, our Chief Privacy Officer, has been very closely engaged with our colleagues at the Office for Civil Rights, with our colleagues at NIH, with folks in the Executive Office of the President with a very strong focus on this, so I've rambled on too long, but we get that it's important and I appreciate you calling it out.

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

Thanks, Jon.

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

John this is Lisa Gallagher if I may?

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

Go ahead Lisa.

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

I think the discussion also included the fact that with a Task Force of this nature and the time schedule that we had this was something of the scope and magnitude that was kind of...we didn't have the time to really delve into it and do it justice but it is something that we feel, you know, needs to be continually looked at.

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

Thank you all and I appreciate the engagement you had on it and I certainly understand the limited time and certainly the approach you are taking seems quite accessible. The only comment I'd send back to Jon and the ONC is the market seems to have a great confusion on both those great past public published works and how to secure this information as well as the work underway and I think anything that ONC can do to clarify this for the market so we have very strong, secure PHI I think that would be very well received.

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

Okay, it's a great comment and consider it well received.

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

Okay, where are we in the queue Michelle?

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

There is no one else in the queue.

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

Okay, so let me just describe with that first slide it sounds like Michelle you've captured this but it's that the first two seem reasonable. The last one more yellowish but we kind of divide it into a green part and a yellow part. Is that an adequate summary? Dave McCallie? Dixie?

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

Yes, I agree with that, yes.

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

Okay, very good. Well, let us move onto yellow. So, we've got FHIR, OpenID, OAuth, UMA, computable patient consent, authorization standards and IOM genomics roundtable. Comments?

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

I have one comment.

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

Please?

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

Is that on the last line here you mention the GA4GH I would just mention, that's the Global Alliance for Genomics in Health, the regulatory and ethics workgroup of GA4GH has an active task force that's addressing computable patient consent. It is being led by John Wilbanks from Sage Bionetworks and it maybe something you'll want to try to engage with or at least follow.

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

Great and so...

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

And...

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

Okay, it sounds like...

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

This is David.

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

There are multiple comments there, please go ahead.

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

John it's David.

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

Yes?

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

Can you hear me?

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

We can.

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

I just wanted to also point out that the report from the Precision Medicine Task Force on building the cohort calls for some fairly radical new models for consent. I don't think I've read deep enough into their 100 page report to know if they nominated someone to be working on that but, you know, they envision a different kind of consent model than traditional research studies. They also proposed some changes to the Common Rule that governs traditional research style consent.

So, I think there are an awful lot of moving parts in the space of computable consent and it's not necessarily a good idea to keep consent associated with sharing one's health data separate in one's mind from consent associated with research but we might want to do that here.

I mean, I know we want precision data to get back into the healthcare system for clinical care and that's what the computable consent I think is that's referred to here as following the existing standards bodies but I think there's a whole bunch of new stuff going on in the research community that's not what we typically focus on with the EHR technology side. So, maybe we need to make that distinction.

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

Yeah, that's a really good point because even the, two things, this is Dixie again, it's widely recognized, and this harkens back to the earlier conversation, that genomic data are generally identifiable and certainly whole genome sequences are identifiable so the GA4GH as well as the NIH is going toward models that are more finally granular than, you know, yes/no, in/out that we usually think of as consent and that's kind of the work of the GA4GH that I mentioned is going in that direction. How granular is certainly something that everybody is talking about and how they'll do that is something they're talking about. But David is absolutely right the whole opt in/opt out, all or nothing is breaking down.

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

Yeah, so it's Jon White, great, great comments and they're very, for me they're very well taken. Two quick things I want to say, the first is that just David a slight correction, the NIH Group is the Advisory Committee to the Director and there was a working group for the Precision Medicine Initiative and you said Precision Medicine Task Force and I just want to make sure we weren't getting, you know, mistaken the blue wire for the yellow wire. So, there is a separate group.

So, you know, and the second thing is I'll just say is that, you know, number one we completely plan on being engaged with those discussions as they go ahead, you know, and I hate to say it but it brings back to me echoes of the JASON Report we spent so much time discussing last year and the trust bundles that they brought up there when you start getting down to the granularity of, you know, who you trust and who you don't, so it's interesting to see that come back to light for me. So, great comments and if there's particular ways that you'd have us change the recommendations here I am open to it otherwise if you want to leave it like it is but just with those stipulations in mind I'm good with that too.

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

Jon, this is David. Thanks for the correction on the various names I can't keep them all straight. But the, you know, the things that we all know pretty well now is that, you know, there are two separate rules that have overlap namely HIPAA and then the Common Rule. And when we talk about ordinary progress of standards bodies working on computable consent you may need to specify in the context of HIPAA or in the context of the Common Rule or both because I think those could be relatively different pieces of work.

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

So, the final Common Rule that just came out kind of helps things. So, I'm sure the OCR is following that, but it makes...

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

Proposed.

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

It makes it a little bit better aligned than they were.

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

Yeah, just remember it's a proposed rule at this point.

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

Oh, I thought it was final. Oh, is that the same thing as...you think I'd know after all these years, is that the same thing as interim or...

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

No, so a proposed rule is something that's out there for comment but hasn't taken effect.

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

Okay.

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

And an interim final can be further amended but has the effect of enforce of law and then final of course if final until it's not.

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

So, this is the second NPRM we've had on the Common Rule right?

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

And one question that I have for Jon and Leslie on the yellows is that we have computable patient consent on yellow but we also have computable patient consent on red. So, you just clarify that?

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

That's a good point. So, you know, my...I think that's probably, in terms of looking at what went on the slides, I think that it is recognition that while there's good work that's out there now that there are potential gaps. I think the way to fix that is probably just strike it from the red part. Yellow means there is a lot of promising work but more work that needs to be done that we should be engaged with and I think that that's adequately captured by keeping it in yellow but striking that part from the red.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I...

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

And any comments on that proposal?

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

I'd lean toward striking it from yellow maybe or make it orange.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And Dixie this is Les...

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

Well, Dixie remember...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think the issue is in order to manage this particular cohort we can constrain this enough...

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

I see.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

To manage it and so it's appropriate to put in yellow with maybe more of an accelerated process for that particular area.

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

Yes, that sounds good.

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

And so remember, the parsimony principle suggests we can only have green, yellow, red. No orange. Okay, so it sounds like we've got a friendly amendment on constraining it and leaving it in yellow. Okay any other queue people for yellow Michelle?

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

No one is in the queue.

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

Okay, well, let us move onto red. We have agreed to strike the computable patient consent from red. We have race/ethnicity. We have minimum dataset. We have microbiome. And we have sexual orientation and gender identity and that particular last item I'll comment on because the Fenway is actually one of the Beth Israel Deaconess affiliates and there has been really great academic publication that's very multi-stakeholder about how to ask the patient specific questions the answer to which will yield enough information for clinical care on sexual orientation and gender identity because it is a very hard categorical classification but the questions can really be informative. So comments on the reds?

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

I have a question.

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

Yes?

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

On slide green the slide eight, sexual orientation and gender are on green and on this one they're on red?

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

And here, let me just...

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

The first slide. The first row on slide eight the e.g., include sexual identity and sexual orientation, gender identity and sexual orientation.

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

Sorry, I'm using a Macintosh and oddly enough it truncated that sentence I didn't see it. Okay. So, race, ethnicity, family history, gender identity and sexual orientation, patient...okay, so I would turn to Jon White and Leslie and say might it be appropriate to strike gender identity, sexual orientation from that green slide?

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

I am looking between the two.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, I think that this is where we have gaps and we have overlaps both at the same time, right, so we have some overlap around what's already happening in existing standards but we have gaps that are represented around sexual orientation, race, ethnicity that are still not yet solid. So, Jon, what recommendation would you have?

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

Well, so, it's a great...and Dixie thank you for calling it out, sorry that this kind of worked its way in there. Let me...why don't I make the following suggestion, on slide eight for the top row, where it says e.g., race and ethnicity, family health history, clinical genomics because this way this gets you to count for the clinical genomics too, what would you think about striking the language that's in the parentheses so it's less confusing and then we can say where we got things and finalized guidance or regulation that we should be pointing to those with the possible exception of certain callouts, okay, where they are specifically identified but otherwise that we're going to broadly point to those.

And under the red we can say that this is one of the callouts that captures sexual orientation, gender identity remains challenging and consider recent efforts that have been in this area, you know, it's still...so I have more to say, but what would you think about that change to the recommendations?

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

That sounds...

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

That sounds good to me.

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

Yeah, just about everything in those parentheses are problematic. So, yeah, that sounds good to me.

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

Okay. Leslie does that sound all right by you?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It sounds great.

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

Cool.

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

Okay, and any other red queue people?

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

No.

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

Okay, we are onto blue. Any comments on accelerators? Okay, well none of being heard I think then Jon, you know, what you wanted to come out of this was the committee offering a level of endorsement to red, yellow, green and blue and it seems like with the few edits that have been suggested remove the parenthesis on the green, split the Clinical Genomics Workgroup into green and yellow, and then computable patient consent narrow that on yellow, remove it from red then I think we're actually good. It seems like we are pretty much taking what you've recommended and moving it forward. And, Michelle, did you need a formal rollcall vote or is it just this discussion that would suffice?

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

No just approval from the committee. So, as long as everyone is in agreement with those few changes that we discussed and moving forward then we're good.

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

Okay, well any objections then to moving forward with the recommendations as amended by all the Comments you have made? Okay, well, very good. Well, we will go forward. And amazingly enough, Jon White, we are right on time.

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

It is almost like we planned it.

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

I tell you, well, thanks very much for a great discussion there and so I gather now we turn the floor over to Steve Posnack.

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

All right, sound check, there we go. There we go.

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

The sound is on.

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

It's the having to enter your password to then access your phone to get off mute.

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

Ah ha.

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

Okay. I appreciate the pause that people experience. All right thanks a lot for having me. I'm going to give you a preview of the Interoperability Standards Advisory 2016 version which is going to be made available for comment today, probably in the next hour or so, getting it up on our website. So, it's not yet up in case people are hitting control F5.

So, I'm going to cover four aspects of the agenda. Just a quick reminder, especially for those that may be new and haven't caught a presentation from me before about what this thing is, where we are in the process, what's changed and what's up next in terms of the rest of 2015. Next slide.

So what is it, the Interoperability Standards Advisory, so again, the scope is focused on clinical Health IT interoperability so it doesn't include aspects related to administrative transactions, you know, those aspects that already are regulated and part of the CMS administrative process related to HIPAA administrative transactions, that's not within the scope of this document.

It is as John Halamka mentioned a non-regulatory document. It's hopefully a straightforward approach with an interactive and predictable process for updates of which you all are experiencing that right now. It reflects the "best available" standards and implementation specifications as of the end of the calendar year so we're approaching that and as we're working on what we'll publish by the end of this year will be the 2016 Standards Advisory.

And per the initial mention, when I presented on this earlier this year, when we released the 2015 version it is designed to create common ground so looking at areas where we can get specific and identify particular Health IT interoperability purposes, what needs...where we need standards and where I think, per last month's call, which is really a good concept that I've been using ever since, you know, where are the standards, you know, subordinate to reaching particular outcomes and needs that stakeholders have to achieve interoperability

So, getting beyond that to move to having this be a single public list of standards that people can go to, certainly in the vision and make this, you know, a web kind of accessible experience as well, for the moment it's been constructed in a document that people can interact with, you know, print and download, but I can see us, you know, moving in that direction as this process matures.

Also, to reflect the results of ongoing dialogue into being consensus, so earlier this year we had a public comment period at which point took those public comments and fed them into the Interoperability Standards Advisory Task Force which completed in August, so thanks again to all those folks that set aside some of their time this summer.

And one of the other aspects that we included as a result of that Task Force recommendation from the Standards Committee was structural in nature in terms of any known limitations, pre-conditions, dependencies that stakeholders would need to be aware of relative to the standards that are mentioned.

So, an overall goal for the Interoperability Standards Advisory is a widely vetted resource, right, to these opportunities for public comment throughout the year, feedback from the Standards Committee and to have it all done in one place that people can go to and, you know, kind of put in parentheses, as I've said before, before and without regulation being kind of part of that component.

And also as we move forward if we're successful together in accomplishing this being this widely vetted resource having it be able to be this "look first" or achieve this "look first" philosophy for government programs, procurements, by private sector stakeholders, for testing and certification programs, for standards development, as we've started to work through the revisions to the Standards Advisory that I'll cover in a little bit more detail, to me at least, speaking personally, and I'm a to do list kind of guy, you can look at this a little bit like a to do list in our standards world of saying if we know that there are limitations, pre-conditions, dependencies, if we know that there are gaps that come out of this work process to create the Standards Advisory then as we look to prioritizing what interoperability needs stakeholders have we can focus with significantly more precision toward taking actionable steps that will result in improvements to those areas. Next slide, please.

All right, so here's the process in terms of where we are and I put in parenthesis "ideal" because we are a little bit behind the ideal process because we published the Standards Advisory at the beginning of 2015 as opposed to December of the preceding year. So, we're going to make up a little bit of time.

So, stepping through the advisory getting published, there was a period of public comment. The Standards Committee weighed in. Now we're at the point in time where we're publishing the advisory for the second round of public comment after the Standards Committee's recommendations that are hopefully factored in as best we can into this preview version of the 2016 Standards Advisory, I've been joking around and calling it the beta 2016 Standards Advisory, but really it's a draft for public comment that gives everyone an early opportunity to see what we hope the 2016 advisory would look like by the end of this year and give us some early feedback on any other improvements or value added suggestions that we can include as we work the next 90 days now to shape this thing up in its final form. We have one more step to do which will get us to the end of the year and then we'll basically repeat this process again going forward into 2016. Next slide.

So, what's changed? Based on public comment, which we processed and worked through the Interoperability Standards Advisory Task Force as well as the Task Force itself, we've done a major restructuring of the Interoperability Standards Advisory to take on I think a lot of good constructive criticism.

So, if you recall for the 2015 advisory, a pretty simple table structure we listed a “purpose” which folks, you know, gave us feedback that it didn’t necessarily provide enough context. We have added an emerging row to our table so folks could see what was going forward into the future and that is hopefully to provide some transparency and trajectory in terms of where the industry may be going, where standards development is going, as new versions come out that they may not be sufficiently mature or, you know, tested at this stage but important for stakeholders to know that there is something on the horizon in that particular area.

We have inserted an appendix containing the sources for security standards, so this was one of those aspects that was debated both in public comment as well as the Standards Advisory Task Force and hopefully we’ve included and been responsive to that recommendation. So, we have a page at the end that includes the kind of authoritative sources to go to that maintain security standards information.

And then per the...as I mentioned earlier at the beginning, we’ve looked at putting in six informative characteristics for each standard and implementation specification that we referenced to give more context which I think was one theme that echoed across of both the early feedback that we got from you all at the Standards Committee, from the public comments and then from the Task Force’s work.

So, we take on the standards process maturity which is roughly categorized into final and draft, we’re trying to keep it simple because you can see how this could get really overly complex and bog everything down pretty quickly, but mostly a heads up view so that people have a general sense of where these standards and implementation specifications may be at relative to their maturity and adoptability.

So to again contrast this to our earlier 2015 version we essentially just put out the purpose, the standard and the implementation specification and the stakeholders had no additional context on which to base or judge whether or not the standards or implementation specification had been pilot tested, was in production, the scale of adoption. So, that’s the additional context that we hope to provide in addition to other elements which, you know, are laid out in the often cited now Dixie Baker paper from JAMIA, you know, the cost, which we’ve tried to take on in terms of whether or not, you know, it’s free or freely available or if there are additional, you know, types of costs like needing to be a member of a particular organization to get access to the documents.

And then for stakeholder benefit and awareness if there are testing tools available associated with conformance, assessment to the particular standards or not. So, where we can and where we have been able to we have included hyperlinks to all of this information more specifically the standards and the implementation specifications as well as the test tools.

And then, as I mentioned already, we’re looking to provide additional context structure that includes limitations, dependencies and preconditions and other kind of qualifying information that would be beneficial for stakeholders to understand as well as this construct of security patterns which was recommended by the Standards Advisory Task Force.

So, for both of these areas you’ll notice, if you look at the 2016 draft for comment, we haven’t been able to populate all of these and in part that was intentional because we want to make sure that the structure overall, so as I said, you know, everyone’s expectations, we really need your feedback and help to make sure that the structure resonates and adds value for you.

And we have included a number of specific examples that tried to flesh this out in detail for some of the standards and interoperability...some of the standards and implementation specifications that we've included in the Standards Advisory but it's not fully fleshed out that's something that we hope to be able to do with your feedback and comments over the next several weeks as well as with any other interactions and collaborations that we can have with stakeholders in the field that may have a particular expertise in these areas.

And then last we've included, hopefully, to folks benefit, a revision history section which helps to show, you know, we had this in 2015 we changed it, you know, to this in 2016. Next slide.

All right so here's an example of what you'll see in the new table structure. So, a pretty big expansion structurally in terms of how we represent the context as well as the particular aspects of the standards and implementation specifications and this is just a mockup of what you'll see with...in the Standards Advisory with particular information.

So, where we can we've, like I said, tried to keep it simple. We've used for the adoption level a bubble approach that people may be familiar with to give some intuitive sense of what the level of adoption may be and then included below the limitations, dependencies, preconditions for consideration as well as the applicable security patterns that might be relevant to that particular interoperability need.

And in the limitations, dependencies, preconditions component the number of areas where, as part of this public comment process in the fall giving the public an opportunity to weigh in on any additional information that the Standards Committee provided, so we've specifically called out aspects right now that were recommended by the Standards Committee for inclusion so that stakeholders had the context and opportunity to comment on those and provide their insight as well. Next slide.

So, this should be a specific example of the Interoperability Standards Advisory and how it looks with something in...it hasn't migrated for me to the next slide, which could be my VPN, all right there we go.

So, we tried to categorize, and you'll see there is a large table of contents at the beginning of the Standards Advisory, to give people the ability to click straight to the interest that they need or that they're interested in. We tried to roughly bucket the aspects of interoperability needs under a specific area.

So, you'll see one for public health reporting that then has five or six interoperability needs underneath it and so to address the feedback that we've gotten for...not to just say, summary care record as a purpose we tried to provide more context on the interoperability need that stakeholders would express so to support a transition of care or a referral to another provider and then we go into listing the standard, the implementation specification and the alternative implementation specification.

So, for those of you that have been tracking the Consolidated CDA, you know, this has been an area where, you know, we have the CDA proper then you have the C-CDA release 1.1 and as of, you know, the past few weeks a new version of the C-CDA which we would say is an emerging alternative to version 1.1 which is release, you know, version 2.1 and we've, you know, put in as we know right now where we think it is relative to the other six assessment characteristics. Next slide, please.

So, there are other Task Force recommendations. We had a number of principles that were expressed. We believe that the Standards Advisory really embodies many of those principles and we're attempting to build them in incrementally into our operations and how we shape it overall.

There were recommendations to convene groups which I think we'll take under advisement and work through as we can. Like I said in the beginning, as there are areas where, you know, we have unknowns or blanks that becomes essentially, you know, the to do list for us to get work into our processes with stakeholders to coordinate to get more information relative to those standards and how they address an interoperability need.

Several other additions and changes to standards and implementation guides that I think we've reflected in the Standards Advisory thus far but, you know, in the next 90 days I'm expecting that there will be other things that we will update and change to continue to make this current. And then other recommendations that we received will, you know, continue to be considered incrementally and building out into the future. So, next slide.

The Standards Advisory will be published on our healthit.gov website at the following link probably within the next hour or two. And then to make up a little bit of time, I know ideally we said we'd like to have a 60 day public comment period, we'd like to receive public comment within a 45 day period so that would be November 6th to give us enough time between then and, you know, Thanksgiving and the holidays approaching in December to refine, revise and publish ultimately the 2016 Advisory.

As I close I would be remiss if I did not thank a few members of my team who were burning midnight oil candles whatever other things you can burn to get this turned around within about four weeks since the Standards Committee's last meeting Brett Andriesen, Chris Muir, Nona Hall who is our colleague from the DoD VA IPO Office that's on detail to my office and a number of other folks on my team that were available at the drop of a hat to provide us input.

So, that's the end of my, I guess, I suppose, prepared remarks. I'm happy to take any questions from folks but wanted to give you a preview of what to expect from the Standards Advisory and let folks know that it will be available for public comment starting today and just to say we really need your help and we'd really appreciate your feedback. Like I said there are a number of structural changes that we have made to advance everyone's understanding and the context and to increase the dialogue and debate about standards.

There, I'm sure, will be particular areas where, you know, the level of adoption bubbles someone disagrees with entirely and that's the type of feedback that we absolutely want and I expect that, you know, we have perhaps either underestimated or overestimated some of those but ultimately, you know, if you're able to provide feedback and comment to us in this 45 day public comment period that will help us refine this advisory and make it the most valuable publication to everyone in the field as time goes on. Thanks.

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

Well, thanks very much, Steve and one comment, Dave McCallie wrote a guest post on my blog noting that standards are necessary but insufficient for interoperability. Your change of purposed interoperability need really identifying what is the business case or purpose, the driving need to have some kind of data exchange is really welcome and of course it's always welcome when you incorporate the Dixie scale so that everyone can really get a sense objectively as to how mature these standards are and is there a testing tool available? So, I certainly like the new format. But, Michelle, is there a queue of commentators?

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

There are, Eric Rose.

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

Eric?

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

Hi, thank you very much for this. I have just a very quick question. What does it mean for a standard or an implementation guide to be regulated in this document? Does that just mean it's required under a...its use is required under a regulation?

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

Yeah, so for that one to be a...you know, it's at this point a yes/no but open to feedback from everyone. We do have a description, a more detailed description for each of these characteristics to give people context but generally speaking the easiest way for us to, you know, put a "yes" in there is if it's included as part of ONC's certification, you know, regulation.

Other areas where, take for instance like the ePrescribing standard that are required by CMS regulation for Part D prescribing, so we've tried to reflect where we know and are aware and have been, for some time, the areas where particular standards are named in regulation to meet particular interoperability needs.

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

Thank you.

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

Next in the queue?

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

Sorry, Dixie Baker.

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

Dixie?

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

I just wanted to clarify something that keeps coming up, you know, I agree with John that it truly is gratifying to see the work of a Nationwide Health Information Network Power Team being actually used again and again, it truly is gratifying so I certainly personally appreciate that and I will accept credit for my persistence in advancing this work to a journal publication that can actually be cited but the concepts that certainly of the Dixie Baker scale certainly are not my own and I just wanted to mention some of people that are on this call that really certainly deserve credit David McCallie, Wes Rishel, Cris Ross, Arien Malec, Nancy Orvis and Floyd Eisenberg were all on the NwHIN Power Team that brought this work, you know, brought it all...brought these ideas forth and, you know, I appreciate it and I appreciate seeing it being used.

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

Well, thank you and of course we absolutely recognize all of the contributions of everybody who went into this work it's just Dixie we have such affection for you, it's great to put your label on it.

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

All right.

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

I think it's become a mean now you know?

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

Thank you but I can see I see David and Wes kind of cringing.

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

Oh, no.

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

Okay.

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

Thank you.

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

Well, if you have, you know, a fancy acronym that incorporates all of your names I'm sure we're happy to use that instead.

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

Okay.

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

So, next comment Michelle?

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

We actually don't have any others.

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

So, Michelle did you want any particular endorsement of this or is this just purely informational?

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

I think it's purely informational.

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

That's correct, yeah, just to give everyone a heads up that this was coming out, to thank you again for all the work and input of the Advisory Task Force as well as the Standards Committee as a whole and, you know, we look to, like has been discussed, a number of work products from different Task Forces and Workgroups over the past year to help inform and shape this. So, please everyone and anyone else on the call today that's listening in over the web, certainly give us feedback, we'd very much appreciate it and thanks for your time.

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

And any other final comments from the group on this presentation, structure or the format or the rubric?

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

This is Nancy, DoD, I would, even though my name got mentioned before, I want to commend the new format. I think it's very strong, it's very clear and I believe it will help implementers immensely. And it's very clear for those directing, you know, advising trying to discern are we ready to put in requirements to make these mandatory internally in organizations. So, again, kudos, thank you Steve, good work and I think the new format is going to be immensely useful.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Yes, Wes, go ahead, you were so quiet we were feeling lonely.

Wes Rishel – Independent Consultant

First of all, thanks to Dixie and I think those of us who worked on it need to be particularly careful to recognize Dixie's leadership in taking a very controversial topic and finding a horse in there somewhere.

The question I have that is not sort of specific to the format or even the content we saw today is how the bubbles are arrived at? And I'm specifically sensitive to the ambiguity in terms of how the interoperability needs are met by a standard.

So, to take a specific example, earlier versions of the CDA or CDA derived documents were often described as supporting both a text representation and the ability to carry structured detailed information about a data and a reasonable amount of data collection probably would have shown they were widely used but the recipients, to the extent they used them at all, only used them for display or another possible outcome that may have occurred with some Meaningful Use regulation is that the documents almost irrespective of the standard format were received but not found useful and not frequently retrieved by physicians working on cases.

The concern I have is whether the process of creating these documents does now or could include some fairly specific evaluation particularly of the ones that are into the high bubbles in terms of actual value received meeting the interoperability purpose. Thanks.

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

Well, Steve any comment on that?

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

Sure, sure, I knew I was going to get away that easy so I'm glad Wes chimed in. I mean, you know, for this one, especially with the bubbles as we've affectionately started to call them internally, you know, this is, for lack of a better word, you know, a known unknown in terms of our knowledge of how widely used particular standards are and that's why I mentioned earlier, you know, I'm sure we've either over or underestimated at this point to give people the ability to react, you know, how bubbles are there for the level of adoption.

But this is an area where I think, and I'll speak from other experience with the interoperability roadmap work and other work that all of us have done, in terms of the measurement and then the utility of the standards overall to meet particular interoperability needs, that collectively we need to do a better job and hopefully if out of this process that prompts that type of work and prioritization to improve our measurement abilities or our understanding of how the standards are used, you know, end-to-end, would be great.

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

I imagine, as you said Steve, that as this publicly released and reviewed that if there are debates about the bubbles you might actually get enough public comment to be able to refine the rubric.

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

Yeah, absolutely, I mean we don't...

Wes Rishel – Independent Consultant

John...

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

I don't have a, you know, a back room of some type of, you know, supercomputer that is calculating this. So, we don't have a lot of intricate science and empirical data behind this but hopefully with this first round, given that, you know, this our first approach with the bubbles that it will engage a lot more interest and involvement from everyone that may be using or implementing or know how the standards are used in practice and can give us more refinement to how it's represented.

Wes Rishel – Independent Consultant

John, I particularly appreciate Steve's observation that coming out with the bubble format is not only a concise way to display but also a way to stimulate a conversation on what's behind the bubbles. I have had occasion to work with the government on evaluating public comments in another area and they're usually more polite than the typical Internet flame wars but often more difficult to trace back to substantive or at least dispositive information.

So, I'm just hoping that in the process of commenting, in the process of maybe getting a year's experience using these that ONC may find the opportunity to build some information gathering processes into the next cycle. Thanks.

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

Great, well, thanks. So, Michelle, any other comments in our queue?

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

No further comments in the queue.

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

Well, it does appear then that we are through our agenda today a bit early and so Jon White do you have any additional comments on the work ahead or the October meeting, anything to add?

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

Only the following, first, you know, I'm sitting here basking in the afterglow, so I'm just going to say how the precision medicine work is, you know, I'm really grateful for the opportunity to be able to bring work to the Standards Committee and to, you know, get such tremendous work out of folks that, you know, advances the healthcare system in ways beyond, you know, that are...in ways that are not so, you know, certification focused and standards program focused. I hope that everybody feels like we're having a chance to build on the work that we've done in the past to advance towards the future. So, I will say thank you for that.

You know I think that when we get together in person in October I think that there's going to be a lot of substantive and chewy updates there for folks to be able to hear about. Of course, you know, I'm looking forward to our new members being there formally for the first time and engaged.

I think that, you know, it has not been a quiet summer, it has been a busy summer and that's been good and I think that, you know, come ready to engage, come ready to discuss, come ready to think because whether it's getting to that October meeting or, you know, going in the months beyond that, you know, there is a lot of important work that's got to happen whether it is, you know, executing on the strategic plan, whether it's executing on the interoperability roadmap, whether it's rising to the challenge of new direction from the administration and congress to try to achieve some of the things that we want to achieve, you know, it's a great time to be involved with these efforts.

So, I'm just really grateful for everybody's hard work and engagement and thoughtful, as I just said, to Dixie and David in an e-mail, you know, collegial engagement with each other, I'm really grateful for that and for everybody's efforts. So, thank you and I look forward to a lot more work ahead of us.

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

Well, great and certainly look forward to seeing you all in person in October and getting together with our colleagues from the Policy Committee and hearing updates from ONC. So, with that Michelle, any other final administrative items? We have public comment of course.

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

Yes that would be it, public comment. So if you're ready let's open up the lines.

Public Comment

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

Let us open to public comment.

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.

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

Do we have any public comment?

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

We have no public comment at this time.

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

Well, very good, well, certainly thanks to the presenters today for doing such a great job, very, very well done and foundational for the work that we're going to do in the months to come and as I mentioned when we got together the last time that in some ways we have reached the end of the debate on Meaningful Use and are now moving onto things like precision medicine and this is going to become the new foundation for our discussions of creating the learning healthcare system. So, the work has already started and will continue to be robust. So, Jon White, final words of benediction?

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

...thank you everybody.

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

Okay, well have a lovey day and enjoy the fall, thanks so much.

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

Thanks, everyone, see you in October.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Bye-bye.

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

Thank you.

Public Comment Received During the Meeting

1. Donna Doneski: The National Association for the Support of Long Term Care (NASL), whose members include health IT developers/vendors and providers of care for the long term and post-acute care (LTPAC) sectors, appreciates the work of the Health IT Standards Committee. Our members are actively working on the exchange of health information for their clients, to include electronic exchange of health information across care. We will look forward to reviewing the 2016 Interoperability Standards Advisory and to offering comments. Thank you.

Meeting Attendance								
Name	09/22/15	08/26/15	06/24/15	05/20/15	04/22/15	03/18/15	01/27/15	12/10/14
Andrew Wiesenthal	X			X	X	X	X	X
Angela Kennedy	X							
Anne Castro			X	X		X	X	X
Anne LeMaistre	X		X	X	X	X	X	X
Arien Malec			X	X	X	X	X	X
Charles H. Romine				X	X	X	X	
Christopher Ross			X	X	X	X	X	
Dixie B. Baker	X		X	X	X	X	X	X
Elizabeth Johnson	X		X		X	X	X	X
Eric Rose	X			X	X	X	X	X
Floyd Eisenberg	X		X	X		X	X	X
James Ferguson	X			X	X	X	X	X
Jitin Asnaani	X							
John Halamka	X		X	X	X	X	X	X
John F. Derr	X		X		X	X	X	X
Jon White	X		X	X	X	X	X	X
Josh Mandel	X							
Keith J. Figlioli			X	X		X		X
Kim Nolen	X		X	X	X	X	X	X
Leslie Kelly Hall	X		X	X	X	X	X	X
Lisa Gallagher	X		X	X	X	X	X	X
Lorraine Doo	X		X		X	X	X	X
Nancy J. Orvis	X		X		X	X	X	

Patricia P. Sengstack	X							
Rebecca D. Kush	X			X			X	
Richard Elmore	X							
Steve Brown	X		X		X			X
Wes Rishel	X		X	X	X	X	X	X
Total Attendees	23	1	21	21	22	26	25	22