Collaboration of the Health IT Policy and Standards Committees

Final Transcript
June 23, 2016

Presentation

Operator
All lines are bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – 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 Joint meeting of the Health IT Policy and Health IT Standards Committee. This is a public meeting and there will be time for public comment before lunch and at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded.

We have a few new folks in the room today. There was a press release sent out this morning so we are going to go around the room and take roll first and then we will allow some time for the new folks to introduce themselves there are some of them on the phone as well, but first let's start with Anjum and come around.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Good morning, Anjum Khurshid on the Policy Committee.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Good morning, Jitin Asnaani, Standards Committee.

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science
Dale Nordenberg, HIT Standards.

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

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
Rich Elmore, Standards.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Kim Nolen, Standards Committee.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Troy Seagondollar, Kaiser Permanente.

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

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Gayle Harrell, State Representative from Florida on the Policy Committee.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Leslie Kelly Hall from Healthwise and the Informed Medical Decision Making Foundation, Standards Committee.

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

Larry Wolf, MS – Principal – Strategic Health Network
Larry Wolf, Standards Committee.

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Aaron Miri, Imprivata, Policy Committee.

Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition
Karen van Caulil, Florida Health Care Coalition, Policy Committee.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
Andrey Ostrovsky from Care at Hand and Mindoula Health, Standards Committee.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Lisa Gallagher, PwC, Standards Committee.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Kathy Blake, American Medical Association, Co-Chair Policy Committee.

Gretchen Wyatt, MA – Senior Strategic Advisor, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology
Gretchen Wyatt, ONC Staff.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Paul Tang, Policy Committee.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative
John Derr, Standards Committee, long-term post-acute care.

Carolyn Peterson, MBI, MS – Senior Editor - Mayo Clinic Global Business Solutions
Carolyn Peterson, Policy Committee.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
Floyd Eisenberg, Standards Committee.

Kim J. Schofield – Advocacy Chair – Lupus Foundation of America
Kim Schofield, Standards Committee.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Lucia Savage, ONC Staff.

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System
Brent Snyder on the Policy Committee.

John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense
John Scott, Department of Defense, Policy Committee.

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

Jennifer Brown - Office of the National Coordinator for Health Information Technology
Jennifer Brown, ONC Staff.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And on the phone we have Cris Ross?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Cris Ross, Standards Committee.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you, Cris. Liz Johnson?

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

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

Wes Rishel – Independent Consultant
Wes Rishel, Standards Committee, pre-emeritus.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Terry O'Malley?

Terrence (Terry) O'Malley, MD – Medical Director for Non-Acute Care Services, Partners Healthcare System – Massachusetts General Hospital
Hi, Terry O'Malley, Partners Healthcare, Standards Committee.

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

Peter Johnson, MBA – Senior Vice President & Chief Information Officer – Dartmouth Hitchcock Health Care System
Good morning, this is Peter Johnson and I'm on the Standards Committee.

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

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
Good morning, Michelle, Policy.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Good morning, Chris. Scott Gottlieb?

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute
Good morning, Scott Gottlieb, Policy Committee.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Lorraine Doo? Nancy Orvis?

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

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And Jonathan from the VA just walked in.

Jonathan Nebeker, MD, MS – Deputy CMIO – US Department of Veterans Affairs
Jon Nebeker, VA.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Is there anyone on the phone that we missed?

Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health and Human Services
Lorraine Doo, I got disconnected.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Lorraine. Okay, so I first want to thank Wes Rishel, Cris Ross and Liz Johnson who have stayed…and John Derr, who have stayed with us as we waited to appoint our new members. They have been with the Standards Committee for quite some time and we greatly appreciate you holding on and staying with us as we waited for our new appointees to come aboard.

So, now we are just going to take a few minutes to quickly introduce our new members, maybe just a couple of sentences of who you are and where you come from. So, we'll start on this side of the room, I think the first person I see that is new is Aaron, oh, I'm sorry Larry Wolf, sorry.

Larry Wolf, MS – Principal – Strategic Health Network
Good morning, Larry Wolf with Strategic Health Network, I have 40 something years on the development side of health IT mostly clinical systems and many years working in long-term post-acute care as well as a lot of experience with the Policy and Standards Workgroups and I'm really glad to be here. Thank you.

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Aaron Miri with Imprivata out of Boston, Massachusetts. I'm the Chief Information Officer and VP of Government Relations. Prior to that role I was a CIO of a hospital in Dallas is Texas, Walnut Hill Medical Center, before that CTO at Children's Medical Center of Dallas. I was in provider care over a decade before that I was in telecommunications and so back on the vendor side now loving it and I appreciate being here.

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

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
Andrey Ostrovsky I'm the CEO and Co-Founder of Care at Hand. Our company was acquired two weeks ago by Mindoula Health which is a behavioral health case management company. You guys will probably hear from me about the emphasis on home and community-based services and extension of health IT standards beyond the EHR and ensuring that we also are a representative of holistic approach to consumer not just patient care.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Andrey. On the phone we have Peter Johnson?

Peter Johnson, MBA – Senior Vice President & Chief Information Officer – Dartmouth Hitchcock Health Care System
Good morning everyone. I served as the Chief Information Officer at Dartmouth Hitchcock which is an integrated delivery system in Northern New England and I retired a couple years ago and I do a little bit of consulting in my retirement.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Peter. Terry O'Malley?

Terrence (Terry) O'Malley, MD – Medical Director for Non-Acute Care Services, Partners Healthcare System – Massachusetts General Hospital
Yeah, hi, I'm an Internist and Geriatrician with about 40 years of practice in long-term post-acute care and for many years was the Medical Director for Non-acute Care Services at Partners Healthcare which is a big integrated delivery system in Boston and the last several years have been working on several of the ONC S&I Framework Initiatives around transitions of care, longitudinal coordination of care and most lately on the ELTSS Initiative. And I'd just like to put a call out to John Derr who has been such mentor and a guide and a voice in the wilderness for many years for post-acute care, so it's an honor to be following him on this committee.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Terry. And so not with us today is Raj Dash, Kay Eron, Kyle Meadors and Wanemei Ou. So, we'll have them introduce themselves at our next meeting. So, thank you to all of our previous members who have stuck with us throughout this time and we welcome all of our new members.

As you may have noticed there's a little bit of traffic outside, there's also some airport delays so that is why we started a little late so I apologize to the public. We also are missing a few members in the room because of that. So, Jon White is not quite here yet to make a few opening remarks so maybe he'll make some comments either before lunch or at the end of today's meeting. So, I'm going to turn it over to Paul to review the agenda.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Welcome to the new members and thanks to the departing members who've given so much of their time to this process and contributing to the country's development of HIT. Let me just review the agenda, but before I do, just so I don't forget, you got distributed the minutes from the last meeting and I'd entertain a motion to approve those. Thank you. Thank you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
If I could just ask for a correction on the minutes which is that with one of the comments that I made, the minutes state that the core measures collaborative was an effort of the American Medical Association, it was not. It's an effort of CMS and America's Health Insurance Plans or AHIP and we were a participant as were many, many other organizations.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Good, if you wouldn't mind just sending an edited version of that we'll submit those.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Sure.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you, I had a similar correction. Any other corrections or additions? If not, all in favor? And any opposed or abstained? Thank you. So, let's turn to today's agenda which will open with an update on the privacy activities in ONC with Lucia Savage.

Then Cris Ross and I will present the final comments on the NPRM for MACRA. We went over the draft last time and we'll be looking for your final comments today because we have to submit those later in the week.

And then we're going to go over some draft recommendations from the Joint Committee's dealing with interoperability one on the experience that is getting the job done and the other on the Interoperability Standards Advisory and so we're going to hear some initial recommendations from both of those Task Forces and then we will conclude with public comments. Any other additions to the agenda? Alrighty, if not then we'll start out with Lucia Savage updating us on some of the activities in her office regarding privacy.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Good morning, everybody, are we on? Okay, I've live. I just wanted to give you an update on some of the things besides APIs that we've been working on lately and I reserved some time for questions at the end. Hopefully, I'm not very good at clickers but let's see how I do this. This must be advance, nope, one back.

So, I'm going to talk about some work were doing on security and cybersecurity. I'm going to talk about what we have planned next relative to these fact sheets, this campaign we've been working on to give stakeholders a sense with drawings and stories about what HIPAA really means and then I'm going to talk about the work we committed to doing on opting in an opting out in the roadmap.

So, the first thing I wanted to go over with you is what is happening with the Cyber Information Sharing Act of 2016. So, those of you who follow politics closely will recognize this as a component of the budget Congress passed in January. And in that budget there were three specific tasks assigned to Health and Human Services and I wanted to remind people what those were and let you know what is ONC's role in those tasks. Those tasks sort of fall, to the extent they fall under ONC, to my office.

The first task is 405 (b)(1) which is the Secretary is supposed to develop a report for Congress about what HHS is doing to secure its own systems. One of the best parts about my job is I don't actually manage a data system. So we have a very little role here. I'm sure that we'll be offering whatever support the Secretary needs to get this report across the line but we are not actively working on it.

The second task for HHS was a Task Force of industry stakeholders to develop best practices for improved cyber threat sharing in the healthcare industry. So, let me sort of back up, particularly for people who don't live and breathe security standards, so this is a concept which is, I've described to lay people, it's sort of like a neighborhood watch for cybersecurity. It's very well developed in some other industries, most notably energy and finance, it's less well develop in healthcare, although there is cyber threat sharing occurring.

The task for this Task Force is to look at what other industries are doing and figure out how those things can be leveraged to improve cyber threat sharing in healthcare. So, what cyber threat sharing is, if you are an organization that has a data system and you're doing your diagnostics and your preventative measures and all of that kind of stuff and you notice something funny, you tell the other people in the industry so they can go look for those things that are happening in their systems that aren't supposed to be happening there as well and in that respect it is very much like a neighborhood watch. If you notice somebody who didn't belong in your neighborhood casing the houses and checking the doors to see which ones were not well locked, you would want to tell your neighbors and it's really that simple of a concept.

This has been very hotly debated in Congress but this Task Force is well underway. It started in March. They meet publicly once a quarter for a whole day so there is one more coming up later in July. And then they'll produce a report in the first quarter of the calendar year of 2017.

The kind of testimony they had at their first public meeting included representatives from finance, energy, transportation about how those industries cyber threat share and how those concepts could be migrated to healthcare.

It's a very passionate and active group of people. We had volunteers from leading cyber threat security consulting firms in the country, from major hospital systems, from technology companies and from the consumer space. There's a lot more information available about it on HHS.gov and you can look for updates as they're available from the committee.

There is a third charge from CISA which has not yet taken root or been commenced but I wanted to pass it along to you because I thought it would be of particular interest. This is a Task Force that is designed for the healthcare industry to identify common security engineering techniques and I'm translating a little bit from the statute but I've given you the highlighted language at the end where it says "a common set of voluntary consensus-based and industry led guidelines, best practices, methodologies, procedures and processes to improve cyber hygiene in health care."

So, we don't know exactly how the Secretary is going to implement this, we always stand ready to bring our standards experts, I see Steve Posnack just walked into the room, and our security experts to the table for this so look for more to come on that in the future.

Next up, what else are we doing on cybersecurity? So, I thought I'd pass along to you this very interesting quote from Defense Secretary Carter, the Department of Defense recently concluded their first ever exercise on ethical hacking. I know that there are people in the room who know what ethical hacking is, but I'm going to assume that some of you don't really know what ethical hacking is so let me explain that.

The idea of ethical hacking is creating a space where well-intentioned and non-malicious hackers can help you find the bugs in your system and present those bugs to you and you look at that with an open mind and an open heart and you evaluate whether those bugs are real and need fixing and then you fix them and in other industries, this is much more well-established than it is in healthcare and then it has been in the Department of Defense.

Now defense is a little bit different than healthcare because they have different things they need to worry about relative to security, for example confidentiality of special employees. We have special rules in healthcare about the data that hacking might occur in. And I went to an FDA device security workshop for two days last February, it was fascinating but this was a very hot topic there. This is a struggle for

devices as well. In the field, you can't hack something in the field because what if a hacker disrupts the operation of the device?

Similarly, health data and EHRs you may not want to have your hacker accessing your live data because that might cause other problems relative to your obligations to keep that data confidential. Given that space and given the need improve cybersecurity is there something ONC can do to improve the rate at which ethical hacking occurs in healthcare. So, we are working on some plans more to come on that later for Standards Committee and the Joint Committee depending on how the agendas comes out, but I think this is a technique that has been found highly valuable in the rest of industry and that's why I gave you Secretary Carter's quote.

They did hack-a-thon, and ethical hack-a-thon at the DoD, they had, I'm going to guess, I just saw the number yesterday, 1600 hacks but 100 of them were valid, they fixed those flaws in their system and they can do it again. So, one of the things we're thinking about is how do we get this to take root as a security hygiene process within the healthcare system.

All right, next steps, fact sheet, so you all remember that in February we released four Blogs and two fact sheets in conjunction with Office for Civil Rights and they were about scenarios for actual permitted sharing of health information under HIPAA, one is for treatment and one is for operations.

And first time ever we included illustrations and real life stories where we took the verbs in the regulations and worked with our doctors to figure out what those verbs meant on the ground. What did sharing to develop a care plan look like? What did sharing to find the next long-term care facility for a discharged patient look like? They are very popular, prepaid, free, un-copyrighted by the American public, please go use them as you need to and we have a couple more in the pipeline.

So, first step in the pipeline is a set of fact sheets on public health activities. As we move to the learning health system and to delivery system reform we're going to have to have much more fluid movement of data between the traditional healthcare system and public health organizations. I think you are all familiar with Dr. DeSalvo's work with Flint and that is a great present example but we've had that same challenge with regards to Ebola, with regards to Zika and if we'd had a health IT system in the 1990s we would have had it with regard to HIV AIDS.

So, we'll be working on some fact sheets about what does the public health authority that a state grants its public health agency mean under HIPAA and how does that enable physicians in practice to share as needed for public health, we will not be addressing what can the public health agency share back, that is a creature of state law and we really have to delegate to states to explain that for themselves so more to come on that.

After we finish public health, we'll be working on health oversight which is kind of the last bucket of these permitted uses that really have to do with things outside of law enforcement. Health oversight is how a state regulates the health insurance system of its citizens. So, it includes departments of insurance, Medicaid agencies, everything related to how the insurance system, the health insurance system works and we think that is relevant for the ambitions of the insurance exchanges whether the federal exchanges or the state-based exchanges and for the desires of states to understand why insurance costs what it costs, how do benefit structures relate to the incentives they're trying to develop for delivery system reform and alternate payment models. So, that will all be…all that is a work in progress and more to come. Hopefully we'll get those things out the door this fall.

Lastly, basic choice. So, the Policy Committee and particularly members of the Privacy Security Workgroup will remember we had a very intense dialogue about this about a year ago, maybe 15 months ago when we first released the draft roadmap and in that roadmap my office hypothesized that while we had done a lot of policy work to develop information about consent in an electronic environment it wasn't particularly clear and it was very hard to get through and my personal confession, I read it all and I do this for a living and are days that I'm like "what, what is that" and if I was confused that meant that stakeholders who didn't have the same training and background I had were even more confused. So, we committed to trying to sort this out.

So I just wanted to show you we've just started the first step in that process. In this graphic here what we're illustrating, I'm really bad with the clicker, you guys can all see, the green lines mean data is flowing and what we've done in this illustration is try to show what happens if you insert a requirement for electronic consent under HIPAA. The insert requirements for electronic consent for sharing you still get to share it by fax. You still get to share it by fax, you still get to share it by mail doctors can still call each other.

So, this is an illustration that we just posted on our website under the title computable privacy for the annual meeting we'll be building this out as we go and we do have work in the pipeline that goes through the normal ONC input processes that will help sort out, you know, when is it that you actually have to, by law, offer people the right to choose whether their data is exchanged electronically or when do you not have to offer that and what are the consequences when you're not required to offer that choice if you offer it anyway? So, we'll be working more on that as we go.

And I think that is all the slides I had today. I'm happy to take questions. I don't know what's the balance of my time Michelle?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
You still have time.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Okay, perfect, are there any questions or comments, or things you wish I was working on that I'm not?

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Oh, okay, go, ahead, Kathy, you go ahead, I'll be last, I want to ask about something that she hasn't talked about.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Ah, okay, so, thank you. I'll go back Lucia to your comment about the meeting and collaboration with the FDA and the dilemma really of how to evaluate medical devices and how to hack them. And certainly this is something Dale Nordenberg is very, very familiar with but the National Medical Device Evaluation System is looking at developing a public/private partnership that will evaluate the safety as well as the effectiveness of devices not just at the time that they are approved but also going forward as they are used in patients sometimes for many, many years.

There are some key opportunities or best times in which medical devices could or might be safely hacked and one certainly is at the time of initial implantation and the second would be at the time of replacement of a device because it's at both of those times that there may well be less dependency on

the device or there maybe the opportunity to have a new device functioning while an old device is being hacked an old device for that patient but one that others will still have. So, just a comment there.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
That is really helpful. I will follow-up with you Dale. But I wanted to be super clear, our focus is on security hacking for the devices we don't have any authority on safety or efficacy of devices for Health IT, my office certainly doesn't. So we will not be looking at that.

I will say that this work we're doing, we're doing it in concert sort of thinking through how to solve the problem and what is the problem we're trying to solve with the FDA because we really…our portfolio is health IT and their portfolio is devices and there's overlap there on the security side, but they do have the Center for Disease and Radiological Health which has a very extensive portfolio on other things related to devices.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Right. So I'm being very specific to the issue of when could you hack a device to meet the concerns of ONC.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay, Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So, I have a clarifying question on the fax example that you used. Many times people are using fax servers the transport mechanism is still a fax line but the receiving systems are servers. Would you make sure, as you look at this, how that might also be considered in the data flow and if those are exempt, those servers are exempt because that information has been transferred over faxes. I would like to get some clarity on that.

And then what was the timeline, I missed that, of when you expect this report to be on the opt-in, opt-out to be completed?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
So, our work on opt-in, opt-out is contingent on other work that ONC is doing so our plan was to issue it and get feedback on it this year, but I don't have a specific date because it's part of other moving parts. I will answer about the fax. So, HHS actually has very specific guidance on the line of the fax machine versus the server in the receiving or sending fax machine so I'm happy to send you links to that but if you went to, you know, hhs.gov/ocrhipaa and searched fax machine I'm sure it would pop right up.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Dale?

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science
So, very exciting to hear the topic emerge. We've been working on it at the Medical Device Innovation Safety and Security Consortium for about six years so it would be great to catch up there. There is a lot of caution around stepping into the domain of hacking, ethical hacking, of devices for various reasons one of which is that because it is a regulated device it's not possible, as in the case for managed IT products, like a computer that sits on an administrative desktop, to fix a vulnerability or to patch a vulnerability at will.

So, the issue is that once a vulnerability is identified the industry is highly resistant to exposing to the public that specific vulnerability because the manufacturer has to get engaged and then the manufacturer has to be part of assessing whether or not there's a…this is an important vulnerability and then what solution would be and then they need to do that for all of their devices.

And the issue is that pretty much every medical device out there is hackable, literally. So, what we've been working on and struggling with concretely for the last 18 months with the FDA and the NIH is actually a system, the medical device vulnerability information sharing initiative, which is designed to create a mechanism to take the published vulnerabilities that are in the NIST national vulnerability database which is between 6000 and 8000 of those each year and then to figure out how to assess those and get them into a workflow where manufacturers can deal with them and assess them and then if necessary patches could be identified.

And I look forward to catching up with you off-line, but the manufacturers really are saying it's not really possible to be addressing the workflow and so what's really happening at this point is as those vulnerabilities get identified more and more we're looking at environmental controls with health systems. So, it's a great idea and devil is going to be in the details in terms of doing it safely.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Absolutely, among the other details besides the live environment and the intellectual property and the who supplies the equipment and then how do you remediate a hack, I mean, we have a list, it's about a page and a half long, of things that just our team came up with most of which are actually not the privacy and security challenges and that's why we're working on developing these ideas in conjunction with the FDA.

The other thing I would point out is at this workshop, and I believe the webcast is online, I'm not 100% sure but I've been waiting to get the notes…two days everyone in the room kind of had the realization that we really have the Internet of things in healthcare and we have to not think about devices independent from the EHRs, independent from the patient's actual life. It all kind of is running together which was in fact the point of improving the digitization of health in the system but now we have some spillover effects that we also have to solve for as things don't operate independently anymore.

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science
Right and I'm not sure if folks have seen it, but I think just last week, we released a press release…we sent out a press release with NIH, ISAC and MDISC that announced the formation of the information sharing and analysis organization specifically for medical device vulnerabilities to satisfy the FDA guidance on the need for manufacturers as part of premarket to submit or even post market, I should say, to submit any kind of vulnerabilities that they're aware of.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Right, so I'm going to take chair's prerogative and ask my question because it really follows up with this discussion. Lucia, another component of this is actually the codification of ISAOs into law and clarification of the regulatory relief for organizations in health care to share threat data. So, I wanted to see what you all are planning in terms of pushing the word out on that and supporting the industry on that. I mean, I'm working on it with providers and I'm very happy to hear that Dale's organization is utilizing that structure and process for sharing threat data across the medical device vendors.

So, I feel like this is really important for the industry. And, you know, as I go out and talk to people there's not a lot of widespread knowledge about the fact, you know, there was a presidential directive and then codification in law and CISA personally trying to educate, but I think it's important and just wanted to see what your efforts are planned or future in that area.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Sure, thanks, Lisa, because I realized there was something I forgot to say and I'm glad you reminded me. So, first of all, first up from ONC directly we committed in the roadmap and we are putting the final touches on a funding opportunity announcement to help fill gaps for cyber threat sharing in healthcare so we had hoped to have it out by now, you know, the government we move slow, because we're very methodical. It will be out this summer. So, we hope it will be a multiyear, subject to appropriations, a multiyear grant opportunity in the healthcare system we have NHISAC, we have HITRUST, we have some other information sharing going on but they tend to be subject to the members of those organizations so they maybe don't permeate the entire industry in a way that we really need them to and we want to help fill that gap with some grant money. So, that's coming down the pike and we'll Blog it when it comes out.

But, secondly, as to CISA itself, so that is correct, Lisa, Congress did create some basic rules regarding the liability of the threat sharer in how they share those threats and the Department of Homeland Security is tasked with actually fleshing that out in better guidance.

So, we're kind of waiting for DHS to finish its work and depending on timing it will either be looped into the Task Force that I talked about before or if it's, you know, after that and it's something that's appropriate for ONC and my office to take on and sort of, you know, that's what we do, we take information and turn into practical, useful, educational materials for the industry. We can do that but we need to have to DHS act first.

The last thing I'll say is my office along with several other offices at HHS, you know, we collaborate with Homeland Security with the FBI, with the NSA, pretty much every week. I can't even keep track of the alphabet soup of committees and meetings that my security team goes to and they're very frustrated by the fact that I can't keep them all straight in my head, but there's lots and so that all happens kind of behind the scenes and not really in public but there is a cross agency staff actually supporting this Task Force on information sharing that includes, you know, DHS, FBI, NSA, many, many HHS organizations. So, that work all goes on every single day.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Thank you. And just to clarify, the statute is pretty clear in the areas of regulatory relief protection from liability, antitrust exemption, exemption from FOIA, exemption from prosecution when you share with DHS and so what I really want to get across to the industry is that the framework for sharing that the ISAO Act is encouraging folks to do is already in place and in fact some are forming or thinking about

forming in healthcare. So, you know, we'll keep doing our best to get the word out on that. And again, kudos to Dale's organization for starting that up with medical device centers.

We have two more questions, let's see, Aaron next?

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Thank you very much, Aaron Miri, Imprivata, so two comments and two questions. Number one, I want to thank you for your office and what you're doing. As a very recent former hospital CIO the clarification that you're office has given to the healthcare community and providers has been crucially appreciative. We've been able to really steer around several items that were questionable because of your guidance and very clear instruction. So thank you to you and your team.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
You're welcome.

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Number two, comment, I state that with frameworks related to what we've talked about here I've stressed that there are a number of great frameworks out on the market, but some of them have a price point that prices out some of the rural community hospitals and others being from able to implement. They're very strenuous as well as information sharing, you have to sort of pay to play and those kinds of things are barriers that will impede the progress. So, I stress please make sure we encourage frameworks that are free information sharing, that is free, easily distributable and, as Lisa was saying, easily understandable by all.

Two questions for you. Number one, related to the FDA items, do you envision some sort of guidance coming out after the fact, like recently with PCI mandating two-factor authentication. Do to see those kinds of technical standards starting to become commonplace in the industry maybe long-term?

And my second question to you is regarding the hospital hack-a-thons, how are you going to encourage hospitals to allow for this to occur with medical device manufacturers?

Recently there was a medicine pump out there was shown to be hackable and it caused sort of a fury in the medical industry because people had these medicine pumps which caused some concern on hospital administration, like "oh, no, we're at risk" or "our patients may not come here" those sorts of things. So, how are you weighing that balance?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
So, addressing the FDA first, I have no idea what guidance the FDA plans but always happy to take those questions back and figure out if there's a way for us in our coordinating role to get the FDA, CDRH people here to tell you about some of the things they're working on. It seems like that's an area of some interest.

Secondly, as to hospitals, you know, like I said there's a very long list of problems to solve and the reason I wanted to bring that today is because I really was struck by Secretary Carter's quote and if DoD can figure out how to do this surely the healthcare system can figure out how to do this. That doesn't mean I have a ready solution to present on the table.

I think it's more to start this conversation that you're asking questions, Dale is saying, hey, I have some resources here. We are all in this together and we have to figure it out. And I have no idea if we…at the end of the day if we facilitate more ethical hacking in healthcare will it be happening at hospitals, will it be happening in some kind of lab where the data is not live, like I don't really have an answer for that today.

I can tell you that that's exactly the kind of thing we're thinking about. You know even in the non-healthcare software world there are companies that really raise ethical hacking and companies that don't and it is very company personality driven what their risk tolerances are, how they perceive their IT, what they think about their reputation.

And again, we're looking at how do we create a path to improve the uptake of this, apparently quite efficient process more but…we're not going to be…I have no plans to require anyone to do it and if I wanted to do that I wouldn't have the authority to do it in the first place. It's more about how do we facilitate awareness and uptake for people who want to.

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Larry, next.

Larry Wolf, MS – Principal – Strategic Health Network
So, again, many thanks a lot of great work is going on and I've been poking around during your presentation to try to find the link for the threat sharing task force I'm stymied.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Okay.

Larry Wolf, MS – Principal – Strategic Health Network
So, lots of information out…no some information out there about membership and things but if we could get links for what's going on, I know that there's a lot of interest in the healthcare provider community.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I'll send it to Michelle and then she can distribute it. I'll send it when I get off…

Larry Wolf, MS – Principal – Strategic Health Network
Thanks.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
The stage.

Larry Wolf, MS – Principal – Strategic Health Network
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Paul?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
And really appreciate these updates in the area of privacy because I think it is a challenging area as you mentioned. I had a question, a follow-up really to something Leslie brought up in terms of the faxes and you were declaring that mail is not covered and fax is and this whole evolution of I don't get paper mail anymore and I also don't get faxes because of course "copiers are now fax machines" and so maybe…I'm not sure I got your answer as far as are these electronic transmissions of paper documents, I'll call them that instead of faxes, covered in your expiration both from a policy point-of-view and from a security point-of-view.

From a policy for example, like I discover our copier/scanner keeps track of it in their database and so I just asked for it to be deleted but surely other people must need this same guidance in terms of we should have all of these receiving computers and storage deleted, you know, cleared or purged of the PHI and the second is the security part.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
So, I will bring back some additional information at a time that Michelle and Elise, and we all decide is right for you about faxing and security, but I will tell you in general my understanding from OCR's guidance, which I think hit the market in 2013, was quite a splash because it surprised people is that where it is fax server the security rule applies versus a thermal fax. Do you guys remember thermal faxes with the curling paper, okay, so that's what I was referring to and in answer to Leslie's questions. I'm pretty sure there are clear statements about that from OCR because I remember being in private practice at the time and having my clients go…having an "oh my gosh moment."

So, the security rule would apply theoretically to a fax server because it's electronic in nature even though it prints out in an image. Does that answer that question for you?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
No, the question is, it's going beyond these "servers" in the IT department, every copy machine now has become a fax server both to generate and to receive and store. So, we basically have this distributed "server" and has that been recognized and is there any policy guidance as well as security coverage?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Right, so the security guidance is that when it's a fax server the HIPAA security rule would apply. So, that's…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Including the…

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
My understanding of guidance from OCR.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Including the standalone machines in offices?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
That is my understanding. I will have to circle back to you after I check it, but that is my understanding. I haven't looked up the rule in a little while. As to policy guidance, I think the point we're trying to drive is the…it can be organizational or it can be state law driven but there are basically policies and rules that are not HIPAA derived that say, you know, individuals should be able to choose whether their data is electronically exchanged or not.

To my knowledge having read many of them, but probably not all of them, because I haven't read…I've really only read the statutes and policies that are published, those policies and the people who author them are drawing a line between say a direct protocol or a health information exchange environment what we might think of as more traditional exchange compared to a fax.

However, the security rule would apply to both of those circumstances so that's what we're trying to clarify, you know, our goal is to put out something for stakeholders to respond to, is this helpful, are we being clear, what else haven't we accounted for in our normal way.

To Leslie's question about timing, my hope is to get that out by the end of the calendar year but I can't guarantee that. And through that iterative dialog with stakeholders to really be able to help get clear information out and then separately address stuff that is unclear.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay, I think we'll take someone on the phone next and then…go ahead Michelle?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, I'm a little bit worried about time because Cris Ross has a hard stop.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Wes Rishel had his hand raised, I think he took it down.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, I know there's two questions left in the room, if they aren't urgent maybe we could move on but I'll check with you all.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Dale.

Dale Nordenberg, MD – Chief Executive Officer – Novasano Health & Science
Just a comment, because there's lots going on and no need to have a full detailed discussion today, but just in reference to the question around the infusion pumps one of the things that we've clearly identified and are working through is that there are jurisdictional chasms in this domain so everybody

looks to the FDA to solve the problem but the FDA really only has regulatory domain over devices. Once they get implemented in the hospital now you're in the domain of the accreditors and what Joint Commissioner, the other two small accreditors may or may not require in the context of how devices are implemented.

And then finally, you're looking at the issue of critical infrastructure because if essentially these devices form a national biomedical device network that nobody planned and nobody secured and that gets into the issue of critical infrastructure. So, last year we were fortunate enough to get Homeland Security funding to deal with that.

And lastly one point of clarification, we are doing some things but we're working really closely with NIHSAC and FDA, and NIST, and HHS and Homeland Security, so there are a lots of folks, you know, we're doing our small piece but lots of great partners.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay, and finally, Troy, quickly.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
I'll try to be brief. One of the things that I'm really concerned about is the restrictions of this stuff, you know, when you look at the sender transmission and then the receiver aspect of this the operations aspect of being the sender, you know, Paul said, you know, rarely do you get mail anymore, but we do send quite a few documents by mail. And the burden for us is to make sure that the receiver has confirmed receipt of that mail. The same thing is holding us tight with even faxes or electronic transmissions. There are a lot of operations that go behind verifying and validating that the receiver did get the information.

So, my concern is this, and what I'm hoping part of the discussion will be is, really looking at the liability of the sender in verifying and validating that the receiver has a secure fax server or that they're receiving it and how that whole process will take place because right now, I mean, it's really difficult. So, hopefully that's part of the discussions that are taking place.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
So, we've started addressing that in the current fact sheets with OCR. I won't belabor the point, but the language in there, to the best of my recollection, is along the lines of, it's focused on electronic transmissions so we weren't really writing about US mail. But the idea was that the sender has to take the steps required to transmit it under the security rule and I believe the language is with, you know, a reasonable likelihood that they know that it's going to the place it's supposed to go.

I don't recall any language in those fax sheets that say you have to confirm receipt, which doesn't mean an organization may not have assumed that responsibility in their own policies and procedures. So, there's nothing that prevents organizations from being more cautious than the law requires and in some circumstances that could be useful and in some circumstances it might be burdensome. There also is very clear language about that in the HIPAA regulations and the receipt on mail dates back to 2000 and 2002 so you have to get out the musty old book.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay, well, thank you Lucia…

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
For the wonderful discussion. I'm going to turn it back over…I'll turn it over to Kathy for introduction of the next panel.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Great, and thank you so much and Cris Ross is on the phone, Paul Tang has joined us here and both are Co-Chairs of the Joint Committee's Quality Payment Program Task Force. This is material that we had the opportunity to consider in draft form at our last meeting and this is being prepared in anticipation of submittal in time for public comments to CMS which the date is June 27th. So, I'll turn it over to Paul and to Cris.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Great, thank you, Kathy and Gretchen Wyatt has joined us as the head of the staff supporting this and she has done a wonderful job helping us, one, to understand even what's in the proposed rule. So, Cris for organizational reasons has had to stay back in Minnesota so he and I will be sharing this presentation. Can we go to our slides please or do I just…okay, here we go.

This is a list of members who served on the Task Force and I have to say we had a very tight timeline so up through this morning we were trying to get our comments in and reconciled amongst the members to try to reflect the discussion. Here is the charge for the Task Force. I'm going turn it over to Cris and Cris just direct me to go to the next slide as you wish.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Thank you, Paul. We reviewed this when we provided an update on June 8th, our preliminary update, highlights we were asked to review the MACRA proposed rule with specific focus on the use of certified health IT and a sub focus on value-based quality focused care under the Quality Payment Program.

Specifically we were looking at policy approaches within the Merit-based Payment System, the Alternative Payment Model Scoring Standard and the Advanced Alternative Payment Models sections in particular. Next slide, please.

This is a recapitulation of the comments that we made on June 8th so I'll be very brief but it's important to have them because they set the context for all else that we're going to say.

Our first observation is that the proposed rules objectives are good and we want to recognize that this is a regulation to implement a statute which provides some very explicit objectives and we want to acknowledge that the proposed rules make a solid intention to implement that legislation in an effective way.

But our second observation is that in the process of increasing flexibility in pursuit of those objectives the proposed rules become too complex and we break that into two pieces. One, the difficulty of understanding it. We tried to help with this a little bit during our deliberations and Paul will comment further on ways to try to make the regulation more clear.

But more important than that is even if it is easy to understand it will be very challenging to implement and later we'll talk about focus on new participants and on providers with less resources, small providers and perhaps those in rural areas. Next slide, please.

The proposed rule in particular we want to note that it introduces many new options and requires participants to make choices very quickly. We believe that this would be especially challenging for small providers. We believe the complexity may be a barrier for many to migrate towards APM participation which is one of the main objectives of the legislation and the regulation.

And then finally, to some degree, a trade-off between the Advancing Care Information category requirements and the Quality Payment Program requirements so that in order to meet one may discourage clinicians from participating in QPP. Next slide, please.

Two more general comments, the first was the decisions on reporting, whether to report as a group or individuals which measures to use and whether to participate in MIPS or APM will provide a significant impact on practice and we wanted to note the difficulty associated with each of those.

To recapitulate essentially our recommendations, it is that CMS should make the final rule explicitly clear to achieve the goal of reduced burden and increased flexibility and we make recommendations around making the program easier to understand and implement and that simplicity and clarity will encourage more providers to participate. Next slide and then I'm going to turn it back over to Paul.

This was feedback from our meetings this month including the June 8th Joint meeting in which we provided the recommendations that you just heard in slightly different language and you provided the feedback that's listed here. I won't read all of them, most of them are in line, I think, with our overall recommendations.

At this point I'm going to turn it over to Paul who is going to go through the first set of detailed comments and focus areas for the final rule improvement.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health

Thanks, Cris. As we mentioned, we really appreciate the listening that CMS did in terms of feedback from the field. It's very clear that they both heard it and tried to build that into this proposed rule. The rationale is clear in the 900 pages but in the course of doing that it has become complex and difficult to understand and so that's probably one of our biggest messages.

I can certainly sympathize when Lucia, as the head of the privacy office, finds it difficult to understand some of the privacy regulations and statutes and then the world changes. So, we were just talking about this previously. I think we find ourselves in a similar position where it is a complex issue, the world does change constantly, and it's hard to make sure we bring as many people along as possible and part of doing that is to make sure everybody can even understand what is being proposed.

So, we really emphasized the role of visual materials in trying to help people see the whole picture and I'm going to illustrate in the following slides so that we get more clarity around what is being asked and then people can follow through and implement it.

So, as an example, and Beth Myers helped us with this, thank you, so, one is just to look at it in an overall context, things have gotten simpler and the burden has, in theory, been reduced. So, for example, we've gone from nine CQMs to six and there's some additional rules about the six, but it's a reduction.

The second line says that we used to have to cover three of the six National Quality Strategy domains, which is a good point, but then it introduces complexity and there is no longer those domain requirements in the proposed rule.

And similarly, the electronic reporting has been changed. So you can see that in a sense where we are today going to the proposed MACRA regulation actually does reduce the burden as it intends to and in theory simplifies it.

The next table, and this is, I think, especially helpful and this is what Beth put together, let me explain the columns. The first, third and fifth, so the first is where we are today in 2016. The third is what's proposed for 2017. The fifth is what would be proposed for 2018. And these intermediate, the equal and the arrows, is a comparison of the column before it to the column after it.

So, let's talk first about the 2017 and that's particularly relevant because as we have also been saying it's really a tight timeframe to say get the final rule in the fall and then implement it or start working on the reporting on January 1st of 2017.

So, the first question in people's mind is "well, what do I have to do to meet those requirements?" So, if you look at this table you can see that from the first column to the third column, from 2016 to 2017, is either equal or a reduction in the requirement so that's very reassuring.

And then as you go from 2017 to 2018 on this page of the table you can see that it basically stays the same. So, for folks who are already, let's say, in Meaningful Use and trying to move over to MIPS, there aren't any increased requirements in order to go from today's world to the 2017 where we have to start measuring in January.

The second half is now shown, similarly, no change. The only thing at the bottom two rows, the current requirement…there is a new requirement that goes into effect as part of the optional Stage 3 but those requirements themselves are optional because you can elect to go to Stage 3 or not even under the old MU3. So, that's shown from today to 2017 there's a new optional functionality you could introduce but you don't have to. So, in other words things could stay the same.

And then moving from 2017 to 2018, as you know, Meaningful Use Stage 3 was required by 2018 and that's where you get a bump in functionality in the right most column.

So, in summary from where we are in 2016 going to 2017 there doesn't have to be any change in your systems or your practices from that point-of-view. That's reassuring and it was really hard to get out of the hundreds of pages of reading and so really thanks both to the staff and to Beth for putting this together because that's the kind of thing we think will be very helpful just to know what am I facing in this next year.

Okay, moving on. We do think there's still opportunity not only to clarify, which is what I just went through, but to simplify the final rule in order to fulfill the requirements or at least the desire to reduce the burden.

So, one is we agree that eliminating topped out measures such as for CPOE and the CDS is a good thing. So, compared to the alternative we would agree with reducing the number of objectives for ACI which is the new Meaningful Use.

The thing that we've been talking about is trying to ensure a reasonable on-ramp for folks who were not eligible for the Meaningful Use Incentive Program such as behavioral health and nurse practitioners, and physician assistants. So, how can we ease the on-ramp for those people and we came up with a couple strategies and understand that it's not a simple measure to implement them, but one instead of starting January 1st if you could start later, in other words, have a six month instead of a 12 month requirement, that would ease the burden of somebody trying to move into the use of EHRs, recognizing that this would be a burden on CMS from an infrastructure point-of-view one of the reasons to go to a year-long is so that it could align with other CMS programs and we understand that.

The second point was there was a use of this reweighting of ACI and what that means is you essentially reduce the score contribution to zero and what that does is then it shifts more of the emphasis, more of the scoring on the other categories. So, that's one way of helping people get additional time in order to implement their EHRs if that's what they need to do.

And we recognize, again, this is a trade-off between, what does it take from a CMS implementation infrastructure point-of-view, and in the second bullet, what does it mean in terms of a scoring point-of-view and its contribution to determine whether you qualify for an incentive or an adjustment.

But those are a couple that we came up with our limited time. But the point was for the smaller providers for the new folks in Meaningful Use how can we help them bet on board with the program because that's our ultimate goal is to get everyone on board.

I'm going to shift back to Cris to take up the rest of the comments.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Thank you, Paul. So, to continue over the recommendation that Paul began on this slide we wanted to also identify the opportunity to reduce process oriented measures in the CPIA category and instead of that to build on activities clinicians are already completing.

So, the possible strategy associated with this is to use CPIA as a testbed for innovations to identify activities that will lead to improved outcomes and readiness for APM participation. So, CPIA essentially can it create some sort of on-ramp into APM participation. Next slide, please.

Also under this category the goal here was to make participation in APM more possible. So, observe the opportunity to reduce the reporting burden for providers and APMs and assist providers in decision-making. Those strategies would include things like allowing a clinician that achieves QP status to automatically satisfy MIPS reporting the following year, and so on, so that would also allow the eligible clinician to be exempted from MIPS reporting for that year.

In addition, processes to convey new models, whether the new models will have advanced APM status when they're first released. So, the clinicians are going to have information up front when they determine which program do they want to participate in. This was one of our observations originally was to try to make the program as clear as possible with the decision choices as straightforward as possible so that clinicians and their organizations that they manage can make good choices as they navigate through the multiple choices in front of them. Next slide, please.

In this recommendation we suggest a process by which we focus policies more clearly and distinctly on the QPPs desired outcomes. We had a lot of conversation about process measures versus outcome measures and in particular our workgroup wanted to focus these activities on interoperability and patient engagement. We had some specific recommendations around that, one was around bonuses for

performance on information sharing measures. So, are there ways to award bonus points to the composite performance goal for example or tailor awards to outcomes achievements rather than process measures.

A second recommendation would be to develop effective methods to reward clinicians for improvement. So, calculate progress towards achievement on a goal on a relative basis for example so that we don't inadvertently penalize baseline good performance.

But overall embedded in this recommendation was, I think, a flavor from the workgroup of focus on outcomes rather than process and focus on some of the clear desired outcomes like interoperability and patient engagement. Next slide, please.

And then our final recommendation is to take further advantage of opportunities under MACRA to promote more seamless measurement and reporting infrastructure across providers. We had a lot of conversation around the difficulty, challenges and opportunities in providing data both for quality reporting purposes and reporting to payers both CMS and private payers.

We had a couple of strategies here that we listed things like increasing bonuses for electronic reporting within the MIPS quality performance category or to clarify where certified technology is required for third-party data submission methods in a way that would allow vendors to focus on as focused a process as possible that might meet multiple third-party data submissions requirements.

You can read the other recommendations that we made around bonuses for example on eCQMs and to clarify links within the rule to CMS measure development initiatives.

And then, last but not least, is to allow sufficient time for developers to implement the new eCQMs. We had good representation from our group from providers, payers, vendors, regulators, those with patient interests in mind, I think we had near unanimity on our discussion, not complete unanimity, but near unanimity and we would be pleased to…unless Paul has any other concluding comments we'd be pleased to respond to your comments and your questions.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thanks, Cris and Gretchen anything we missed or misstated? Okay, thank you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
All right.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Open to your questions.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, we'll open it to questions and I'll take Chair's prerogative and Jon White will start us off with a few remarks.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Thank you very much, Kathy. So, to Paul and Cris and all the members of the Task Force I wanted to extend to you, on behalf of ONC, our gratitude both for your thoughtful expertise that you, you know,

really grappled with this significant request from us and that you applied yourself in a serious way and really gave us back thoughtful, constructive comments which we genuinely appreciate.

Personally, I'll just thank you for the collegial tone. I think that makes a big difference and I think that…I know that you guys know this, but I'll just…I know what happens behind the curtain on the federal side and, you know, certainly you see the leadership whether it's Karen and Vindell or Andy and Patrick engaging with our stakeholders, but, you know, there's a lot of other folks that bring these things into being and they're all working hard and they all care about doing this right. So, on behalf of them I appreciate the constructive tone and again the thoughtful way in which you gave it.

I personally want to extend my thanks and gratitude to the service of Gretchen Wyatt and Beth Myers, and their colleagues, thank you so much for what you did it again, you know, it makes a difference it's how these things get done. So, thank you on behalf of ONC for what you all did to help this Task Force do its work.

We reviewed your comments in advance, I know you were kind of up to the last minute working on them, but we still got a chance to take a look at them in advance and Karen and Vindell and I want you to know that we hear you loud and clear, simplify and clarify. All the, you know, the very specifics are often but we hear you loud and clear, simplify and clarify.

We are going to work very closely with our colleagues at CMS, again, who take this very seriously, to try to address those comments, to work to make the final rule the best it can be, to simplify, clarify and, you know, meet both the letter and the spirit of the law as it was passed, you know, we are all serving our shared master, which is the beneficiaries of the Medicare Program and trying to make this the best for them that we can be. So, thank you very much for the opportunity to kind of start that off and look forward to the discussion.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
All right, thank you, Jon. Andrey?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
I wanted to ask a question from slide 11, this is an incredibly helpful summary that table and the second part of the table, the second to last from the bottom right, this 2018 requirement to incorporate patient generated health data or data from a "nonclinical setting" for at least one patient.

I'm really encouraged to see it's a move from not applicable, which is obviously not true, to care, but I'm also curious, from a design perspective, is that the right type of requirement to just have one patient as a requirement, is it the right number, absolute number, of patients, just one, and more importantly, is it the right type of measure to incentivize or measure quality of sharing of information between the medical and the community settings?

I think this is probably a broader design exercise, but I think it's a design exercise that will have huge implications on how clinical providers are paid and how seriously they take in the future home and community-based service providers.

So, I'd love to hear any thoughts from folks on can we make recommendations to have a better suited quality measure and could we reference some of the work that NQF is doing in creating a new framework for HCBS quality measurement?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Maybe I need to set a context, this is a context of probably seven years of work that in particular the Policy Committee has worked on with ONC and CMS and so there's been a lot of lessons learned from the Meaningful Use Program.

This whole reduction to one is a really a recognition of all of the unintended consequences you can have when you set certain thresholds and apply it to everyone because it just hasn't worked that well in that way.

So, this is a recognition, the whole one, obviously it just means you have this functionality and it is turned on and over time there will be more and they even allude to that in the proposed rule, there may be other more stringent requirements if the market doesn't react as even your comments reflect. The market has to pay attention to individuals, i.e., patients and consumers and we expect them to under the new payment system.

So, I think this is, I think, a good compromise in terms of trying to highlight for the industry, the whole healthcare sector, what's important in order to meet the needs of the new payment models without being overbearing in terms of requiring things. So, that's my interpretation of the rationale for why CMS and ONC have gone this direction and we've learned that through the Policy Committee in terms of we understand why they did it this way.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
Thanks.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Great job and loved to see the emphasis on patient engagement in your recommendations. I did have a question, whether the group considered along with clarity in the items you've mentioned, clarity about use of health information technology, you've asked that this be clear where that is mentioned and how it is used, but under the CPIA and also the quality measures there's a lot of discussion, actually discussion mentioned, communication with physicians mentioned and high thresholds of engagement of physicians and patients, which of course is wonderful, we'd like to see that communication and discussion be defined more broadly in terms that the patient might want.

I might have a very meaningful discussion on texting, I might have a discussion on e-mail, I might have a discussion on telehealth or with a coach on a phone, I might communicate in a variety of different ways with my provider and so this notion of face-to-face communication and discussion is not scalable and the use of technology can really help to allow patients to communicate with providers in a way that they choose.

And that's especially meaningful in the idea of providing services 7 by 24 to patients from an advanced practice and it's difficult to provide all your services 7 by 24 without the use of supplemental and complimentary technology.

So, did the group get into any details around these definitions of communications or engagement, or discussion so that more uses of technology could help provide scale to the providers?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Cris, I'll give you first crack at that.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Sure, Leslie, thanks for your comments and as always the focus on patient engagement is vitally important. I would say that, you know, within this context we had a limited time to look at the way that these combined regulations come together. And, as you know, the Meaningful Use rules embedded in them measures that we're encouraging the kind of digital connection exchange of data and patient engagement that you referred to.

I think the only…we did not go through the Meaningful Use 3 requirements in detail simply because of lack of time and did not make recommendations about how those might be modified or improved in context of the MACRA legislation. If we had more time to do so maybe we can and I think comments made to CMS and ONC about that I'm sure will be well received.

The only thing that I would note would be, if we could go to slide 11 I think it's…yeah it's the one that's on the screen now, the only place where we have explicit comment about this Leslie is on the first row of this table around the ability to send or respond to secure messaging and, as you know, the requirement here is consistent across the board, which is a threshold requirement only as opposed to a performance kind of goal.

So, I don't think we had explicit recommendations that would satisfy the explicit, you know, objectives that you speak to. I think we would say that they are, to large extent, embedded in the Meaningful Use 3 requirements and to the extent they are that this makes complete sense to continue.

But most of our focus was really on balancing the legacy or classic Meaningful Use requirements, if you will, with the payment and quality outcomes that we tried to achieve. So, probably not a terribly satisfying answer, but would note that I don't think that there's anything in here that degrades the trajectory that ONC and CMS had put us on with Meaningful Use.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So, then maybe just with your comments about clarity in your recommendations that these actual items I'm referring to are in the table H and E of MACRA, that define these new discussion opportunities and don't clarify the use of technology so just some clarity and consistency about complimentary technology to scale discussions, communication and interactions with patients.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Leslie, thanks for the explicit linking back to the regulation text, I think that's really helpful, thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I'll just add on, it's similar to the previous comment, in general and I speak a lot from the Policy Committee because we made a lot of these recommendations in Meaningful Use, we've learned along with CMS in terms of what's been the experience in the field and what are some of the unintended consequences of being either be prescriptive or process oriented so that's why we had a very strong emphasis on the outcomes and then that also allows more innovation to take place.

So instead of prescribing the use, it's sort of obvious, as you described, that we need to use technology in order to be more scalable and to make it more accessible to people. I think the whole industry knows this and it's in their best interest to do that. Prescribing them to do things gets us back into the process realm and that is what we really tried to avoid that was one of our recommendations.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I agree. I just don't want discussion to be…and communication to be limited to face-to-face interaction…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
If not available.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
That's a good point. So, in general with the whole CPIA category, although that's a required category, we tried to move that off in two ways, one is, if somebody is already accrediting processes like, you know, Joint Commission, and others, let that be deemed that they are in compliance with that and focus on the CPIA and we suggested a path for innovation, if to make it more accessible you want to do things that employ technology, however you decide to do that, to improve the discussion and communication do it and be recognized for that. So, that's sort of the kind of spirit that we wanted to introduce into that program.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Thank you, Paul. Next Larry Wolf?

Larry Wolf, MS – Principal – Strategic Health Network
So, again, thanks for all the work you guys have done. I have one sort of technical question and one more open-ended one. The technical one I think is probably a short answer. You're suggesting a six month initial period as an on-ramp for folks. In the past there has been a lot of initial periods that were ¼ long, 3 months long, was there a thought of why six months was better?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
It was a compromise. So, as you point out, we've been using three months in the past and then you heard that some of the comments back were "well, gosh that doesn't give us enough time to get data" and that's the 12 months. So, the compromise was to make it long enough have data but shorter than the one year and that's all there was behind that.

Larry Wolf, MS – Principal – Strategic Health Network
Okay, thank you. The more open-ended one, going down the road to outcomes and we've had this discussion in the past in some ways, interoperability and patient engagement in some ways could themselves just be process measures and in fact what you've suggested here is that you send one message securely, etcetera, really is a process measure, if you will.

Was there much discussion around things that might actually be outcomes that were sensitive to those process measures? You know things like patient satisfaction as a measure of improved engagement or patient goals being met or other clinical outcomes that might be the result that was enabled by the improved electronic communications?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, so what we're doing is we're working in the…working within the construct of the law and working with CMS's proposed rule. So, there are process measures in a sense, they're not onerous anymore in terms of thresholds in the ACI for example so that's a holdover from Meaningful Use and they have their use really in driving vendor functionality.

The reliance…moving towards outcomes is probably in the quality category of MACRA and that would be equivalent to the eCQM in the Meaningful Use days. So, I think the spirit is to do exactly what you suggested, i.e., one to have the functions available and that's actually what the ACI or Meaningful Use does, make it available in the EHRs, but truly the reward and the performance incentives come in how well you do against these outcomes quality measures.

Larry Wolf, MS – Principal – Strategic Health Network
Thanks.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
This is Cris…

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I'd like to comment on that just really briefly if I might. I wonder if we might advance to slide 15 just for purposes of addressing Larry's question. I don't think we're…well, if we can get to slide 15…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah, it's just catching up I think.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah, yeah, great, thank you. This is where we addressed that issue specifically around interoperability and patient engagement and I take the point that the measures that are included in the regulation are arguably more process oriented than outcome oriented.

This was the section where we had some potential strategies that address outcome oriented results around, you know, for instance on the interoperability measure bonus points on the composite performance score to mark improvement here and with respect to how to get to patient engagement scores, you know, we made a general recommendation around calculating progress towards achievement of the target goal on a relative basis.

We'd take feedback from this group, and I'm sure that other comments to CMS will be useful in this area around what particular kinds of things could you incentivize in order to maximize patient engagement.

So, you know, our recommendations are one stage, I think we're expecting obviously that there will be a substantial public comment in addition.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Thank you. Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
I'd just like to add to those comments especially in response to Leslie Kelly Hall's question. I think if you look at slide 16, the third bullet there, talking about bonus points for those who implement eCQMs addressing patient safety, efficiency experience, care coordination, outcome measures, crosscutting measures, in our discussion there was basically agreement that repeating the same process measures over again was not where we would recommend eCQMs go but create measures that require use of the

constructs that enable interoperability and patient engagement so that could include a care plan as part, not just sending a summary of what you did but a care plan with a target outcome is in the measure if you would use an example.

The concern is, how fast can these be implemented with existing technology, so that last bullet of allowing sufficient time and perhaps even time if you wanted to know the full provenance that the outcome came from the patient that will take some time. So, it would be incremental and we talked about the eCQM should allow that incremental growth toward what we need but start with the interoperable components.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Comments from the Co-Chairs? If not then Josh Mandel?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Thanks and I have to apologize for coming late to this session I was on a delayed flight, but I just wanted to briefly raise an issue about the summary table with the sort of up and down and equals arrows, I thought this was a great way to compare what was in the Meaningful Use requirements versus what's in the MACRA requirements.

One thing I didn't see in the comparison table was the patient API access and I thought it would be a good thing to call out because on my reading, at least, under the proposed MACRA rules there is sort of a weakening of that requirement down to just one patient and I see a little bit of dissonance between that weakening and some of the language that expresses the importance of patient engagement. So, I thought that would be a good thing to include if you haven't already considered it.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I don't whether…we can't read it from here, but I think it was in some version of it, yeah, it's just intended to reflect, essentially in Meaningful Use…oh, there we go, so there is a missing table that shows that transition and the way we…the way it was crafted as an up arrow with an IT next to it which meant really the providers don't have to do something different we do have to have the IT functionality, the APIs so I'm not sure why it's not in the one that's in front of us but it was in there. It didn't fit. So, the PowerPoint…if it didn't fit on the PowerPoint then it…but it still exists.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Okay, thank you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, we have…just to confirm so we have confirmation from the Chairs that will be part of what is transmitted to CMS?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yes.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
And so is there any need for further clarification Josh or any others just since we've not actually seen it?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
That Josh mentioned or just the table is captured?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Can you…I couldn't hear the first…

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
The dissonance that Josh…Josh do you want to…

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Or is there actually something on the table that is specific to APIs?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
There is something on the table that I guess didn't fit on the slide.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Okay.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, there's rows on the table that referred specifically to the API requirement.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
And so if one then…just to help us who can't see that version.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Right.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Could you walk us across those rows?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay.

Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology
I think that might be helpful.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Sure, so today's world, actually…so today's world it's basically, you know, the VDT, right, and in 2018 there must be VDT and the public API. So, that is an increased requirement from where we are today.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, Leslie, Josh, does that take care of the question that you had which is that is it there and it is mapped out as something that will be a requirement in 2018?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah, so we didn't do anything…we haven't touched the requirement. We've only tried to visually depicted it so people can see what do I have to do in 2017 and what changes in 2018. So, all that's missing is something that didn't make it to the slide.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, it's a statement of fact.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
There's no change in the Meaningful Use requirements.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
And there's no change…and there's no impact on the comments that we will be submitting?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Correct.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Okay.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
So, I thought I understood but now I am not sure so let me just double check.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
All right, yeah.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
My apologies. On my reading for Meaningful Use Stage 3 providers have to make patient APIs accessible to, you know, basically…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
And they still do.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Most patients…so, what I was…at least when I was trying to read through the MACRA description they really only get scored on whether they make it available to one patient or not. Did I misunderstand this?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, now I'm interpreting what CMS wrote in their proposed rule. So, in the Meaningful Use days we would have set a threshold…

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Right.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
That was greater than one, and by the way we talked about the threshold of one during the Meaningful Use discussions as well, and I think interpreting what they have done is the threshold became very hard to set because it has to apply to everybody whether you're in an urban Silicon Valley, or in Montana and it's just really hard.

And so what they want to do…I think there's two things that are accomplished here, one is by having this requirement it means that the vendors have to supply it. That's a huge advantage for us that we've learned through Meaningful Use.

And two, without having a threshold you neither have to…then a threshold of at least one is you have to have turned it on and have it implemented yet you don't have to go through the burden of reporting and deciding what's in the numerator, denominator, etcetera so you relieve the burden of that while still achieving the fact that this functionality is available to everybody, it's turned on and accessible and then use the quality measures, the outcome oriented quality measures to drive its effective use. So…

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
I think what you just said makes sense it's just when it comes to "it's available to everybody" I don't see that captured in the MACRA language. I see one patient has to use it but I don't see "it's available to everyone" in the current language. I'm not disputing whether that's a good thing or bad thing, I would just capture that as a difference or in particular it seems like a weakening of API access guarantees.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
That's not my…I mean, Beth can say what CMS means.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services
In the rule itself there is a difference between the base score and the performance score. For the base score it is a one patient concept and it is all four of the functions so VDT and API. API could potentially be used for VD and T.

In the performance score there would be significant room for additional points and additional awards. You have to keep in mind that it's a sliding scale and so that's what CMS is looking at. They're setting a baseline here and then reward for additional performance above and beyond so performers who are actually actively engaging and focusing on that do get significantly rewarded by their point scoring.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
I mean, I won't claim to understand the entire metric, but I do understand the separation between the base and performance score but when I looked at the numbers it seemed like a clinical provider organization could get 100% on the performance score without actually needing any of the points from API access which is why I'm concerned that it might not really be required.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I think one way to look at it is, this is consistent with the move from a transaction fee-for-service world which is process oriented to one where you're saying, reward for what's important to the person and to stay with the process, you know, you must have it and you must count how many…it goes back to

volume measure versus the outcome measure, that's my interpretation of the stance that they've taken and it seems very consistent with APM paying for value, etcetera.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
This is Cris, I wonder if I might comment as well. Josh you're points are extremely good and I think they ought to be reflected in the eventual regulation as completed, I would just put it that way, I don't know what the mechanism would be for that…how that comment gets included but I think they makes sense.

The other piece that I think is relevant is most of our discussion today has been around the certification requirements of providers on the organization as opposed to certification requirements of vendors under the requirement and I think there may be an opportunity to clarify that API requirement with respect to the certification requirements on vendors would be another way to cement what you're talking about.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Thanks, Cris, yeah, I think that would be helpful across the board.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
I think let's move on then. Rich Elmore you had your card up? It's down now? Okay. Gayle Harrell?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you very much and I'd like to move to slide 12, please, and this is where we are talking about simplifying the final rule and reducing burden for eligible clinicians and one of the things you're suggesting here is an on-ramp for ACI category for eligible clinicians who did not participate in the EHR Program and specifically I want to make a comment and then ask a couple of questions.

In reweighting the ACI scoring to include behavioral health providers and communicating and working with behavioral health providers I think that's an absolute fantastic idea to be able to use that as one of your measures to move forward so that they…on both sides, both for the integration of physical health and mental health, I think that is key to where I think we need to be going.

But I do have some questions as to how you envision that being accomplished and does that put…where do you go with the privacy and security requirements on the behavioral health side that vary state to state?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Cris, do you want to…

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Paul or Cris?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, let me try to summarize, so your question is on where to go with the privacy…can you state the last part of your question so that I'm sure…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Yes, my question specifically is, requirements on mental health behavioral health records, electronic records, vary, the privacy and security requirements vary state to state. Certainly you have SAMSHA

requirements, you have, you know, various federal requirements beyond HIPAA, but you then have state requirements that differ state to state. So, how would you do that in order to…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Right…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Expand the ability to use this as a reweighting of the ACI and how would you accommodate the differences at this point?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Gayle, I'm having some trouble understanding. So, this was that you're referring to the last bullet on the slide.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Yes, I'm referring the possible strategies would include the six month shortening of the period, reporting period, but then you're also reweighting the ACI scoring until 2019 for newly eligible clinicians such as behavioral health providers allowing additional time to gain experience with…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Right.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Certified electronic health records and ACI objectives. So, if you're going to use that and say you're going to get bonus points, you're going to get bonus payment, which is assuming…is what you're assuming how do you…how does that…you validate across various states when you have differing requirements in different states on privacy and security.

So, if I'm in Florida for instance I may not…that might not be an option for me to gain additional points for additional payment because I may not have the ability to exchange records with a behavioral health clinician.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, so I'll try and then maybe…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I'm assuming that's what you're meaning.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
If Gretchen…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Right.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Maybe I'm misunderstanding what the…you're reweighting the ACI for?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, so let me try to explain the statement and then let's see if it's still just…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Explain the statement and then my question perhaps goes beyond your statement.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I think that's what's going on here. Okay, so the statement…so the proposed rule says that HHS can reweight, meaning zero out, the ACI requirement for somebody newly entering that wasn't a participant in Meaningful Use. So, what that does is when you bring that category to zero the other three categories raise in their relative weight toward your CPS, Composite something…

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Performance Score.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
But your ending score and what this is doing is letting you out of the ACI requirements while you implement your system that was the intent of this. So, that's why I'm having a little trouble understanding how the privacy worked into the statement.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Okay, so basically, maybe if I could just give a clarification because this is in one of the examples that I had given but certainly it's not as a newly eligible provider to participate and with the expectation participation.

So, I think the concept first of all is not unique to behavioral health providers, but Gayle perhaps what you're trying to get at is that there may need to be a reweighting of scoring for those individuals who are restricted by state law…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Correct.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
In fulfilling some of the obligations or requirements as laid out in the rule.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, it would be…if I understand what you're saying I think that affects the denominator. So, for example if I cannot exchange this patient's record with you then it shouldn't be in the denominator and that would fix the "score." Whether that's specified to that detail I don't actually know.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Right and that's where…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Cris?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I think…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah, this is Cris, if I might comment briefly, I agree the direction where Paul is taking us. I guess I might try to provide some other context from our conversation, hopefully, this is helpful. We had an overarching observation that the burden for new providers was going to be significant associated with this, we had a secondary one around certain providers without deep resources may have difficulty with the complexity of this regulation.

Within the context of our work we didn't try to step into CMS or ONC's shoes and try and rewrite a regulation but made observations that we hoped would help them improve it.

I would say the items that are on this page should be considered necessary but by no means sufficient to solve the problem for new entrants. We just did not have the time, the scope nor the responsibility, to be honest, to try to articulate what a new set of regulations would be.

I think it's quite relevant to point out, and we did discuss in our Task Force, that for new entrants, and let's keep talking about behavioral health because it's a particularly cogent example, a behavioral health provider that is not currently associated with a group that has had some experience with Meaningful Use is going to have a very large uphill climb to become part of a new regulation and we just to acknowledge that.

And so I don't think that what's recommended on this page or in the rest of our recommendations sufficiently addresses that challenge. We want to ask CMS and ONC to consider it and try to find measures above and beyond what, you know, we were able to describe in the scope of our work to address that problem.

So, by offering this specific recommendation I don't think we want to give the impression that we believe that this completely resolves the kind of class of issue that you're raising and that this is only, as I said in the beginning, necessary but not sufficient to address the challenges of behavioral health and other new providers. Hopefully that helps.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you very much that does help in that certainly the goal you're trying to achieve here I absolutely agree with 100%. But I think…when you get into the realm of behavioral health and you're trying to go down that road and integrate them we have many, many barriers and, you know, there are certain…you have certain abilities within existing regulation to do this, but it's going to be beyond that I believe, you're going to have to have a major discussion on how this happens.

So, I think this recommendation here, although the goal is absolutely wonderful and fantastic, I think there is a whole lot of discussion that this committee needs to have around that topic before you say ONC go forth and conquer on this and CMS, you know, make this or allow this to be part of a final rule without serious conversation on it. So, that's why I went down the role of trying to question how you're going to do this. The "how" is very, very important.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah, completely agree.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
And there are germane barriers.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Completely agree and this is a case of where the legislation has a specific desired goal which is to bring these additional providers in place and I don't think we have a sufficient answer for how to accomplish that to meet the two goals of integrating new types of providers and also making it possible for them to do so.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, this bullet was only trying to help the on-ramp, the timing, but you bring up important things and potentially that was actually what was in the legislator's mind in the original HITECH and why they excluded behavioral health because it is hard.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
It's hard.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Thank you, Aaron?

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
So, great work on this, I also want to focus on this bullet point and bring up one other point of consideration and this comes from a prior life of mine in the pediatric sense and given especially with behavioral health and other normally not included in the ecosystem yet of exchanging electronic records the difficulties there once you get dealing with children and children's records and whatnot and the privacy concerns around that and there may be some additional barriers that need to be considered especially towards what even Gayle was saying earlier with state to state and as it varies.

So, I think it would behoove us to consider that aspect, it's important for the on-ramp to what you guys have done, so great job, but I don't want to lose sight of the fact that that's another world that does need to be addressed quickly.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
I see, Paul nodding, any comments from Cris?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I agree, I'll nod virtually.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
There you go. Are there any other comments from the Joint Committee? I might just make one comment myself which does have to do with the challenge that some are already envisioning of

changing EHRs during this very complicated year of transition and I think that its I think a concern that hopefully in the transmittal letter or in some way could be communicated because we certainly don't anticipate that there will be no new EHRs purchased or implemented during 2017 that would be extraordinary. Some are already sort of in the pipeline and I think the rule just doesn't sort of acknowledge, at this point, how that might impact the physician payment schedule.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Actually, I think there's a hardship exclusion for that and Gretchen probably knows.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Is it?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah, for the change that you described.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Okay.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah, so if you're in the midst of that change I think you do get…you qualify for a hardship exemption.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Thank you. Are there any other comments from the committee? Seeing none, we are ready to move onto our next…

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
I'm going to suggest…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I think you have to vote.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Excuse me? Any on the phone? No? So, we're really clear, going once, going twice and so our next report will be led by…

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, no, you have to actually…these are the comments of the committee so the committee needs to approve them.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, we need a vote.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Excuse me. It sounded so congenial. So, shall…I will entertain a motion for acceptance of the recommendations? And a second?

M
Second.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
And is there any further discussion? All of those in favor say aye?

Multiple
Aye.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
So, I think that you have the approval that you sought. Thank you very much.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Kathy. Because we actually have a little extra time, I might suggest that we take a little break and reconvene at 11:05, something we don't often get so take advantage.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
I think it's also fair to Paul since he manages the next discussion.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Okay, good.

Break

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
If everyone could take their seats we're going to get started. If everyone could take their seats we're going to get started, please and thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Is the microphone on yet? There we go. Thanks for returning from the break and next up we're going to talk about interoperability experience and I think what everybody knows is that the current experience is not what was intended or what we need in order to take better care of patients and so we have a Task Force to help us solve that problem. So, we're going to hear from the Task Force on Interoperability Experience and this is their draft recommendations they're presenting.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
So, my name is Anjum Khurshid and my Co-Chair is Jitin Asnaani so we are very pleased to have been given this opportunity to work on this important topic. I'll just launch into this and these are the members of the Task Force. What is important is that…I mean, there were some really important contributions from this Task Force. The Task Force really worked very diligently on the task that was assigned to us and both Jitin and I have tried to capture some of the very substantive discussions that took place in the virtual meetings during the Task Force duration.

And what we tried in terms of the composition of the Task Force, which is also important, is to…besides obviously the usual suspects to also include patient representatives, providers, you know, look at public health contributions as well to the Task Force. So, as much as we could we tried to create a diverse Task Force that brought in expertise from different parts because this is a topic that is important to a lot of people and has to be dealt that way as well. So, the recommendations that we will present to you have been vetted by the Task Force members as we have presented this.

So the way we will present this is Jitin and I will just tag team. So, I will present most of the…describe the charge and the approach that we took to try to respond to the charge and then Jitin will describe like the results of our discussions and recommendations as they go forward.

So, as far as the charge of the Interoperability Task Force or Interoperability Experience Task Force and I think it was important because this is a very broad topic and one of the things that the Task Force did struggle with was to really understand what was feasible and practical in terms of what the Task Force could do.

And so the key charge to the Task Force was to look at the most impactful policy, technical and other approaches that could be implemented to improve the interoperability experience for providers and patients and we took that statement really seriously in terms of thinking about really from the perspective of providers and patients and emphasizing the experience part because, as we all know, a lot of work has been done in interoperability and it is a bit natural that as get into these discussions we get back to some of the basic discussions that have been going on in many of these meetings.

But what we thought was unique about this Task Force charge was that we had to actually move beyond just the interoperability piece to also think of the experience of providers and patients and emphasize that in terms of the charge of this Task Force.

And since the topic was found to be fairly broad from the point-of-view of the Task Force members there were, in our charge, at least some guidance in terms of, you know, how to narrow this to a more doable task, one was to assume that we are talking about interoperability where stakeholders have access to a system that can interoperate, so there is some basic interoperability, that's how we start thinking about the experience of that interoperability.

And our goal was to identify the top priorities or needs for these stakeholders in order to improve their experience of interoperability and in looking at that the priority of this has to be around what is most doable and impactful and then that we have to make specific and actionable recommendations to ONC.

So, it was obviously clear that the topic is broad and so it was not realistic to think that we would be able to solve the entire thing but I think what we all agreed to was that we definitely wanted to have recommendations that are actionable and that will move the needle in the right direction as far as improving interoperability experience.

And we relied on, obviously, a lot of work that have been done in the past. There was a recognition and something that the Task Force members wanted to communicate to the committee as well is that just the fact that we are focusing on the interoperability experience to some extent is also an indication of the progress that has been made in interoperability because now we are moving beyond just the basics to really think of how do we improve the experience of interoperability.

So, it was a recognition of the past work that has been done and through the help we must commend the team from ONC that helped us, you know, Michelle and Stacey, and Doug and Kim, and others in terms of helping us not only link to the prior work that has been done but also several other pieces of work that are going on under ONC. We had regular meetings with other Task Force Chairs to coordinate the work that we were doing so that we are basically duplicating the work being done in other parts and are able to help this.

So, in trying to then figure out how we move forward in this direction the Task Force members actually started really thinking of more real world and concrete examples of interoperability and where improvement in that experience will be meaningful and impactful. And so we started off by really thinking of five broad applicable use cases so that we could quickly identify what are the needs or how do we prioritize the needs that will improve the interoperability experience.

And as you see here we have details of each these use cases because that's how the Task Force really started addressing this issue. So, think of a use case on transitions of care where a patient who is seen in an emergency department in one state what needs to happen for the patient and the clinicians who are involved in taking care of that patient to have an improved experience in terms of providing the right care and the best care that they can.

And if you think of this and the steps that are needed when the primary care physician for the patient is in another state, so in this case let's think of a patient who presents in an ER in Florida and the primary care physician is in Massachusetts then the EHR system in the ER in Florida has to first identify the patient locate where the records of that patient are, be able to query where the records are and also identify the roles of the providers so whether the records are in the PHR or in another EHR system or multiple EHR systems and then the PCP's EHR system has to recognize the patient, recognize what the authorization or consent status is, be able to provide data in a meaningful way that can be absorbed by the EHR system in Florida and then the EHR system should be able to present those things to the clinician who is looking at the patient and be able to then subsequently publish the fact that this patient has been seen in Florida.

So, these are all steps in that use case and so as you think of how do we improve the experience of all those who are involved there are components under each of these use cases that we identified in detail.

And then we went through a process of really working through what are those needs and then are those needs being met today and are they impactful so do they need to be addressed immediately and what is the priority in terms of the impactfulness?

Then we also looked at for instance use case two which is more about sharing care plans so think of an oncologist that has ordered a blood test that will be conducted by a home health care agency. So, I think the Task Force also wanted to expand the purview beyond just acute care to really throughout the healthcare continuum and see how do other players work in because…work into this experience and then who all has to be informed about the actions that are being taken under this shared care plan by an oncologist.

The third use case we talked about was around patient initiated data. So thinking of a caregiver for a diabetic patient who wants to add some data and provide that to a PCP, an endocrinologist. So, again this is a very different use case than the one that we talked about from an ER perspective.

We also…a fourth use case was that of a hospital discharge of a high risk patient to post-acute care, again we are trying to…the Task Force was intentional in terms of thinking about, you know, the broader healthcare continuum and seeing how that transition takes place and what will be needed, what are components for making this happen where patients can access that information, they can view medications and pharmacies, and coverage and those kinds of things.

And then the fifth use case was more of a population health quality management use case which we also considered is an interoperability experience where provider organizations or those like ACOs may want to collect aggregate data and be able to report quality measures around this so what would be the components of that? You can see the details of this in appendix A that we have attached to this presentation but so this was where we started.

The next step was that after we had broken down each of these use cases into the various needs that would improve the interoperability experience in each of these use cases was to then go across these use cases and see what are those common needs and where do they apply in each of these use cases.

So, we then created a matrix where we looked at these five use cases and then started putting these needs together and as we started discussing the needs we identified that, you know, there were more than like 35 needs that were initially identified. So, and there could…probably that list could go longer as well.

And each of those needs is important and some work has been done on those needs. So, really for the Task Force members it was very clear quite early that we will have to go through a process of identifying the priorities because otherwise we would not be able to address such a broad issue as we think of these needs.

So, as we went through these needs, and all of them were important, but then we tried to, at least wherever possible, bucket them under some broad headings. So, there were seven distinct priority needs that were identified through the discussion of these five use cases that you see over here, ability to identify patients nationwide, ability to locate relevant patient records, ability to locate and identify providers, ability to access and interpret consents and authorizations, ability to encode data that is syntactically and semantically interoperable, ability to exchange health information and then a broad topic of governance which included training and accountability, and compliance and other issues.

So, for instance in the ability to locate relevant patient's records we identified sub needs which related to being able to show providers who are affiliated with the patients and understand what their roles are as providers because those could be different. Then ability to show prior authorization for communication with specific providers so there are a lot of sub needs under each of these just as an example.

And then once we had identified these sub needs we wanted to make sure that we have captured, you know, all the aspects and while there was obviously a fairly diverse group in the Task Force but then we wanted to reach out into the industry and the healthcare community to make sure that we are hearing from all different avenues as well.

So, we held virtual hearings where we actually heard from three different panels. There was a panel that represented providers and healthcare stakeholders. There was a panel that represented health IT stakeholders and IT vendors and then there were state and federal stakeholders which included HIEs and other public health applications.

And one of the important things was that the Task Force really worked quite deliberately in terms of identifying this broad spectrum as you will see in this list there are some organizations that are not usually represented in these discussions so we brought in some new blood in terms of, you know, discussions at the ONC level.

And then through those virtual hearings, which were very informative, we realized that there were some things that were mentioned across these panels. Things like increasing cognitive burden for providers or things like privacy and safety or how do you integrate data that is generated by patients or through wearables, or alignment of incentives. So, these were topics that were addressed across these panels.

And there were some that were mentioned for instance the limitation of existing vendor solutions or regulations and mandatory standards, you know, the impact on innovation and creativity in the industry and there were some surprises in terms of topics that were not mentioned very frequently that otherwise are talked about quite a bit in interoperability discussions like prior auth's and provider directories and locator services.

So, in the virtual hearings I think our panel members also focused a lot on the experience of patients and providers, which was a very positive aspect of what came out of these discussions and informed the future discussions among the Task Force members.

And here just to give you a taste of the kind of things that were mentioned if you…we had some quotes here and what you will see is they were really highlighted in terms of true interoperability is more than sharing of data and that it has to drive better patient outcomes or that we needed to create an ecosystem or marketplace where patients can decide what tools to use in order to get the information they need and that served them best.

And similarly from a provider perspective the fact that the burden of reconciling outside data into an EHR is sometimes so grand or so great that most providers just don't do it. So, these were really, I think, very clear indications to the Task Force in terms of what we were hearing from a broad spectrum of users. And then we had subsequent discussions in terms of how do we prioritize within those needs as we move forward. So, I'll let Jitin take over from here.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Thank you. So, I'm Jitin Asnaani and again, thank you for having us and giving us the opportunity to share what our Task Force learned. So, up to this point what we've really shared is what is the approach we took and what did we start learning sort of in raw form from the Task Force members themselves and our diverse group as well as the panel members who joined us for those virtual hearings and their diverse membership.

And really as we kind of took all of that input together and tried to synthesize it into some insights and subsequent recommendations the first thing that hit us is that there two broad insights that we were discovering in the process of the interop experience that we thought were worthy of capturing and so the next two slides I'll show you what each of those two insights are.

One was, you know, and Anjum referred to this in the last slide and on this slide, that there was little talk about things which we do spend a lot of time talking about otherwise in the interop discussion like provider directories and patient record locator services and so on and a lot of talk instead around things like reconciliation and usability as, you know, these quotes illustrate.

And we came to realize that there is in some sense folks are really talking about two phenomenon that are driving the interop experience. There is the delight of using…of being engaged in interoperability versus the friction in being able to interoperate and so from that we synthesized, you know, fairly simplistic equations, I'm sure if we got some physicists here they'd throw some, you know, constants and so on against this.

But we kind of roughly synthesized that the interoperability experience is proportional to the user delight. Things like the relevance and timeliness of an insight, the surfacing of previously unknown information that can improve care, relevant pertinent data, etcetera, etcetera versus…but it's on the other hand, sorry, inversely proportional to the perceived friction.

Things like the number of contracts you need to sign to be able to interoperate or the number of connections, degree of deviation from regular workflow for the provider or the caregiver or whoever that may be, the number of windows you had to go to, the number of steps, the number of clicks and you can imagine there's a whole variety of different factors that feed into it now we…into friction, we deliberately called this perceived friction because for sure to some extent there is reality behind it, to some extent there is also not reality behind it but whatever that total sum maybe from the user's point-of-view if the experience or they believe they're experiencing friction they are that much less likely to engage in interoperability and that actually led us to the second insight.

That second insight was there is…by focusing on the interoperability experience we have an opportunity to drive up the demand for interoperability. There is a conundrum that a lot of us who are in the industry phase, and certainly this is expressed by several members of the Task Force, that the average provider knows that they could use some data and they want the data to be able to take care of their patients and yet despite the fact that we have a lot of supply out there, HIEs, data sharing networks, interfaces, you know, all over the country they really don't use them a whole lot and they still complain about not being able to get the data and realize that's because, you know, we are at the stage where interoperability experience matters where driving up the demand will matter and that will improve the supply on the backend that will drive the pull through for the supply on the backend but itself is an important area to focus on and that allowed us to really hone in on those, you know, the initial set of, I think the word we used is buckets, buckets of sub needs, to figure out which of those buckets or sub needs is really critical for the focus of interoperability experience.

And really out of the initial seven we had two bubbled up to the top, the ability to encode data that is syntactically and semantically interoperable, as well as the ability to exchange health information. And really our panelist from our virtual panels really identified a third one which we somehow had not created our first pass together as a Task Force and that's the ability to effectively utilize health information.

Now from a process point-of-view I'd like to be very clear here, these are the three buckets that clearly came up to the top. If you look at sort of the discussion and we actually even conducted a poll within our Task Force, an anonymous poll within our Task Force, to figure out which of the, you know, the total of the eight categories of sub needs, which as Anjum mentioned in total encapsulate 35 needs underneath them, which of the eight were important and these three came right up to the top after which there is a precipitous drop to other items like ability to identify patients, ability to locate relevant patient records, ability to identify providers, ability to access, interpret consents and authorizations, and the need for governance and training and the like as well. Not to say that none of these are important, in fact each of these did get a fair bit of mention and at least, you know, one or more votes during our discussions, but these three really came up to the top.

And so in the next couple of slides, I'm sorry, in the next three slides specifically, I want to share with you some of the discussion underlying these three, we know that these three buckets are sort of vague in and of themselves so I want to give you a better understanding of what it is we are talking about when we talked about these three items and from there I'll take it to the recommendations that we have based on our insights as a workforce.

So, first starting with the aspects of the ability to effectively utilize health information and there were several points of discussion that this really entailed and encompassed. One, I'll really bucket the first two bullets together, there is the ability to effectively incorporate things like user experience design, task center design and goal centered workflows into the interoperability experience. That is clearly where there was a lot of focus and call from the community as an opportunity for greater improvement as an industry.

In a very related vein there is a great intelligence and a curation process and those two sort of speak to each other, again, with the focus on reducing the cognitive burden to the caregiver.

Another aspect that's slightly different but fairly related is under this bucket was reducing the burden of the clinical data import in particular, the time spent navigating and reviewing imported data for example looking for that specific clinical information or the contextual information that makes a difference to the provider who is giving care including, you know, some aspects which were repeatedly mentioned in the discussion such as effective reconciliation of the data, application of automation where it is possible to things like reconciliation and to import of the data as well as data provenance of the data.

Actually data provenance was not as much brought up by the Task Force as much as was by unbelievably a whole lot of public comment around it. So, the Task Force incorporated it in respect to the public actually participating in sharing that particular concern with us.

Maybe what I'd call the third big sub-bullet under here is reducing the burden of clinical data entry. This was an odd and one and got a lot of discussion within the Task Force because on the face of it, it doesn't sound like an interoperability issue. It sounds like an, you know, EHR user issue or an HIT application issue. But what we realized and what came out through both our discussion as a Task Force as well as from the virtual hearings is that it's a property of that system, the burden of the clinical data entry, that has a significant impact on the demand for interoperability.

The time that a user has for interoperating for…feeling like they can use the system to do things beyond just check the boxes is directly impacted by the usability of that system. So, this was an insight which, certainly as Chairs we did not expect to get from the Task Force members and I'm not sure all the members themselves expected. But it turns out that to this…what again I would not call it an interoperability issue is actually fairly fundamental to the interoperability experience for the provider.

And then lastly, again I'll group these last two bullets together, the logical integration of information into the relevant workflows and the alignment of that data and information with the policy business and technical needs of that caregiver are critical components together of the ability to effectively utilize the health information that is obtained through interoperability.

In terms of that bucket of needs called the ability to encode data for syntactic and semantic interoperability clearly there is some work that's being done here as an industry. We certainly acknowledge that there is an opportunity to build upon existing work that's already been done to develop the C-CDA and the numerous efforts around the industry to improve the C-CDA, as well as the work, the efforts to identify and refine the parsimonious set, we borrowed this word from John Halamka, the parsimonious set of interface terminologies, code sets, etcetera.

There has also been discussion previously as well and we acknowledge it here as well, the ability to code data to improve the specificity of the clinical interpretations. For example, when a blood pressure was taken in what position, what method, etcetera, etcetera. And these are obviously are important to the seamlessness of the care transition from an operational point-of-view, the patient's safety, and have to always be balanced as with any code set or any recommendation for improving code sets out there, there is a balance between the specificity of the coding versus, you know, turning the provider into more and more of a, you know, professional coder and having them do extra work with minimal extra value. So, we acknowledged these as aspects of this bucket as well.

Then there was a fair bit of discussion here around the usability of the data itself. There are code sets that exist out there, a number of us are familiar with them, the RxNorm and LOINCs and so on of the world and their ability to perform in various aspects of healthcare is mixed.

So, an example that was brought up several times is LOINC, you know, fairly substantial as a code set for results more mixed when it comes to orderables. Certainly, when we had our Task Force members and panelists discuss quality measures there were a number of points brought up around quality measure improvement opportunities for code sets that exist out there.

That third bullet, the ability to exchange health information, and again, this is not…this is something that has been discussed by certainly the Standards and Policy Committees in the past and so some of it is an overlap of what we knew already which is enabling easier access.

There was definitely a discussion from a variety of different constituents around the importance of fostering open APIs on building on the existing exchange infrastructure things like the 2014 Edition EHR's data sharing networks, HIOs and the plethora of exchanging…sorry, existing document messaging and transport standards, etcetera.

But a theme that came out here, and it came out…you'll notice it repeatedly as a sub-bullet on this slide, is around transparency of cost and it came out in a few different ways. The first way in which it came out was under enabling easier access. The transparency of the interface cost to the provider organization was repeatedly brought up as an issue. Not knowing what it's going to cost from their vendor to get

what would otherwise seem like a standard type of interface, at least to the extent that that's what our panelists and Task Force members articulated.

When you think about harmony of policies from state to state then some of the common themes emerge which…among other people have addressed, consent, privacy and security. Again, there was a question on the harmony of policies for the cost of doing exchange, particularly in terms of working with the state HIE and particularly where providers feel like they have no choice but to work with the state HIE usually for a good reason. There is an opportunity to be more clear about what that cost is and why it's different from one place to the other.

Totally apart from the…sorry, actually I'll go to the last bullet for a moment because it's also a cost point. Transparency of the cost burden to the consumer, again, not a surprise to anybody here but both from the point-of-view to the providers as well as the patients that really is an opportunity for interoperability of that type of information, to know of that type of information, to improve the experience of the consumer clearly, as consumers we all understand that, but also for the provider as they are often on the hook and certainly take the blame when the cost transparency doesn't exist from the consumer point-of-view.

Lastly, under this bucket there was the very different point around excepting direct communication from patients and other forms of patient generated data where we think that there's a lot of opportunity, and we're probably at the stage now, as an industry, to start doing some focus in that area relative to the past.

So, again, these last three slides are not recommendations in and of themselves, they are an articulation of what the key discussion points were around these three buckets and I want to make sure that we shared them.

There's a clear set of caveats with this as the Task Force focused on the experience of interoperability we deliberately avoided going down a technical rabbit hole. We certainly started out, especially given the makeup of the Task Force, there was a great desire to go down and understand what are the issues of provider directories for instance that have stopped penetration and adoption of those utilities and we really kept ourselves out of that because what we found as our mission and the place where we saw a big gap was that there is not enough focus and there's also just a plethora of different places you can go around the experience itself and so we focused there.

And of course subsequent analysis of, you know, the recommendations that we're going to make and of the places we're going to suggest that be studied might uncover that there other priority needs that actually are the underlying root cause and, you know, that's absolutely a possibility as we go forward.

Some priority needs simply implied other sub needs and we didn't specifically mention all the sub needs. I think our slides are robust enough without us going in all that detail but we did include some more of that in the appendices.

And subsequent work will need to factor in a couple of things, we'll need to factor in user preferences as well as the context for the clinician/patient encounter because a lot of interoperability is driven by operational practices and by the way an operation is set up to take care of patients and so both of those things are really critical for interoperability work.

Over the next three slides I'm going to present the recommendations that we have based on each of those three buckets. What we did for this draft set of recommendations is that we included not only the

recommendations we're going to make but as well as some of the key considerations and things that we think will feed into…assuming for example where we have suggested that a new Task Force potentially be created.

There are some things which we learned in the course of our discussions and our inspiration that we don't want to simply lose as we tell another Task Force to go forward. So, we've included that over here for the purposes of completeness and for transferring as much knowledge as we can.

Likely in the final draft as we represent this a month from now we will take some of these elements and we'll put them in an appendix so that they're available but not necessarily crowding up the slide as they've done over here.

So, I'll read through really only the recommendations. I won't go through all the potential key elements of the solution and all the key considerations largely in the interest of time and partly because I actually can't read them all from here so I'll just focus on the recommendations themselves.

So, our first recommendation here in terms of being able to create the ability of effectively utilize health information is that we suggest that a Joint Task Force be created to improve…that focuses on improving clinical information reconciliation specifically across interoperability contexts.

So, for example, for what data and what circumstances should data reconciliation automation be expected and what are the expected behaviors of the individuals and the data involved? There is obviously some amount of art to this that needs to be bespoke to systems, we're not suggesting that a Task Force necessarily try to figure out for the country what every EHR should look like in terms of usability of reconciliation, etcetera.

What we are suggesting is there is an opportunity to help raise the floor overall and there is certainly, at the least, some recommendations if not some concrete actions that will enable vendors and providers to be able to feel that they are actually getting more out of reconciliation than they do today where it's a very uneven process.

We called that reconciliation specifically even though it's a subpart of effective utilization, because it was brought up repeatedly by every type of individual who we…by type of individual I mean really the context in which they came from provider or vendor, or PHR, or whatever the case may be. This issue came up again and again so clearly there's an opportunity here to raise the floor.

There's also something around user centered design. This was a very big theme for us and the challenge in making a recommendation here of course is that we're not recommending that all EHRs or all HIT systems look alike but there is an opportunity to bring out some of the best practices across the industry in a way and we suggested perhaps sponsoring challenges and that's a role that ONC can play or play in conjunction with others in the industry, sponsor challenges centered around user centered design opportunities, again, an attempt to bring up the floor and help share best practices across the industry in a way that still enables competition. Those are two recommendations under this category.

Under the category of ability to encode data that is syntactically and semantically interoperable we really focused on sort of two types of recommendations. One is, again we suggested a Task Force that's focused on recommending a path forward for standardizing nonclinical data and really the focus was there's a whole plethora of important data around behavioral and social determinants of health other non, you know, what we roughly called non-Meaningful Use data elements. And there is an opportunity now to start working on, how do we standardize that or make those more accessible and computable.

In a related vein we suggested there could be a number of different types of activities, we called them work streams because we're not sure whether to articulate them as Joint Committees or work streams initiated by ONC so we were deliberately vague at this point and are looking for input but we felt that there are at least three different things we could be doing to improve the semantic interoperability.

One was, understanding the tools and opportunities and data to be efficiently captured in the first place. It was, particularly, among our provider panelists or provider members of the Task Force, it was brought up repeatedly that one of the issues of interoperability is that they spend a whole lot of time inputting structured data that subtracts from the patient experience, that subtracts from their ability to spend any more time extra with the EHR trying to get more data. The last thing in some sense they need is more data to then somehow incorporate. So, there is some…there is an opportunity here to try to figure that out.

And then there are two other sub recommendations. One is understand how, for unstructured data particularly, how we could use techniques such as natural language processing, data mining, how are they really being utilized out there in industry, if at all, and highlight those, bring those to the forefront.

And thirdly, and this is a continuing stream within ONC anyway, how to continue and renew efforts with terminology stakeholders to improve the coverage and value of the existing structured terminologies that exist. So, for example, you know, I mentioned LOINC as an example, it's a known example and we simply want to encourage that kind of work continues.

Finally, under the ability to effectively exchange health information we had two recommendations one is, you know, from the point-of-view, as I mentioned in an earlier slide, open APIs, fostering open APIs is a critical part we think of the ability to exchange information. Clearly there is some work happening here and particularly we've been coordinating with the API Task Force and our incremental suggestion to the API Task Force is that they think about a little bit the requirements and considerations, if there are any at all, around other health IT systems, in other words, beyond the EHR what are the other considerations we should be thinking about to enable openness of sharing of data through, you know, let's say skilled nursing facilities, home health facilities, etcetera.

And finally, highlight the opportunities and best practices for successful incorporation of patient generated data into the decision-making process. Today that incorporation of data is very uneven across the industry and there is again a chance for us to figure out…to highlight where those places where it is working and make that more the standard of care as providers across the country struggle with how do they incorporate patient data.

And so that's it. I hope you found that sort of helpful set of insight as well as recommendations from the Task Force. Just a quick reminder for those of you not familiar, today we are presenting these draft recommendations looking for all the feedback we can possibly get and over the next month we'll refine them and bring them back as a set of slides as well as a transmittal letter for the July 27th Joint meeting. And that's it and I'd like to open it up and look forward to the discussion.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health

Thank you, very much…present it the way you did in terms of what are the common themes and also the themes you didn't hear. I certainly, as a provider, can totally relate to the "we don't need more data elements we need more sense out of what we have."

But the other caveat is what you also mentioned in your last recommendation it's that we have more data about the person not the patient's disease which is all we have in the EHR. So, I really sympathize

with the nonmedical data that you talked about and how we need to bring some order to that so that we can make sense of that as well.

So, that leads me to the question I had which is what I didn't see as part of your criteria in terms of what should be recommended is what should…what are these things or actions the federal government can take? There's clearly all those things that are needed to have meaningful exchange and meaningful experience what of those recommendations are most relevant for the federal government?

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Sure, absolutely. So, from our perspective the federal government opportunity there…a few different sides. We didn't, in any of our recommendations, go straight to something like recommend legislation. We think there is still exploration to be done along each of those buckets of needs that we identified.

What we suggested in some places where it was quite clear that there is enough…we can probably get enough mileage out of a Joint Committee that can continue the work, for example the work that we started or the work that we've seen started in other committees, so that's where we recommended Joint Task Forces.

In other places we think there are opportunities for ONC to participate in sponsoring either challenges or studies. There are some places where we really were not prescriptive partly because we were not sure, partly because there was…there is probably more than one good way to go about in terms of for example, highlighting and incorporating opportunities and best practices for incorporating patient generated data and within the balance of the Task Force as regards to the recommendations we felt that there could be more than one way that this action could be followed upon.

All of the actions that we suggested we think there is a federal government role in at least facilitating or creating a venue for those types of learnings to be gathered and that's where we really focused our recommendations. We did not, I think, make any recommendations that were addressed towards the private sector specifically. Does that help?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yes, thank you. I can't see your name...Kim?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thank you for the presentation. It was really excellent. I enjoyed hearing everything and my creative juices started flowing and Rich and I are on the Interoperability Standards Advisory Task Force that is presenting this afternoon and as I looked through this, and this is really more of a comment than a question and probably more to the ONC, but I thought about how a lot of these use cases or the three core things that y'all had laid out really could fit into the ISA document with needs or things that could be provided in there to help solve some of the problems even with like the ability to identify patients that was something that has come up in our group to talk about and put recommendations forth.

So, I think this is a nice foundation that could be incorporated or somehow structured with the ISA document that could help give it…and this came up, you know, right now it's really a catalog, a listing of standards but they talked about how to profile them to make it happen and this could be a way to help start profiling those standards to make them real with real use cases that could help solve problems. So, thank you.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Absolutely I'll add…I'm going to share some discussion that we had within the committee which I didn't bring out here but it's reflective of that point. One of the things we realized is that the standards that exist out there and the opportunity for articulating standards out there could inform two things. It can informed the supply things like enabling us to locate those patients, locate those providers and so on and, you know, we really focused and realized we had to focus on the demand and so there could be enablers of the buckets that we brought up to the top here as well.

One of the discussions we had, and we never actually landed on a clear consensus, was should the demand opportunities that are addressed by things like usability, should they be informed by or inform standards activities that will really be…are really focused toward supply and I think on the whole we landed towards yes it should. It should be a factor as we think about what standards are required or should be required like broadly across industry, probably not the factor but should be a factor.

For example, the fact that, particularly when it comes to code sets, if there's a code set that meets a variety of informatical criteria that makes a ton of sense and can fit into EHRs and are implementable and so on, if the provider still cannot actually use them for the job that they're trying to do in clinical care then there's still work to be done. So, in some sense it needs to be factored in but that's probably just one of several factors and I'm sure the ISA is calling out.

We do call out the ISA specifically on one of the slides as a potential element of key solutions and key considerations and certainly did come up more than once.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
In our second recommendation.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Over there, yes, the impossible to read text at the bottom of this page on the slide anyway.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
In the small print.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Andy was next and now we have a whole lot of cards and limited time so please be concise both in the questions and answers, thank you. Andy?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So, two questions, one related to the fact that most of what I'm seeing here and what I've heard as related…as a practitioner to what practitioners and healthcare providers need in order for interoperability to be functional.

There is one need that my patients have often expressed and my family members routinely express and that is how do I know whether they got all of the stuff that they're supposed to get before I go for my visit? And I was wondering if you talked about a consumer view of whether or not interoperability actually happened?

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Yeah, I think that was definitely something that was raised in the virtual hearings by several of the members I think in terms of, one that as we think of interoperability experience it can be around different roles and it definitely has to look at the roles other than just clinicians or practitioners to patients and caregivers so we tried to at least wherever we have some of these recommendations at least within the Task Force we have reiterated that these are not just for providers although that's kind of the context in which currently we understand this more but that it should apply to patients as well and be seen by the point-of-view the patient's perspective as well.

So, when we think of transparency I think there was a lot of discussion around from the patient's perspective to even know what these prescriptions will cost or what they are eligible for in terms of, you know, their coverage. There are all these things that need to be included so that patients are able to make these decisions better and that was I think partly also the context in which the patient generated data was important was that it should also inform, you know, some of the decisions that are being made so it is I think…was highlighted again and again that when we think of practitioners and when we think of patients these are not like separate entities they actually work together as a team that's when success will take place. So, we have to think of this accordingly. So, we had tried to capture some of that discussion although there was a lot of discussion of that. So, wherever we have failed to reflect that I think we'll try to improve it but that was definitely a theme.

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

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Thank you, Paul. First of all I want to commend you this is absolutely fantastic work. Thank you for what you're doing and for your recommendations. But I want to go back to Paul's question as to what the federal role is here in making this happen. Certainly, I tend to be the bottom of the funnel when it comes to complaints especially on the usability aspects of things and the expense of interfaces.

And I just want to ask one question as to the federal role in this and where do you…how you go down that road to make sure that we improve that usability and reduce that expense and is there a role for certification and when we look at certifying EHRs what would be the role of certification in perhaps making sure that we have that usability and that we have the potential for reducing the cost of interfaces or requiring APIs? How do you see…a little more specific in that aspect of…

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Sure I…

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Using the lever that we have with certification?

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Absolutely, so I think I heard two…I heard one question focused on two different aspects the usability as well as transparency of interface costs.

On the usability front we did have a discussion as to whether we should go as far as recommending some sort of standard for usability that it could be through a certification process, etcetera, for usability of an EHR and what we realized was…what we realized is that was not the right way for the federal

government to go, to use this certification lever for a number of reasons, one is it actually stifles the innovative aspect that is most on the forefront in terms of that user experience. The second is the federal government is not actually particularly good at it, in fact, nobody is particularly good at certifying what a usability experience is like.

The best usability experiences come from bespoke innovation and that's why we thought that the right approach to take there was to actually make those innovations more visible to the rest of the world so if there are folks who have figured out an EHR usability experience for example or an App usability experience that is more beautiful, that is something that people would gravitate towards let's give those innovators an opportunity to highlight those. It will raise…it will certainly give us an opportunity to raise the bar for the rest of the industry but it does not constrain us to some sort cookbook for what a usability should look like when there really is none for that.

And from the point-of-view of the interface costs we did not really delve much into what could be the federal government's role into making that more clear. I think a little bit of deliberation on that front could help us think through where price transparency could be a potential opportunity for the federal government. We didn't really spend too much time on it this time around so we don't have a very concise recommendation on that front.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I would think that the transparency in both cases both when it comes to usability and for others for the entire community to be aware and to have the ability to know, you know, what's the best product out there on the market although it's very expensive to change products, but at least some kind of transparency both in usability and in expense of various interfaces and things would be a key driver in change. So, perhaps that might be something you want to consider as well in making sure that the recommendations include transparency in both aspects.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Okay.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
That's good, that's very useful. I'll mention that there was a discussion about how great would it be if there was a Kelly Blue Book for interfaces and EHRs.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Great. Leslie, please?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I have a few recommendations, one is in your terminology section it would be nice to include a new need which that is a consumer vocabulary and taxonomy as they integrate that would be good to start bringing that up.

Also the acknowledgment that there are both the need for curation and reconciliation as the patient participates in providing data and as many other stakeholders are providing. Somethings are reconciled because they're duplicate information or they're data points that are in conflict and some are just new data points that aren't reconciled but curated and in fact some of the most profound data points might include a disagreement between a finding or observation by the provider and the patient, and that is an opportunity for meaningful discussion. So, I please implore you not to always think of reconcile and who's right but actually curation and that art is quietly loosely defined.

Then also including the patient as an active care team member in your use cases particularly around cancer care I think would add and enlighten that discussion. And then perhaps in your slide 12 if we could add increase patient and provider collaboration rather than just seeking or pointing out the burdens that this might bring, the efficiencies in collaboration can be quite great.

And then also perhaps acknowledging that in that same slide that the patient's opportunity to have a convenient and seamless healthcare coordination is important, their workflow is dramatic, it's getting and finding copies of things and sending them around, and calling people to make sure they've got the data. There is a workflow that the patient has today that is pretty unbearable as well.

And the other is I don't see anything with regard to a new stakeholder which is precision medicine and as precision medicine comes into play the data sources will be completely outside the EMR and yet profoundly impact care. So, that's a missing area I'd like to see included. Thank you.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Thank you, so much Leslie, we'll take all of these recommendations in there. As far as the use case goes we actually did have two of the use cases that involved patients directly I don't think we captured them appropriately here on the slides and the detail is probably captured in the appendix, but, thank you we'll bring that up. As far as PMI goes you might want to speak for a moment on that.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Yeah, we did initially start with thinking about having a use case around precision medicine and then in our coordination meeting with other Task Forces realized that there is a PMI Task Force that was in operation at that time and so the Task Force members, at least in the Interoperability Experience, decided not to get deep into that because it was being addressed somewhere else as well and there were, you know, a lot of topics but it was definitely recognized as an important use case, you know, going forward.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yeah, so we'll capture it as we have thought about it but we really did defer that to the PMI Task Force.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you. Jamie?

Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy
So, I've been gone for a while from these committees and now I get to come back and look at this work I think with a fresh pair of eyes and so I have three observations and recommendations for the Task Force.

The first is I think that this Task Force and also those to follow would benefit from using the previous work of ONC and these committees more. For example, many of these use cases were previously documented and should not be reinvented.

Also there are important lessons learned that were learned previously that are really important to this work particularly not to overload solution sets with too many diverse requirements and different use case scenarios.

The second observation is that the solutions that you've presented has a very narrow focus on physically moving duplicate copies of data and it ignores the growth of shared access models and shared access has grown dramatically particularly for post-acute care coordination and obviously it provides full access to the complete records not just a small extract.

And then building on that, the third point of mine is the Task Force did not consider the National Strategy for Trusted Identities in Cyberspace but this can apply and particularly the NSTIC IDESG has two scenarios that could apply, one is having a single secure cyber identity for physicians and other caregivers to appropriately access multiple EMR systems from a single logon from a single workstation and so that's a different form of shared access and then also from a consumer and patient perspective a single secure cyber identity can provide seamless access to multiple personal health record systems and multiple provider portals.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Excellent points.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Aaron?

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Just two items here, one is a comment, one is a question just for clarification sake. I think Jamie and I were on the same wavelength here. On slide number 16 you have here a third bullet there appropriate privacy and security safeguards I would recommend, as a comment, that you maybe add the word "necessary and appropriate private insecurity safeguards" for the reasons of, one a need for a national strategy for uniquely identifying patients and providers.

And then number two, really looking at like something, you know, from a privacy perspective around consents and capturing patient consent and choice, patient choice, you know, there are further dovetails of that maybe looking at a biometric identification of patients those sorts of things but we're not here to solve that, but again the need is there and it's obviously be spoken about a lot.

My question for you that I have is regarding which of these three Task Forces would look at the issues that are sitting out there from a state level and this may speak to what Gayle brought up earlier and I'll speak to Texas since I just moved from Texas to Massachusetts even today there's not a statewide syndromic surveillance system in place for hospitals and I have suffered from that as a hospital CIO attesting to Meaningful Use. So, to the degree of it, which Task Force is identifying and capturing state issues like that which lead to varying experiences of interoperability from state to state?

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
I'm not sure.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
That's the short answer.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
That's a good question though.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
We didn't recommend anything specific on the state front. There are a couple of reasons for it, one was going down the path of trying to reconcile and understand what's going on from a state by state basis is a tremendous amount of work and the value to the experience is high but it's secondary to some of…I think it's secondary to some of these other aspects that we've encountered at least that was our opinion.

Certainly don't disagree with the need having had several folks who are involved in national networks and involved in the Task Force and so on realized that those solutions, and especially in either our EHR vendors who are really across the nation as well, realize that there is a set of activities which are probably hindering them first before it comes to the state by state vagaries which we agree totally are an issue.

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
Yeah, I would add to that just look at maybe some of the use cases as to why statewide HIEs failed and some succeed and there be some definite characteristics that are uniform among them.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yes.

Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata
So, I think it is very important.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Yeah, okay.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Andrey?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
Hi, guys, I think you guys did a great job offering recommendations. I just want to add or reinforce one thing for each of the recommendations.

For the first recommendation I like that you guys emphasized utilizing challenges and going beyond challenges. I think aligning challenges better with the direction towards value-based care and ensuring that we're not just reinforcing fee-for-service models of care with interoperability sandbox or innovation efforts.

The next recommendation, you mentioned the importance of the nonclinical data being standardized. I want to reinforce the Electronic Long-Term Supports and Services, ELTSS, Workgroup that is charged with creating use cases around a care plan, eventually what will hopefully become a standard in the community setting. So, I don't know if an entire Task Force needs to be created perhaps just that workgroup can be utilized as a foundation for that.

And then finally, the last point around the emphasis on API. I just want to reinforce as a software vendor that tried to interoperate with the hospital EHR we found that using exchange of CDAs actually did not have a viable business case because it took such a long time for community providers to sift through what effectively was like a PDF and that APIs really are, I think, the only true hope of a business sustainable exchange of information.

And so I would encourage from a federal government perspective we may actually be able to avoid legislating or regulating things if we utilize the venture community and say, hey, you guys why don't you go invest a lot of money into what could be big market opportunities using some of these recommendations that you guys are putting forth.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Excellent, thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Kathy?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
I'll be brief and mine are primarily comments. First of all I'd like to compliment you on the graphic on slide 10 which I think is one that should hopefully be carried forward looking at the interoperability experience. I think that it communicates it very well.

Secondly, in terms of potential strategies for evaluating the user experience, I'm thinking back to some of our earlier discussion about the experience in the Department of Defense of hack-a-thons and thinking that this would really be an ideal subject for hackers coming together, users coming together and being able to essentially run…test the user experience for all of these various systems.

In terms of what kind of data could be used, your discussion brought to mind the idea that is developing amongst medical schools currently which is to develop what are called teaching electronic health records and so large datasets often times with up to 10,000 you might say made up patients and could some of what we're looking for in terms of the user experience be tested against those kinds of datasets because we then get around the whole problem of testing with real patient data and so having that as a potential resource.

And then lastly, with regard to sociodemographic and socioeconomic factors I would just sort of point or give a pointer to the fact that the Assistant Secretary for Health on Planning and Evaluation is supposed to be issuing recommendations this fall that will be their response to work done in part by the National Quality Forum to try and move us forward on risk adjustment based on those very important attributes.

So, my recommendation would be (a) that we track closely to that, but (b) also that if we do choose to tackle that of what would be the standards, how would we capture that information that we include perhaps an expanded group that includes experts in quality measurement, some feedback from that experience at NQF so that electronic systems are lined up to capture what those data elements will be. Lots of work being done currently in the field. Thank you.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Thank you that's very useful information.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you. And on the phone Michelle?

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

Chris Lehmann?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
Thank you. Two things, one, a comment you proposed a Task Force that shall identify data under and what circumstances that the automation should be required. I just wanted to note that different specialties and subspecialties have very different needs. So, I think this Task Force should be fairly broad and it should certainly include people that will pay attention to vulnerable populations.

But, I also have a question and the question is about your use case four and that use case is talking about cost transparency for patients, you know, right now I can go anywhere across town to get an x-ray and it is unclear until I get there what the cost would be, what my copay is, etcetera based on what location I am. I don't see this really addressed in your proposal. I love this use case but I'm not quite sure how you are addressing it and I was hoping you could expand that?

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Yeah, actually in the discussion of the use case, although the transparency aspect was raised but we didn't necessarily get into the detail of that for this use case particularly and we mentioned this because it was raised at least by some members but we didn't have a detailed discussion on this so that's a good point to have raised that Chris.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yeah, I'll add in that we came to that point several times and realized it was a pretty systemic issue to the structural sort of organization of healthcare and we did not…we could not come up with…well there were two issues, one we couldn't come up with an immediate sort of recommendation for a particular action to be taken there.

Secondly, although the use cases came from the Task Force and that came up as a priority from the Task Force when we actually went through the panels it was brought up once but only once. There were so many other issues brought up ahead of it that that's where we ended up with the three buckets that we ended up with and focused there in terms of the interoperable experience. It really did end up focusing more on the clinical data and those other elements of behavior like social determinates, behavioral health elements, etcetera rather than the cost elements as much so that's why we do not come up with the…we didn't spend an inordinate amount of time trying to think of what would be the structural fix to that problem.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
I…

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
We're still open towards any pathways that might make sense there.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
I understand that other things came in priority but, you know, I'm probably an average consumer of healthcare and I know that information if available…

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yeah.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine
To me as a consumer would make a big difference on my decisions and it probably would make a big difference nationwide on the cost of healthcare in general. So, I really encourage that we follow-up on this point and look at ways of making that information available to consumers and providers alike, you know, it determines where you order your labs, it will determine where you get any kind of ancillary services. So, I think this is an important topic to be followed up on and thank you for your outstanding presentation.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Thanks, Chris, we will take this back to the Task Force.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yeah, absolutely.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Carolyn?

Carolyn Peterson, MBI, MS – Senior Editor - Mayo Clinic Global Business Solutions
Thank you, Carolyn Peterson. I had three points I'll make quickly as I can. With some of the different topics that we look at in these committees sometimes the patient and consumer implications are more apparent than in other cases. I think this being a topic where some of those aspects are more difficult to root out and to think about how that applies long-term.

Leslie made some really excellent recommendations around how patient uses and consumer needs fit into this topic and I strongly, strongly encourage you to take a look at those recommendations and see how they can be brought into what you presented with us today.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Absolutely.

Carolyn Peterson, MBI, MS – Senior Editor - Mayo Clinic Global Business Solutions
The second point, there was a previous comment about certification related to usability and you mentioned that the group had considered some sort of government role in terms of usability or certification and had decided not to go that route because it would stifle creativity.

Within the web world whether you're speaking specifically about healthcare or a variety of other industries actually we find that there are some fairly well understood usability principles that apply regardless to your purpose whether it's an individual seeking information or trying to engage in e-commerce, doing online learning through universities or just through general programs that are of interest and service applications and for other things.

So, while I appreciate the desire to leave room for vendors to develop a range of products and approaches I do think there really are some general principles of usability that apply across all things and that can be a standard for technologies and should be a standard for technologies both in terms of

resulting usefulness for consumers as well as for functionality for providers, people who need to use products day-to-day.

And to the third point, on slide 13 one of your sub points was to enable greater usability of the data itself. There was a bit of discussion about that, it wasn't really clear to me and it doesn't become clear in the recommendations. So, I think it might be helpful if the group revisits whether you're talking about usability versus usefulness of data. Sometimes it gets kind of murky but trying to take up that analysis might help you refine what you're trying to convey in a way that makes it easier to write recommendations that are useful for all. Thank you on a really excellent job and a lot of hard work.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you. Jonathan?

Jonathan Nebeker, MD, MS – Deputy CMIO – US Department of Veterans Affairs
I hope I can bring my perspectives as a participant in standards development and support organizations and being a vendor creating EHRs for the government and also an implementer, as, you know, I'm Deputy CMIO for VHA, and I'd like to first answer the question that a lot of people seem to be intrigued by is how can the federal government, you know, what's their role in here and I would say that it's probably to get out of the way of industry.

I'd really like to underline Andrey's comments that if the government can focus its attention on more of the outcomes and the use cases as an excellent area of focus and not on the technologies and so moving away from further developing the CDAs and the CCDs, and getting really more to letting industry innovate on APIs to get us to where we need to get to the right use cases and outcomes.

The second point I'd like to make is that the focus on traditional standards is just not helpful. I had the pleasure of being part of an organization sometimes personally going before members of Congress on a monthly basis and being, I would like to use more pleasant words about euphemisms being instructed gently on how we are achieving interoperability between VA and DoD and I'd like to say that we have sent a certification letter to Congress saying that we are almost 100% mapped, so let me just rephrase that, we have sent a certification letter to Congress we are nearly 100% mapped of data either natively encoded or mapped to standards, yet, between…that's individual agencies, yet, between agencies even though we are mapped to nationally approved standards we do not have the data that works with each other.

The standards, traditional standards, just if you want…if that interoperability means a different person can use your data the traditional standards do not allow for that. So…and we'll be releasing statistics on that to show the exact level of interoperability that we have using traditional standards at two different agencies.

We need to go beyond these to more use case-driven standards and to standards that actually help us get and use the data, this is the great choice of usability of data. We also need to extend the standards work to beyond traditional standards to ontologies, to systems of meaning, so I don't know if Cris Ross is still on the phone but I we've been working well with Mayo Clinic to reconcile the VA and MITRE developed clinical care ontology with their work ontology and this actually is also the beginnings of

trying to figure out the interface and how we link up standards of patient information with clinical information.

And finally, I'd like to just make an advertisement, so VA and MITRE Corporation have been working on usability standards that are intended to supplement the NIST Safety Standards and we've published some initial findings on those and it's called cognate and we'll be publishing…we'll be further extending those heuristic-based usability standards for EHR systems and that should be out in several months.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you and Troy did you have your card up?

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Thank you.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
This is incredible work. I have to commend you. I mean, this is…in my mind this is the proverbial tip of the iceberg. You really started breaking down into these things as evidenced by the fact that the Task Force has now recommended that there be three more Task Forces. I don't know if I've seen that happen, you know, in the past three years, but anyway, I'm trying to pull together, you know, the existing documents that we have now and the attempt to share information and one of those is the C-CDA. We like to call it a summary of care so it's an incidental summary of something that happened to the patient and it gets forwarded onto the next provider of care.

And the newer term, newer basically for this room but not so much newer for nursing and the interdisciplinary care teams is the term of the shared care plan. Now you addressed it early on in the presentation in one of the bulleted points that needed to be emphasized, but I'm struggling in the latter part of it in looking at recommendation one where you talk about clinical data and then recommendation two where you introduce essentially the social determinants of health.

I struggle with the fact that we can separate those two and I'll just reflect back on a TED talk that I saw the other day about a particular provider in a community health center, he was working with a patient that kept presenting with asthma symptoms and a rash and all of the providers and clinicians that had evaluated this person before this provider had really looked at the medical aspects of it, you know, they would give her inhalers and they would give her creams and ointments and things like that.

This particular provider asked her about her living conditions where she lived, how she lived, what the situation was. Come to find out that she was in a rat infested, roach filled environment and that's really what made the difference. When the community…when he recommended community services and got people involved and found out that this was dismal living conditions her symptomology went away, all of those problems.

So, I'm troubled that you've separated the two out and I wonder if you could help me understand what the reasoning was behind that?

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yeah, absolutely, no we…there was strong consensus across the Task Force that social determinants can often be stronger forces than the clinical data or at least equal partners. But the vocabularies that underlie both are in two very different stages of development. Clinical vocabularies and the ability to get

to surface that data in your EHR is much more further along today than the social data and so our recommendations were not focused on separating the two out as much as acknowledging that they're two different types of actions that will take each of them forward.

So, clinical data what we need right now, what providers need right now is that when they get that data there's a lot of work to try to reconcile them sometimes when it's very obvious what can be done and there are a lot of data elements for which it's not clear what the reconciliation should look like.

So, there's an opportunity for us to help figure out what should that…what should the behavior of reconciliation of clinical data look like. On the other hand, social determinants of data, capturing that information still is in infancy, I'm sure there do exist vocabularies out there, which, you know, I'm just simply not aware of but they are certainly not broad-based and not largely implemented if they do exit.

So, there is a stage of development there that's much earlier where we need some focus in figuring out what does exist out there and how do we bring it to the next stage where it's actually available and then you can see beyond that there will be an opportunity to think about how does it reconcile, how does it factor into that patient's risk, into that patient's care, etcetera, etcetera. But it's the beginning of development curve itself.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
So, I reviewed your information...afternoon, so I presume and I'm trying to kind of piece this down to a level for understanding. You're defining the "what" and you will define the "how" later is that…okay. Thank you.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
And is there a card down…I can't see who it belongs to? Okay, great, why don't you go ahead, thanks.

Wanemei Ou, PhD – Director, Product Strategy in Precision Medicine - Oracle
Your second recommendation on the semantic interoperability, so I definitely concur what you find, this is the semantic part is one of the importance pieces in the interoperability experience and I've seen many, many cases that an oncology patient or a cancer patient get referred from provider one to provider two even though they bringing all of the information that they have done in provider one and the clinician in provider two has difficulty to understand what has been ordered. It ends up that they order the same tests again and again causing tremendous waste in the healthcare system.

So, my question is what do you think about the role of the federal government to put the stake in the ground to say that let's use this standard and the problem with standards is no standard is perfect. So, maybe we need to have one standard for a test, one standard for observations, etcetera, etcetera. But in order to improve a standard to improve the semantic interoperability we need to get people to start using it and collectively to improve it otherwise we will get to the point that we have many, many standards situation.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Yeah, so, I mean, I absolutely agree. This is why we borrowed from Halamka's old phrase of, Dr. Halamka's old phrase of parsimonious set of standards. One of the things we realized is that there has

been a fair bit of work that's happened on this front for several years now. We're not at the end of the opportunity to reconcile this, you know, by a long stretch but we are far enough along that our recommendation here is really this bullet point number 2.3 which is there are efforts that the ONC has done by itself, has done with others such as the National Library of Medicine which should be continued.

Our main point here was that the work is not done. LOINC has been, you know, now implemented everywhere because of Meaningful Use Stage 2 which is great but the work on LOINC is not done yet. And then there are probably other standards which I'm sure are being contemplated and worked on through the ISA Task Force among others to bring in other sets of standards.

So, there is continued work as opposed to de novo work on this front at least in terms of sort of the buckets of standards that will enable interoperability, sorry semantic interoperability. So, you know, we actually agree with that point.

We took an even simpler use case of blood pressure, if I get a blood pressure measurement now I don't necessarily know in what position, etcetera that the blood pressure was taken and that's where the balance comes in because is it worthwhile for the provider to spend time documenting all those pieces, is it worthwhile for them to learn a half a dozen different codes for blood pressure or is it better that some amount of it be left to unstructured data and the same would go for even more subspecialized types of clinical settings.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, one more.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
At this point have we given up on lunch is that the point?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah…

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

Wes Rishel – Independent Consultant
Delighted to know I'm holding you all from lunch.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
It's not…

Wes Rishel – Independent Consultant
That's true. The thing that just made…well, you know, LOINC is done. I'm on the board of a rural HIE and we are grappling with the issue that LOINC is not done in terms of the providers of lab data using it. Most HIEs that I know about maintain translation and editing shim features because they have particular difficulty getting hospital labs and other of the smaller, the non-national lab organizations to provide LOINC codes.

I bring this up not to whine about a couple of hospitals in Northern California but to point out that the interoperability experience depends on a thoroughness of the participation of stakeholders that goes beyond the regulatory levers that are available in existing limitations and any consideration about

improving the experience needs to include, in the long-term phrase, an understanding of how to motivate typically data providers to provide data in a different form than they use it because it's extra cost with no benefit for the data provider and it's particularly critical for us now because we're beginning to look at using this data in aggregate for population health data and whereas before we were willing to tolerate a certain amount of error in the method in sending lab results to providers to make the clinical decisions about it's a lot harder to do that when you aggregate the data. Thank you.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Yeah, thank you, I think, I mean that was specifically a point that was discussed in the Task Force about what are the incentives on quality measures on other kinds of, you know, workflow aspects to improve interoperability experience.

I think part of our dilemma was as we were trying to prioritize these things, I mean, they are included in our longer list of recommendations but not specifically in the top three at least recommendations. But it was definitely recognized and I think as the Task Force kind of communicates its work it would like to highlight other than the three topics as well that were mentioned and are still important but I think that was the prioritization that the Task Force did.

Wes Rishel – Independent Consultant
I just want to suggest that the difference between recommendations and outcomes is when the recommendations (a) are acted on and (b) include a complete set of the things that are necessary to do the organization's top three priority might be useful. Certainly this issue of the cost of interoperability goes to the provider of data and the benefit to the receiver has been a…now that we've learned to use fail as a noun it's been a significant form of major fails so far and will no doubt continue to be. Thanks.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
All right, thank you. So, I want to thank the Task Force again for really a nice digestion of the issue around interoperability experience and the not so pleasant experience we are in now and some of your recommendations about moving forward.

I think you had really a very rich, robust feedback. I'll call out a couple of themes, one is, maybe the lamppost theme about looking where we are versus where the light is and I go to Jonathan's comment about if we use the current standards it's not as if perfecting the current standards is going to solve the problem.

The other one was Troy talking about the clinical, and your Task Force brought it up, the non-clinical data, the social determinants, and you said your Task Force members were very concerned about that. Just because those standards aren't as mature doesn't mean that's actually where…that isn't where the meat is in terms of how can we definitely make a categorical improvement. And, as you know, as we do move into the APMs that's where both the quality and the money are and so what can we do to sort of move that along more quickly?

And the shared care plan, again, something we don't have now but could really make a big difference if we're supposed to act as a team not only inside the four walls but throughout the community. Again, something your Task Force brought up but maybe those are areas for focus in this remaining month before you come up with your final.

And then what Andrey said which is if only some key folks, influencers, people with money knew how to define the problem, and you start out with your use cases, maybe that could…a better understanding of it could pull in other resources that aren't, you know, active right now.

So, that leads to I think one of the lenses you might do as you look through both the feedback that was given and what you've come up with so far look through the lens, and Gayle mentioned this, what actions can the federal government do? It's not the legislators. We report to HHS. So, what can the federal government do to further the things that either aren't being done now or aren't recognized, you know, the things that aren't being done that could make a critical difference.

And I think possibly doing the public good kinds of things could unleash other resources let's say even in the private sector. But there may be ways to capitalize on the kind of information you've had especially if you take the lens of the "what could the federal government do to step change." But thank you. You can tell how much the group appreciated your work and really you put together in a very nice package the problem to solve.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
Thank you very much.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
We look forward to…

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute
This was very helpful.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
The next report. Okay, we're a little bit later for lunch. Go ahead?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We need to open for public comment.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, go ahead.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, if there anyone in the room who would like to make a public comment please come up to the table. As a reminder public comment is limited to three minutes and I'll turn it over to Alan to open up the lines.

Alan Merritt – Interactive Specialist, Digital Communications Services – Altarum Institute
Thank you, Michelle. If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We have Mari Savickis from CHIME on the phone. Just a reminder Mari you have three minutes for public comment.

Mari Savickis, MPA – Vice President, Federal Affairs – College of Healthcare Information Management Executives (CHIME)
Michelle, can you hear me?

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

Mari Savickis, MPA – Vice President, Federal Affairs – College of Healthcare Information Management Executives (CHIME)
Okay, great. Okay, thanks very much. Thank you Doctors White, Blake and Tang and member of the committee. I'm Mari Savickis I'm with the College of Healthcare Information Management Executives, otherwise known as CHIME. I would like to offer some comments today for reflection on the ACI section of MIPS.

One issue that did not receive consideration today in the conversation pertains to how what CMS is proposing for MIPS relates to what is being required of the hospital community. The MIPS rule and the Meaningful Use Stage 3 rule put clinicians and hospitals on two different pathways. CHIME has consistently pushed for the need for greater parity between the two communities and what is required of them. The MIPS rule creates more flexibility for meeting Meaningful Use-like measures and we believe the same level of flexibility is needed for hospitals.

CHIME certainly appreciates that CMS is looking for ways to reduce the burden for clinicians. However, we are worried that two different sets of requirements and timelines could actually create more complexity than was envisioned. To the degree that the two communities can be aligned that would be helpful.

We would also like to note that clinicians are being asked to move to Stage 3-like measures ahead of hospitals who are not required to do so until 2018. Finally, we continue to assert that a timeline for meeting any Stage 3 or Stage 3-like measures should not be required before the 2019 reporting year.

Our hospital members continue to express a number of concerns that we are only 18 months away from the mandate to meet Stage 3 and have a new version of certification installed, tested and deployed. Starting Stage 3 in 2019 would bring providers adequate time to prepare and more time for vendor development and testing.

The hospital and clinic CIOs CHIME represents remain committed to improving patient outcomes and leveraging the use of technology to do so but we want to make sure the timeframe and pathway are reasonable.

Finally, on an unrelated, but very important, topic I wanted to note that CHIME is sponsoring a 1 million dollar challenge with the help of the HeroX Foundation to locate a solution for identifying patients accurately and securely which could be nationally deployed. This would solve a key piece of the interoperability puzzle. We have had hundreds of applicants apply and we will be naming a winning solution in early 2017. CHIME welcomes the opportunity to present before this body on this topic and

our challenge for future meetings. I would just like to mention the website for those who may be interesting in checking out the challenge its Herox.com/PatientIDChallenge. Thank you very much.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Mari. And we have no other public comment.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
For lunch until 1:45 please.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
All right, well, welcome back from lunch. Thank you everyone. Next up on the agenda we have the 2017 Interoperability Standards Advisory with Kim Nolen and Rich Elmore. Thank you both and we'll let you take it away.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thanks, Michelle, so Rich and I are going to present, this is a preliminary or an interim draft review. It's not the final. So, we still have a little over of a month for some more discussions. And this is our membership and thank you to everyone who has participated because it is from their dialogue that we're able to provide what we have so far. So, I want to thank everybody that's on the committee and who provides dialogue for us to have this information today and we have a big committee it's two slides.

So, the charge of our Task Force has changed a little bit from the beginning and we're actually putting it into two phases. The first phase is to report out at the end of July so that the ONC can be ready for the next iteration in public comments and then a second phase.

So, in the first phase we're actually going through the public comments and integrating them into the ISA document and then we're also looking at the structural and framing improvements of the document itself.

When we started our discussions we realized that there were really two big components with the ISA document and the actual structure and the content or the structure of the document and what its purpose was and then also the actual standards that are in the document and how those are evaluated.

So, we wanted to spend some time on the actual structural piece of the document and what is laid out in there from a framework perspective because this is a new document and it's growing. It was a…I don't remember what the pages were but it went from, you know, 10 pages to a little over 70 pages. So, the document is growing and Steve likes to refer to it as the infant to the child and now this is the adolescent stage of the document. So, we're in our adolescence right now. So, we're hoping to get out of that soon and move on.

Then we also wanted to look at what are some interoperability needs. And I think earlier today with the Interoperability Experience Task Group that really…I think they could help frame up some of those interoperability needs that we'd want to include into the document that has not been discussed with the Task Force but it's just a thought as I was sitting here today. And then there was a lot of discussion about what best available means and so we wanted to spend some time to talk about what best available means and how that should be framed in the document.

And then for phase 2 with things that come up with discussion that are out of scope for phase 1 then we wanted to concentrate on those to help develop out the document better and it could probably lead to a lot of those interoperability needs. We don't have the time or the manpower to solve all the problems but we definitely have a lot of vision in the group about where that needs to go so we can spend more time on that.

So, here's a background of 2016 document, it has four main sections and the four main sections are the vocabulary and the code set, the content structure and standards and then standards and implementation specifications for services. And then the fourth edition, fourth one is projected additions for future to be included in the future ISA iterations. So, those are the four main components of the ISA document right now.

And then within the new 2016, this came out with a 2016, was to look at these characteristics of the standards. So, if you look at that top blue bar that is supposed to represent a use case in healthcare and then you have the standards, you have the standards implementation specifications, the standards process maturity, the implementation maturity, the adoption level, if it's federally required in any type of regulation, if there is a cost that goes along with it, and if there is a test tool available.

And then there are some limitation dependencies and preconditions that are down below it. So, this was actually new for the 2016 document and from our group they have stated, you know, they really liked this but they felt like there were some things that could be changed. So, those were some of the things that we had in discussion so far and we'll get to those in a minute.

So, for our best available standards discussion, there was a lot of discussion like what does best available mean? Is it the best available to achieve the use case and is it really, could there be something else? There was…I would say this word was quite contentious.

And what the group came up with was it's a recognized standard. That it's recognized to be used and it could fulfill the use case but it's not necessarily the best available standard. They also thought that they should serve these recognized standards should be a way to filter for future use of the regulatory process and this too can serve a purpose and I think there was some concern with the group, you know, is this a regulatory binding document or is it not.

And really the way that it should be looked at, and Steve can correct me if I'm wrong, is that it's there and it gives people the opportunity to make comments to use it and give feedback before it gets to that regulatory process.

So, really it should be looked at as a way to have the information out there for people to use it and see it and to start commenting on because if it does work then let everybody know. If it doesn't work then you need to let people know about that also and what are the things that could be corrected to make it better.

And this next bullet is something we'll talk about a little bit more about how the standards should be dynamically linked to the actual standards development organization or the body that maintains the standard.

Improving use and function of the standards, this was something that came up in that best available discussion. And when you think about regulations they're on a certain timeframe but the standards development and maturity process is on a different timeframe and sometimes the development piece like new versions or different specifications, or implementation guides, or organizations that pull

profiling agencies pull these together and they may change a couple of things and different things that happen a little bit quicker than the regulations. So, for this piece today we're really looking for feedback from the committee like this was just what we started with we haven't had a lot of discussion around it but are there other things that should be added in there. Rich, any…

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
Yeah, just to add…I mean, there was some commentary earlier today about whether or not existing standards work, whether or not, you know, APIs are, you know, the only way to accomplish some kind of interoperability. And, you know, I think that there are certainly challenges with some of the existing standards, the lack of sufficient constraints, other issues with the standards just in terms of their maturity.

There's good work that's going on out nationally some of that is represented here of ways to make better use of what exists today. And as we think about MACRA and it's intended purpose of ensuring that there's interoperability at a national scale in 2017 the only way realistically that's going to happen is through improved use of those standards which are already out in the field today.

And so, you know, the Task Force believes that, you know, paying attention to the next iteration of improvement for those existing standards is an important part of what we need to do through the Interoperability Standards Advisory and hopefully that can eventually reflect into guidance from ONC and to what standards are actually going to be used.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
And these next couple of slides go into that framing and structure of the ISA document. We talked about what the scope of the ISA document should be and these are four bullets that we came up with through our discussions that we feel like should be in scope for the ISA document.

That it should focus on data standards and interoperability needs for certified health IT and will, when appropriate, include an appendix which references authoritative sources for other standards in healthcare including things like security, administrative standards, research and clinical trials.

We also had to define what secondary data use was in the ISA document because there's two ways to look at secondary data what's actually in the EHR or in the domains of the standards that we have today and there's what's used for clinical trials.

So, for the scope of the ISA document we limited secondary data use for ISA purposes will be defined as the reuse of the same data that is collected for clinical care and not in research.

We also recommended that standards for interoperability which connect technologies outside of the EHR so that would be things like patient portals, any other technologies outside of the EHR that we are creating a path where data can be put in once, which would be considered the primary use but used many times which would be the secondary use.

We also thought that we needed to have a section to identify industry gaps that exist in areas where standards would likely be valuable but not known to exist. And one that's already come up, and we have a slide on this later, is data quality and patient matching and, again, this is something that goes back to the earlier conversation with the Interoperability Experience Task Force Group.

And we also thought that somehow the ISA document needs to be able to take standards off the list once they realize, you know, that standard is not being used anymore, it's not sufficient for what is

needed in healthcare and it shouldn't be listed there anymore. Do you want to give any comments? Okay.

Then for the structure, what we discussed was that the ISA document should definitely evolve to be a more dynamic user experience in the sense that right now it's a static document it's a PDF. You can't really link to anything, it's updated once a year. And there were a couple of ideas that we thought would be good for the group to hear around like linking it to things that the ONC are already working on like the interoperability proving ground where people are going in there, giving testimonials of how they have achieved interoperability.

So, if you're going to…if you're building something or doing something technical and you wanted to know what standards were used you could find other people who had already done it and you could potentially reach out to them and ask them questions. It also gives feedback at how well it's working with what they put in that testimonial.

They also thought that you should be able to view the public comments that were related to each of the different sections. And also link to known entities that coordinate the standards listed in ISA document for specific clinical needs and use cases.

There has been a lot of discussion about how to determine standards maturity, so they thought if you linked it to other entities that do that that would be a great way to show where the standards and maturity is and then there's other efforts that go on in ONC like the Value Set Authority Center. So, when you have coded references in there should you link them somehow to the Value Set Authority Center.

Now for the characteristics that was the slide that I showed earlier with the chart that was in the 2016 level. There was some discussion with the adoption level bubbles that people weren't really sure how that was determined and what it meant and where they came from. So, what the group decided on is that they felt like those adoption level bubbles should be more qualitative in nature than quantitative when possible and you definitely should reference the source on how you determine that adoption level because the denominator for the use of the standards may not be the same across the board so it kind of gives…you're not really comparing apples to apples sometimes with that adoption level between the standards. So, that was one recommendation.

Also, and I mentioned this earlier, linking the maturity assessment to the known published criteria or even the standards development organizations themselves so that you could see what other people were saying about the maturity level.

And then also under the category of standards process maturity they wanted to include a category of ballot in development that could reflect emerging standards which may be in rapid development. The next one I'm going to let Rich touch on with the API-based interoperability approaches.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, the Task Force this year had the benefit of the MU 3 rule, the MACRA rule, the 2015 Edition Standards all being published with reference to an open, you know, API for any of the electronic health records and the feeling of the Task Force was that it would be good to begin to offer guidance to the healthcare tech community about what are the implications of that move and so the recommendation was to add a section into the ISA which you're going to be able to highlight the key differences between API-based interoperability standards and prior approaches.

And that it should continue to focus on use case-driven approaches to interoperability guidance but it needs to distinguish between lower levels that are so called building blocks, if you will, that eventually will contribute to higher level use cases that leverage some of those lower level building blocks and I think that the real point here of the Subgroup that focused in on this, we had some of the folks…Dave McCallie led this for the Task Force and he was involved in…along with Arien when they made the recommendations on the JASON Task Force then subsequently on orchestration patterns and so on, so, this really ties in with some of that earlier work from the Health IT Standards Committee.

But the key message is that, you know, kind of lower level FHIR is not enough to say that, you know, those are the standards and that there's going to be a need for use case specific profiles for the FHIR resources, for security. There's going to need to be a definition of orchestration patterns and, you know, even some kinds of technical infrastructure that may be required for deployment.

So, the key message is that APIs are new but folks need to understand the implications of that, the impacts of that on standards and this was some of the recommendations that they made. From a core standards perspective they identified certain key building blocks including FHIR for access to the common clinical dataset, OAuth 2 and OpenID Connect for authentication and authorization, HTML 5 as an interoperability building block and other building blocks obviously to be determined.

But with the idea that this enables some higher level API-based use cases that are leveraging those building blocks and, you know, there's folks involved here…heavily involved in projects around Argonaut, SMART on FHIR, CDS Hooks which is a clinical decision support service, Sync for Science which is part of the Precision Medicine Initiative, if you will, for consumer directed donation of health data to research also based on FHIR. So…and there will be many others.

So, this is not designed to be an exhaustive list. It's not meant to exclude, you know, any particular other standards work that might be going on in the API area but we wanted to give examples so that folks could understand what we were talking about in terms of both building blocks and higher level use cases and for any questions we have Josh here who is heavily immersed in the whole thing and can help us with any follow-up on that.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thanks, Rich and just to add onto that I think what they're doing with the API section is really important for the whole ISA document and this came up during our discussions it's usually not just a standard that makes interoperability happen it's a profiling and a combination of things. So, with the APIs it's the same thing and even with our other standards that are listed through here.

So, patient matching was actually a comment that came in through the public and our group kind of took on that to look at and, you know, we felt like this is a critical factor in achieving interoperability and that the ISA document should highlight what standards are available and in what manner they are used and we suggested some recognized standards that we have seen used in this area.

We also thought that they should start considering or looking at what standard criteria to consider or should be considered for patient matching like are there certain data formats that are needed for submission for patient matching. Are there standards for…could we have standards for algorithms that are needed for patient matching and then probably one of the bigger discussion points was do we have standards to assess data quality when it comes to patient matching.

So, those are some of the ideas that came up that we really felt like there should be a standards focus around the patient matching and there also was the thought that when you're looking at patient

matching you shouldn't just look at the traditional way of patient matching that we should go beyond that because our world is evolving and we're evolving and we should really look at other industries that do other ways to match patients to different things and there's some examples that are being done in our industry right now and outside of our industry where they link people through other attributes and activities. Is this person attributed to a certain healthcare entity in a certain geography those are some of the things that people have looked at and like CommonWell has done something like that and through that they've done it through an opt in process.

So, could there be other ways to look at to improve patient matching beyond the traditional way that we've done it today. And then The Sequoia Project also had published a paper on this where they had used some different ways for patient matching so we put those on there for reference.

And then our group wanted to look at some of the new interoperability needs and this list really could grow through our conversations and as we get through the document because we still have left…we've really gotten through the structure and framing of the document but we have to get through each of the sections which is what's left, the vocabulary, the content and the services, and then the projected additions.

So, we had the API Subgroup which has met and given back those recommendations that we presented. We also have a Subgroup that's working on coded values and value pairs and they've met and they will have recommendations probably by our next call.

And then we also…there was a request to look at research related interoperability needs. So, those are some of the new additions that have come up during our discussions in the Task Group and if there's any that y'all would like to recommend we would love to hear those. And, I think that was it.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay, thank you, Kim and Rich. Do we have any questions? Oh, okay. Let's start with Jamie?

Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy
Okay, thank you. So, thanks very much I really appreciate and think it was a great report from the Task Force. I have four different comments I'll try to be quick about them.

The first one goes back to page 7 on the best available standards. I think that where both accredited and non-accredited standards exist only accredited standards or standards that meet the requirement of the voluntary consensus standards bodies should be selected because they have to meet a set of criteria that is appropriate.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
Jamie, could I just make sure I understood? The point there was that if you have a choice between an accredited and a non-accredited standard that we should default to the accredited?

Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy
You should give preference to the accredited or the one that meets the…it doesn't have to be accredited so long as it meets the requirements of either the ANSI essentially requirements or the WTO's TBT, you know, barriers to trade, essentially it sets out criteria for what, you know, is a good standard process and so those standards that meet those requirements should be given preference. It could be accredited or non-accredited.

The second comment on page 8 and that is, you know, so looking at some of the implementation guides that you've selected here if you're going to recognize additional implementation guides, I would strongly suggest including the implementation guides of the eHealth exchange since that's currently used to, you know, connect probably the most broadly in the country using these existing standards.

Third point is on page 11 for the characteristics. I think in order to get to semantic interoperability it's essential to include a criterion for vocabulary harmonization particularly to identify harmonization of terminology where there are multiple standards and implementation guides that use or express the same concepts and so this is something that NLM certainly could help with.

Then finally, I think that the Standards Advisory should support and recognize…this is on page 14 where you have patient matching. I mentioned the National Strategy for Trusted Identities in Cyberspace or NSTIC earlier, again, I think that the Standards Advisory should support and recognize the standards that are used in NSTIC for unique secure cyber identities that can go beyond healthcare but certainly could be used throughout healthcare. Thank you.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So, a few things, thanks, it's always great to see the work that you do. A couple of opportunities I think. In your documentation in reference to standards it would be great to get some guidance on how standards that are evolving and maturing are treated because today its felt that it's a stagnant process, a standard is named, what happens as that matures with relation to regulatory impact. So, a clear statement about that would be helpful.

Also a recommendation that was made in our earlier Task Force on PMI was that there would be an appendix or a section within the ISA strictly related to PMI so that we would begin to know the inventory of available standards, the trajectory of standards, roadmap for standards that will help PMI.

And also there was really great work, and I wish I could remember her name, Robin from the Advisory Board, used to…the day after the standards were announced or certification was announced she'd make a huge chart that was available to download, do you remember, and she has passed away a few years ago I believe, but it's a great chart so this, at a glance, no matter how big it is, I know I go to

Kinko's and blow it up and put it on my wall, yes, I am that kind of person.

And then also harmonization with the HIMSS and the White House effort on patient identity could be very helpful. Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay. Jitin?

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Does this work? Oh, there were go, thank you. This is great work. Thank you so much for the work that you've done to continue improving the ISA. I guess I actually had maybe more of a high-level question than a detailed question and my question is, when you've looked at an improved…look to improve the

"what's available" in the ISA in terms of the fields and so on as you've recommended over here, which…it seems to be a provider point-of-view and I'd just to validate, what are the points of view that you took as you made these recommendations and is there any known time to how this ISA is actually being used and by whom it is being used?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
That is something that came up in discussion like who is using this and it was in one of our earlier conversations and I guess it didn't make it into our slides, like could we survey how this is being used and Steve had put something together for us like it could be used like in a procurement process. There was like a whole different list. It could be used for technology vendors, new technology vendors who are in development.

There was a lot of conversation around like the EHR vendors, they already know all these things so this may not be where they go but there are other new developing technologies that may use this document and if they do, how can we make it so they just don't say "oh, I need this standard" or if they're in a procurement process and they're really not technical they say "oh, they have this standard so it must work." So, those are some of the conversations. We don't really know how it is used, I don't think, do we?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
We…

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
I mean, like we don't have data. I don't think anybody has done a survey on how it's used. Have you Steve?

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
…so, I don't know if the acoustics…there we go, it was my own voice in the acoustics that sounded loud. Yeah, so, I mean, Jitin to your point, we are obviously using it and I think we've derived some additional value out of its existence since its beginning and the subsequent iterations. I know in our coordination work with other federal agencies we are using it as a tool to help guide those conversations.

And then I think there's probably two different cohorts of people that know it exists and have chosen to use it for a particular purpose. And then people that find it on Google or, you know, your other favorite search engine and happen upon it and they're like "oh, this is great." I'd like to have more people in the "know category" and less people in the "stumbling category" but that isn't doable and I think as it matures will come over time as, you know, some additional value-added recommendations come out of this Task Force, but, yeah, we don't have a sense of people coming to us, aside from like site traffic to healthit.gov and how many people may have downloaded it, we don't have a sense of, you know, yeah, we put this into our procurement unless we were to…you know, someone from a state or something like that were to e-mail us and be like "we took this."

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance
Thank you.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Okay, I'm looking around, any other questions?

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

Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Oh, Larry, okay.

Larry Wolf, MS – Principal – Strategic Health Network
Sorry, my card is hiding. So, I'll concur with all the great comments about the work you've done, the value I've seen in the document over the years I think it's a huge step in the right direction and clearly, as you've said there is more to go so a couple of points on more to go.

I think the model of assessing maturity is a really great one it gets us out of a more traditional model of people saying "well, can you get there in a year, can you get there in two years" and it actually brings forward a much deeper understanding of what is the current state of the world which I think is essential for making policy and setting Regs and also for people trying to assess, is this is a standard I can actually start to use to provide care with and does my vendor support it, and does my partner's vendor support it, and how do we sort of move the maturity process into what's actually in use.

And so I have a question, kind of a leading question, because I have an opinion here, about trying to assess the data maturity. So, we've been focusing on the standards a lot and sort of picking up on some of the questions/comments raised earlier about the VA and the DoD are using standards but they still have issues moving data between their organizations.

And so just saying I used the standards, you know, we're aware isn't enough so in actual data transactions where is moving the data sufficient to get interoperability and where is moving the data then require mapping or algorithmic adjustments to move the data forward and if there's any way to start to actually get information on the data quality which is actually out there, data variability.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
I…

Larry Wolf, MS – Principal – Strategic Health Network
You looked like you were going to say something Rich, go ahead?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
Outside of the scope of this Task Force, but kind of…I think some interesting and applicable work is the feedback that's recently been requested on interoperability measurement and I think Doug Fridsma and one of the folks that he works with had some, I thought, very helpful comments about trying to step back from traditional ways of measuring in terms of following them and trying to think about whether or not the information that was needed at the point of care to give the right kind of care was able to be provided.

And so, you know, kind of what will allow us to know how to improve beyond basic operational integrity, you know, things that fundamentally work which I think is, you know, kind of lower down the food chain problems we're dealing with today.

Hopefully, that measurement of interoperability and our ability to qualitatively assess whether or not the clinician and the patient, and family members get the information that they need when they need it will become key to deciding the next round of improvements.

Larry Wolf, MS – Principal – Strategic Health Network
Yeah, I think focusing on that end goal is really important but I think along the way there has been some work done in data quality. I know Josh did some work earlier assessing the quality of CDA documents. There's a second generation of that work I believe in the works and so I think things like that that create testbeds for people to check that, you know, I'm doing things to the spec and then assessing the actual data in the wild, as it were, of how well do these things conform to our expectations or help inform our guidance on what's actually being done.

And so to the second point, one of the things you talked about for a more dynamic document is it reminded me of the charge that the FHIR folks took on very early and they said we need a developer-friendly way to move the standard forward. And I think to think about that as we look at what new technology do we have in play we're not in the world of…documents for a lot of our life, where can we start to actually look at a more dynamic thing. So, FHIR comes with test suites and it comes with servers that you can query and try out your code on and so are there things like that that can be built into the review so as we look at where the standards are and where they're going to include, and this is how you align with the standard, and so it becomes much more functional and much more operational.

And maybe in the same way that FI HR has a very interactive highly indexed website that you can navigate through and find things that maybe we should think about something like that as a way to bring this document into a more interactive mode.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts
Thank you, I think that's a helpful comment.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
I think we can probably add that data quality into the scope like as a different dimension for the ISA document because I don't think that…other than the patient matching I don't believe that has been brought up and there are definitely models out there for assessing data quality.

Larry Wolf, MS – Principal – Strategic Health Network
One of the big lessons from the work that Sequoia Project did with Intermountain on we know these…we have patients in common the match algorithms are getting very low hits why not and they started drilling into the patients they knew they had in common and found lots of data quality issues. I also like the notion of broadening the criteria for patient matching because that certainly happens in lots of other areas of our life.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
I don't see any more comments in the room and there aren't any more on the phone. Oh, sorry…so thank you very much Kim and Rich we really appreciate it and we look forward to hearing your final recommendations at the July 27th meeting.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, before we go to public comment, I first want to give Wanemei an opportunity to introduce herself. She was stuck on the same flight as Josh I think this morning. So, First Wanemei if you want to just quickly introduce yourself and let us know where you come from? She's a new member of our Standards Committee.

Wanemei Ou, PhD – Director, Product Strategy in Precision Medicine - Oracle
Hi, hello, everyone, my name is Wanemei Ou I'm very happy to join today's meeting as my day one activities. I am from…I'm currently working at Oracle Health Science Group focused on primarily the healthcare provider side and my main responsibility is in the precision medicine area so I've been working on a solution for the past six years bringing in the genomic data into the clinical care. So, I'm very excited that I actually see this Task Force about precision medicine here, so I would love to contribute. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you and welcome. And finally, John Derr just wants to make a few remarks.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative
I would just as an outgoing person from the Standards Committee I wanted to comment just a little bit, we've come a long way with long-term post-acute care and in 2004 when I was at President Bush's Executive Order meeting Secretary Thompson asked me to coordinate long-term care. Right after that I met with David Brailer and the reason I got that is I stepped up to the microphone after all the hospital and the majority of people had talked about how great this is and at the time I was an Executive VP for American Healthcare Association and I said "we want to play too" and he said "okay, John you have responsibilities for long-term care." He couldn't say that legally but I assumed it as a challenge.

I formed, at the time, what's now called the LTPAC HIT Collaborative which is about 20 organizations because we usually speak with multiple tongues which kind of confuses CMS, the acute care hospitals talk in one tongue and therapists in another tongue, and the assisted living and the home care, and the hospice and the SNFs, and ALFs talk in things, so I wanted to talk as one voice on clinical technology.

So, I talked to Dr. Brailer shortly thereafter and he said "John, I really don't understand your segment, I've got to take care of the hospitals and the physicians first." And I said to him "okay, I don't like that, but when you're ready to hook with us we'll be ready to hook with you." And we are on our 12th summit, HIT long-term care summit starting…and Steve is one of the keynote speakers at this and we've had various other people from ONC.

When I got appointed to the Standards Committee I talked to John Halamka and to Jonathan Perlin because we were left out of the HITECH Act, as you all know, and I said I could be the most disruptive person you could ever imagine by raising my hand on a continuous basis saying "what about us" and I said "but I won't do that" and most of you that know me know I don't speak very much at these meetings but I do on the sidelines.

And I think long-term post-acute care has finally been recognized as a very important part of the spectrum of care and I want to thank all of the people, especially the Standards Committee, and the people in the Policy Committee that really did think about us as being very important with a lot of value in the patient centered electronic longitudinal care objective that we have.

I prepared a brief for Karen last year on the advantages of long-term post-acute care as compared to the other care settings and I encourage you all to read that paper.

Anyway my main reason is don't forget us. Terry O'Malley is going to be a great representative for long-term post-acute care. We really want to work, we are a little bit behind and the vendors are very, very good. The top three vendors can do a lot for longitudinal care within nursing homes with 10 or 15 days. We have people in short-term where there's pharmacists, nurses, doctors, social workers, therapists and dietitians all in one spot that can work and do a lot more value to us.

I know Arien has a lot of experience in long-term post-acute care but I just want to say thank you to everybody for including us and also don't forget us, because we can play a very important role in the bundling and all the other things that are coming along and if you want to go to our summit it's in Reston near Dulles Airport and we welcome all of you to do that. Thank you very much for your time and thank you for letting me be a member of the Standards Committee.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
I wasn't sure that they were going to give me the mic. John you have been an extraordinarily valuable colleague. I am…you could have been more obnoxious, you didn't have to be so polite all the time, it's okay, your unflinching and unwavering advocacy on behalf of your community is appreciated by us, you know, not just, you know, shown by the fact that Steve goes to…is going to speak with you all, but such an important part of our healthcare ecosystem and we're grateful both for your representation of it as well as your fellowship and your expertise that you brought to your long engagement with the Standards Committee so we're really grateful, I'm personally grateful for it and I know the rest of the committee members are too so, thank you so much, and, you know, as I've said before, you know, this is not good bye it's health IT so we are sure we will see you again. So, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We've already roped John into the Consumer Task Force so he's not really going anywhere.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative
We're working on the TEFT Grant and the Rand Grant on medication reconciliation and medication review. I'll take more if you want to give it to me.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, thank you, John. So, we do need to open up for public comment. There's not many people left in the room but if there's anyone in the room that would like to make a public comment? Yes, go ahead?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Why don't you open up for public comment and I'll make the comment first.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
All right, yes, if there's anyone in the room that would like to make a public comment you have three minutes and please come up to the table and Alan if you could open the lines for anyone who wants to participate via the phone.

Public Comment

Alan Merritt – Interactive Specialist, Digital Communications Services – Altarum Institute
If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…there you go. So, I was here a little bit late, I apologize I thought leaving two hours to get here would leave me enough time but not today. So, I apologize for getting here late. I just wanted to extend a warm welcome on behalf of ONC to our new committee members, thank you, all. I know you all got introduced at the beginning but we're delighted to have you here, as you can see, the discussion is substantive, it's rich, it's collegial, at times it's a lot more exciting than this, but it's important work and I'm really grateful for your willingness to engage with us and to do this work on behalf of the public because it is, it's your, you know, working on behalf of the public with us. So, thank you, so much and we're looking forward to your continued engagement and rich discussion. So, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you, Jon, and I think Mari Savickis has another comment?

Mari Savickis, MPA – Vice President, Federal Affairs – College of Healthcare Information Management Executives (CHIME)
At the risk of overstaying my welcome and making two comments in one day I just wanted to add with respect to the long-term care post-acute care community CHIME is definitely very interested in exploring ways to partner more with you and we recognize the need to…measuring interoperability to include the post-acute care long-term care community. We've reflected these comments in our recent comment letter to ONC regarding measuring interoperability so your voice is being heard, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Mari. And thank you everyone. And safe travels, hopefully everyone gets out okay with your flights and we'll see you virtually on July 27th. Thank you.

Meeting Attendance

Name	06/23/16	06/08/16	05/17/16	04/19/16	03/10/16	01/20/16
Aaron Miri	X					
Andrew M. Wiesenthal	X	X	X		X	X
Andrey Ostrovsky	X					
Angela Kennedy		X	X			X
Anjum Khurshid	X	X	X	X	X	X
Anne LeMaistre	X	X	X	X	X	X
Arien Malec	X	X	X	X	X	X
Aury Nagy						
Brent Snyder	X	X		X		
Carolyn Petersen	X	X	X			
Charles H. Romine	X	X	X	X	X	
Chesley Richards	X					

Name	06/23/16	06/08/16	05/17/16	04/19/16	03/10/16	01/20/16
Christoph U. Lehmann	X	X	X		X	X
Dale Nordenberg	X		X	X	X	
David F. Kotz			X		X	X
Devin M. Mann						
Donna Cryer			X	X	X	X
Eric Rose	X	X	X			X
Floyd Eisenberg	X	X	X	X	X	X
Gayle B. Harrell	X	X	X	X	X	
James Ferguson	X	X				
Jitin Asnaani	X	X	X		X	X
John Halamka						X
John Scott	X	X	X		X	X
Jon White	X	X	X		X	X
Jonathan Nebeker	X					
Josh C. Mandel	X	X	X	X	X	X
Karen Desalvo	X	X		X		X
Karen van Caulil	X	X	X			
Kathleen Blake	X	X	X	X	X	X
Kay Eron						
Kevin B. Johnson				X	X	
Kim Nolen	X		X	X	X	
Kim Schofield	X	X			X	X
Kyle Meadors	X					
Larry Wolf	X					
Leslie Kelly Hall	X		X	X	X	X
Lisa Gallagher	X	X		X	X	X
Lorraine Doo	X	X	X	X	X	X
Nancy J. Orvis	X	X		X	X	X
Neal Patterson	X			X	X	
Patricia P. Sengstack	X	X		X	X	X
Paul Egerman		X	X	X	X	X
Paul Tang	X	X	X	X	X	X
Peter Johnson	X					
Rajesh Dash						
Richard Elmore	X	X			X	X
Scott Gottlieb	X		X		X	X
Steve H. Brown						
Terrence O'Malley	X					
Troy Seagondollar	X	X		X	X	X
Wanmei Ou	X					