Presentation

Operator
All lines are now 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 the last public in-person meeting of the Health IT Policy and Health IT Standards Committee. This is a public call and there will be time for public comment before lunch and after lunch and we will take roll today by going around the room but before I do that just a reminder if you could state your name before speaking as this meeting is being transcribed and recorded it would be appreciated and we will start with Lorraine Doo from CMS.

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

Kyle Meadors – President – Chart Luz Consulting
Kyle Meadors, Chart Luz.

Rajesh C. Dash, MD, FCAP – Director of Laboratory Informatics Strategy, Office of CIO – Duke University Health System
Raj Dash from Duke University.

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

Angela Kennedy, EdD, MBA, RHIA – Head of Department & Professor of Health Information Management – Louisiana Tech University
Angela Kennedy, Louisiana Tech University, Consumer Advocate.

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System
Brent Snyder, Adventist Health System, Orlando.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Leslie Kelly Hall, Healthwise.
Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Andy Wiesenthal, Deloitte Consulting.

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

Kay Eron, MBA – General Manager Health IT & Medical Device – Intel Corporation
Kay Eron, Intel.

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

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

Anjum Khurshid, PhD, MPAff, MBBS – Director of Data Integration, Dell Medical School – University of Texas at Austin
Anjum Khurshid, Dell Medical School, Austin.

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

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

John Fleming, MD – Deputy Assistant Secretary for Health IT Reform
John Fleming, MD - Deputy Assistant Secretary for Health IT Reform.

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

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Arien Malec, Change Healthcare.

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

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

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

Steve Posnack, MHS, MS, CISSP – Director, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
Steve Posnack, ONC.
Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
Elise Sweeney Anthony, ONC.

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

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

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

Carolyn Petersen, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions
Carolyn Petersen, Mayo Clinic.

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

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

Ram Sriram, PhD – Chief, Software & Systems Division – National Institute of Standards and Technology
Ram Sriram, National Institute of Standards and Technology.

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

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

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

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Yes, good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Josh. Wanmei Ou?

Wanmei Ou, PhD – Director, Precision Medicine and Data Science – Merck
Hi, hello, this is Wanmei.
Good morning. Peter Johnson?

Good morning.

Donna Cryer? Hi, Peter.

This is Donna and I so wish I could be with you over there in person.

Thanks, Donna. Paul Egerman?

Good morning.

Hi, Paul. Troy Seagondollar?

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

Good morning.

Hi, Troy. Steve Brown?

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

Are there any members on the line that I missed?

This is Kevin Johnson.

Hi, Kevin. Okay, with that I’m going to turn it over to Jon White to make a few opening remarks.
P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Oh, all right, thank you very much everybody, good morning. I am so glad that you all are here. Welcome to spring in DC, finally. I’d like to take just a quick opportunity to just personally thank you all, you know, it will be a day full of thanks and that is a good thing but just I’m incredibly grateful for not just your presence but for your commitment.

You are all incredibly talented people and you’re all incredibly accomplished people and you’re busy folks so for you to carve out not just a chunk of today but every day that you do this and, you know, drag yourself to the Washington Plaza Hotel, and to sit here, and to think hard with us about the, you know, things that we’re grappling with and service the American public, and to give us that, you know, good strong advice that we need is, you know, just a comfort that I cannot measure to you, for those of us who are doing this. So, and I know that it’s a lot of effort on your part to do that and it’s a lot of commitment. Thank you for that, I really want to personally thank you.

I also want to say, just, you know, kind of give you a brief update on things. It’s been a busy time, you know, we’ve been keeping ourselves, you know, working hard, doing lots of good stuff not just at ONC but across HHS. You know, of course, as you know, we have a new Secretary, Dr. Price, and I am pleased to be able to tell you that the good Dr. Price has an unwavering commitment to improving interoperability using health IT to get to a better healthcare delivery system and for better health for the nation, and to reduce the burden that the use of these information systems has for our clinicians that we’ve all heard about and that we all know about and I know that that’s something that probably every one of you around the table is committed to too so that’s reassuring to know that the leadership is there with us and that as they kind of are getting settled that they are pointed in the same direction that we are so that’s good.

Of course we will continue to work closely with our esteemed and valued federal partners some of whom are here around the table with us, some of whom, you know, are on the phone, and with the private sector to be able to do what we do.

We’re especially looking forward, as I’ve mentioned to you before, working on 21st Century Cures, which is the culmination of long and thoughtful legislative process and has several important, you know, directions for ONC as well as specific tasks to be working on. So, we’re looking forward to implementing that.

But, you know, for those of you here in the room and listening on the phone probably the big news is the gentleman to my right. So, it is my pleasure to be able to introduce to you our new Deputy Assistant Secretary for Health IT Reform, Dr. John Fleming. I will say to you that John and I were introduced in a late night phone call and it has been a joy and a pleasure to have him at ONC. He has been unfailingly kind and courteous, and, you know, deeply interested in what we’re doing. I’m going to give him a chance here to introduce himself to you but we’ve enjoyed having him at ONC and I’m pretty sure you guys are going to enjoy having him as part of our larger community. So, Dr. Fleming?

John Fleming, MD – Deputy Assistant Secretary for Health IT Reform

Well, thank you, Jon and let me say that I have to practice giving my title it is so long that I have to work on it and I’ve noticed that in Washington there’s an inverse relationship between the length of your title and how important you are so that should tell you something.

So, anyway, my practice history, I am a physician, a family physician, my practice history goes back to the Paleozoic Era. I actually entered Med School only three years after family practice became a boarded
specialty and graduated in 1976, entered the...I was a military...I did my residency in the Navy but then served in the military and then set up my private practice in 1982 back in the golden era of Medicare before we had RBRVS or any of those things and of course I’ve lived through all of these developments and evolutions but I can recall that while I was actively practicing medicine in the hospital how frustrated I was that when time came to see the patient there was not lab, there was not x-ray, what happened to it, and that was always...and I got pretty grouchy I have to admit when it came to those things.

But in 2009 I entered Congress, I’ve been serving there until this past January, and along the way in my medical practice I did see a future in electronic health records as far back to 1997 we implemented the first, as far as I know, the first private practice EHR in Louisiana and we were paperless by 1999.

And believe it or not we actually were able to drop off one FTE, one full-time employee, not a specific person but we just through attrition actually ended up with fewer employees. Why? Because we figured that with our paper chart there was at least one employee at any one time searching for either lab or a chart. The chart could be on a doctor’s desk, it could be in the chart cabinet, it could out for dictation, it could be out for a lab, it just, you know, it was a constant search and we became much more efficient and we developed our practice workflow in electronics, we developed our practice around electronics and our workflow and it worked very nicely.

Then came Meaningful Use and what we found was the vendors were having difficulty helping us meet those requirements and so we’re now...my practice back home, which I’m having to divest myself of, but they’re nearly on the third-generation of records because often times meeting the needs that we in Washington ask and the needs of the doctor have not always coincided.

So, I’m very excited working with Jon and Andy Gettinger and many others that I’ve met, extremely confident people who’ve been with us a long time and certainly you can tell I have a passion for this because I really believe that the future of healthcare is highly dependent on the central and peripheral nervous system that electronics...that healthcare IT provides for us.

So, I look forward to meeting others here today who I’ve not met but also working with you going forward because I see exciting things coming for the future. Thank you.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
All right, like I said, he’s a good guy. So, all right, so with that I do hope that during the break and when you get a chance please come up and say hello to Dr. Fleming, I know he will want to meet you all and with that I will turn it back to Michelle. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you, Jon. I’m going to turn it over to Kathy Blake to review the agenda and approve the minutes from the March 8th meeting.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Sure, thank you Michelle and thank you Dr. Fleming we look forward to working with you and so I’ll now...with respect to the agenda we have two main topics today. At our last meeting we heard from the Public Health Task Force they’re coming to us today now with having received a great deal of input to present their recommendations which will be submitted for a vote for approval.
Following that we’ll then hear public comment, break for lunch and then hear from the Consumer Task Force. There will be an update from them and they’ll be discussing with us the Patient Generated Health Data Draft White Paper and requesting our feedback. There will be no other action required on that.

I’d like next to present to the combined Committees the minutes from our March 8th meeting and would entertain a motion for approval.

So, moved.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
And will entertain a vote now for approval of the March 8th meeting minutes. All in favor?

Multiple
Aye.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association
Any opposed? And any abstentions? And for the members on the phone any votes from them? I think the minutes have been approved by a majority vote but we’ll record their votes if we need to. Thank you. I’ll now turn it...I’ll now turn things over to my Co-Chair, Paul Tang.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thanks, Kathy and I’d like to welcome the Public Health Task Force to the table please. As you recall from our virtual meeting we had a presentation of the draft recommendations, we provided some feedback and the Task Force has been working on the feedback to revise it. This is going to be something we want to take an action to approve, hopefully we’ll approve it since it’s our last meeting, at least face-to-face, and you recall last time I pointed out the intersection really the integration of public health and individual health.

So, clearly the public’s health affects the individual, witness Zika virus, and clearly the individual’s health affects the public, for example, antibiotic resistance. So, this truly is a one health kind of concept, it’s a global health and so in order to facilitate how we accommodate the needs of public health in our records the Public Health Task Force is making some recommendations about how HIT should incorporate these needs. So, take it away Larry and Anne.

Larry Wolf, MS – Principal – Strategic Health Network
Okay. One tech thing, we want to get the sound off on the computer here. I’ve got to fix it before we break it...

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

Larry Wolf, MS – Principal – Strategic Health Network
I thought this was just the monitor.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah, it’s also...
**Larry Wolf, MS – Principal – Strategic Health Network**  
It is?

**Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)**  
It’s the feedback.

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**  
Okay, is that better?

**Larry Wolf, MS – Principal – Strategic Health Network**  
Yes, no echo. No, the echo is back it’s just delayed.

**Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)**  
...here.

**M**  
That will move your slide.

**Larry Wolf, MS – Principal – Strategic Health Network**  
Okay. Well it’s really good to be back here. I think this a really exciting topic, a lot that we can do to make things better both in the short-term and the long-term and it’s really been a pleasure working with Anne and the whole Task Force. And I’d like to also specifically thank the support from ONC, so Jim Daniel who was part of the Task Force really brought a depth of expertise on public health, Rachel Abbey and Douglas Wilson who were both really key for the support of making all this come together and really made it possible for the Task Force to do its job so a big thanks to them and to all of the expertise that the Task Force members brought.

So, a quick outline of what we’re going to go over. We’ll remind you of the charge and the principles that we were working with, our overall recommendations at the beginning and then we will walk through how we got to those recommendations and dive into some of the specifics around each of them, and then end with a summary so you can see what we’re asking you to approve, and then leave some public comment.

So, the overall charge here is as a Public Health Task Force so that was the context in which we were working but really focusing on the health IT aspects of that charge, so we didn’t look to move ahead any guidance on how to manage a public health crisis but how to use the tools that we have both the human and existing processes and where we can leverage health IT.

And then specifically looking at issues around Zika as our use case, if you will, and also as one that really needs continued attention and focus with a real sense of urgency. So, we focused in four areas of capturing pregnancy status because of the important implications for pregnancy with respect to Zika making sure that it then gets transmitted along to public health agencies, that there’s increased use of clinical decision support, we’ll go into some of the examples of why that’s important, and also how to improve electronic case reporting.
And we put forward some principles to try to keep us focused in the work that we were doing, so everything from clarity of purpose to really understand what it is we’ve been asked to do and staying on task with that to finding the bright spots, where’s this already working, let’s learn from what’s actually working in the field and make sure that we engage a broad set of stakeholders, be parsimonious, let’s be focused in what we recommend, let’s look for generalities, Zika is not the only public health issue that needs to be addressed and there will be other emerging diseases in the future. So let’s continue to build on the history of what’s been done and go forward with that looking for things that are pragmatic and actionable, looking to balance priorities because there’s a lot of different demands being made on all of the stakeholders, healthcare providers, their IT vendors, the labs and public health as well.

And finally, that wherever we can to be looking at national scale so a bright spot might be bright because of local conditions but where can we really bring it to national scale.

So, we’ll walk you through sort of the overview of who are the main constituents here. So, we have public health really as kind of the linchpin around which all this circulates, individuals who are looking to maximize their own health and avoid risks, healthcare providers who are the hands on people who make it all work and the laboratories that play an absolutely essential role with things like Zika.

And so the initial action here is guidance coming out from public health and that is distributed in many ways today and specifically in terms of where we focused with clinical decision support, how can we build on the guidance that’s there and make it more embedded in the workflow because it’s part of useful clinical decision support and not triggered inappropriately.

And we also have healthcare providers offering guidance to their individuals as patients and through their websites and Apps.

And we looked at collecting information from individuals about their own health that they could then supply back to their healthcare providers and so there could be a lot of forms in which that happens and the line ought to be hashed to indicate that this is a work in progress. So, we know that there are beginnings on this work but there isn’t a lot to actually build on for immediate action.

Once the healthcare provider feels like someone has qualified for some further investigation they might order some lab work with a specimen that would go to a lab and then when the reports come back if they’re reportable conditions that the lab has found they would send that onto public health directly and we’ll talk a lot about ELR, electronic lab reporting, which is really a main conduit today from the labs to public health and the electronic conduit from labs to public health and some work that’s going on with reporting from healthcare providers to public health under the banner of electronic case reporting. Okay, Anne, it’s yours.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Thank you. So, our first charge was really to focus in on pregnancy status. Pregnancy status is something that is really critical for a number of reportable conditions Zika being one of the most recent and prominent of those and, you know, clearly when you are having a pregnant woman you really have two patients and the impact on the fetus and the newborn infant is something that public health can help to prevent any adverse impacts from these types of infections as well as to help to diagnose what’s happening in the pregnant woman as well as the infant.
So, unfortunately at the present time there is no standard way to capture pregnancy status and associated data in electronic medical records and there is no existing consensus on the minimum public health data elements that are needed to actually capture the information about pregnancy.

So, our goal was to identify these priority elements and we did, we managed to gain a consensus among the public health community, the medical folks who we included in our deliberations and also from others on which a small number of elements we thought were essential to be able to capture.

And those elements are available to you in a document that was circulated which I hope all of you received and we also included the proposed standards that could be used to capture the data and map it to existing documents.

So, while capturing pregnancy status in the EHR in a standardized way and transmitting it to public health electronically is where we want to go this really isn’t possible now and so another way to capture it is to actually ask providers when they’re ordering a test to supply a minimum amount of information for key conditions where pregnancy status is relevant and so we are promoting Ask on Order Entry for transmission via electronic laboratory reporting so that pregnancy status can be transmitted to public health in that way. This is a short-term recommendation or medium-term recommendation which we hope to have implemented before the bridges between the electronic health record and public health are actually implemented and in production.

We also recommend to publish these data standards in the ONC’s Interoperability and Standards Advisory and in response to the Committee’s input during our last meeting we did explore...we do recommend to explore ways for the individual to electronically self-report pregnancy status and other related data and to potentially electronically capture that data, as Larry mentioned, into the provider’s electronic health record. We’re going to dive a little bit more into details on some of these as we go through these slides too.

So, the next charge was to figure out how to transmit that information to public health and the challenges here are that, as I mentioned, public health currently does not receive pregnancy data electronically very...in any consistent way or complete way. So, we do have a really amazing amount of data coming to us via ELR and that’s been really successful...a lot of progress has been made in that over the last few years. In New York City that is the primary way we receive data on many reportable conditions but pregnancy data is often not included, it can be included occasionally in data from commercial laboratories and electronic case reporting is not in place yet.

So, pregnancy status is really needed not just for follow-up of actual cases of Zika or other reportable diseases where it is important but it’s also important for us to capture it at the time of the test order to make sure that the appropriate tests are being ordered for a pregnant woman. The testing is very complicated and we’ve identified a lot of disparities in who is getting tested at all whether women are actually being identified as being at risk for Zika appropriately and also for which tests are being ordered for any particular pregnant woman.

So our recommendations are that we promote pregnancy status to be transmitted for Zika and other reportable conditions where pregnancy status is relevant and I’ll go into what those are a little bit later but I also wanted to mention that we did add to include chronic reportable conditions, it’s important in diseases such as HIV or hepatitis C that the existence of pregnancy in a reportable disease that may have been diagnosed in the past is something that itself should be reported because it can have a potential impact on the infant or the fetus and it enables public health to intervene to be sure that this infant is treated, vaccinated appropriately and in a timely fashion.
In the short-term, because other methods are not in place, we do recommend to expand the use of electronic laboratory reporting to transmit this critical information to public health for Zika and other reportable conditions.

And while we do recommend Ask on Order Entry as the preferred method to capture it we... in the meantime, because that also requires some time and resources to develop and to make it widespread, we would like to promote the use of a specific prenatal test for Zika to indicate pregnancy status and I will go into that a little bit more later too.

And then we recommend publishing these data standards in the ONC Interoperability Standards Advisory and we encourage state and local jurisdictions to use their existing public health authority to require the transmission of pregnancy status, this has been done in some jurisdictions but not in all, and to promote the use of the ONC’s Interoperability Proving Ground as a place where information can be shared on public health interoperability projects and to enable labs, vendors and others, and healthcare systems as well, to share the best practices and processes that work.

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

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
You’re welcome.

Larry Wolf, MS – Principal – Strategic Health Network
Thanks, Anne. So, moving on to clinical decision support, it’s really important to integrate the guidelines into the workflow of the providers and so this really was the heart of what we want to do with clinical decision support and recognizing that the guidelines for emerging diseases are often changing rapidly.

So, whether it was some of the things that were learned around Ebola or the things that are being learned with Zika to know that you can’t just say that there’s a guideline and we can publish it and we’re done, but in fact the guidelines themselves are changing so whatever is done needs to recognize that dynamic state of things.

And that the guidance doesn’t come just from a single source. So, often local health departments, for very good and important reasons, have guidance distinct from what’s being issued by CDC. There may be a local transmission that’s important to be more sensitive to in some of the southern states that have mosquito populations than in a colder northern place. So, they will vary.

There may be a high incidence of travelers coming in and out of a location and public health needs to work with those differently because they represent a different population. So, how do we work with these variations in guidance as well as the importance of it changing as well?

And, you know, we have an example of the... as Anne was saying that the lab test to order are very specific and that we unfortunately had examples of several hundred of the wrong lab tests being ordered and so you get inconclusive results because of that and getting good guidance to people because the window for testing can be really short right after exposure.

So, you know, that sort of summarizes the current challenges that we’re facing. So, most of the recommendations here recognize the emerging state of clinical decision support. So, there are some
demonstration projects that look at using clinical decision support working at public health, the RCKMS Project in specific is one that we heard about so looking for those as best practices emerge.

To explore sharing CDS implementations across providers. So we saw a lot of this with Ebola and we’re seeing it as well with Zika. The healthcare providers, based on the capabilities of their vendor, are sharing with other healthcare providers that use that same technology on how to implement good decision support so that it actually helps detect the people who are at risk and doesn’t interfere with the care for those who aren’t.

We’re also looking to encourage clinical decision support to improve access to human readable guidance. So, the trigger might be in the EHR but the action side might just be informational at this point, it may not be fully integrated into the EHR or fully implement the logic of the guidance but to at least make sure that the providers have current guidance for the patients at risk.

We also looked at mechanisms for consumers to identify their own risk and to be able to then document what they found. So, we know that individuals might be using Apps to plan their travel or Apps to manage their fertility status and so as they use those Apps it would be great if those Apps provided additional support that tied into the guidance that’s available.

And finally, to explore use of open APIs and we heard about CDS Hooks as one example of that, using FHIR, other technologies that are in play that could support clinical decision support.

We also had a fourth charge, electronic case reporting, and the challenges are that there aren’t good standards in place for a connection between public health and providers and to create the two-way connection that’s really needed and we also saw an example of a bright spot where a DigitalBridge is a project that’s really convened a lot of the stakeholders to come together to work collectively on addressing this problem.

So, a big piece here, and the case reporting is, again, to use the standards that have already been put forward to leverage the work on the existing projects like DigitalBridge, to explore use of new and maturing standards because we are in an environment that really is changing a lot, you know, eight years ago we had very low adoption of technology, today we have very high adoptions of technology. So, there is a technology base there although it may be very diverse and we know there are some issues of getting convergence around standards and really moving information, but we see this as really an area where the standards have matured and are continuing to mature and new ones like FHIR are getting a lot of traction and becoming a method that we could use to better tie the information together.

And again, looking to promote existing mechanisms to share best practices, so the Interoperability Proving Ground is a place for projects to publicize their work and to bring people in to some of the practices that are already in place.

So, how did we get here? So, we began our work in December. We had a taste of that last year, Jim Daniel did a presentation to this group in the fall outlying some of the work that had been done and that led to the formation of the Task Force.

We had an in-person hearing in February with panels representing some of the breadth of stakeholders and then we dove in additionally into some other areas specifically around case reporting, the pregnancy registry, Zika Pregnancy Registry.
We did a lot of work around the data elements looking to get good engagement and a lot of vetting and recognizing that’s really an ongoing process but we feel like we’ve got a very good foundation here. Looked further at clinical decision support. The continuing importance of ELR, electronic laboratory reporting, and finally we tried to incorporate the feedback we got last month on things we ought to be acting on.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Okay, so just a bit of background, and I know some of the Committee members have heard this before but there were people who probably didn’t so I’m going to remind all of you about this. So, for the first charge the reasons that it’s important to capture pregnancy status for public health, so multiple infectious diseases are important in pregnancy and those include Zika, hepatitis B, syphilis, HIV, varicella, listeria, other diseases as well such as diabetes clearly and this could be extended to opioid dependence, all kinds of chronic conditions. We’re focusing in on reportable infectious diseases now but we’re hoping that this work would help with management of many other conditions as well in identifying pregnant women and enabling sharing of information that could help to prevent and alert clinicians as well as public health to the pregnancy.

So, lab diagnosed cases are reported via electronic laboratory reporting or via other means to public health but the volume can be very, very high so identifying those in which a woman might be pregnant is critical because when we investigate reports of infectious diseases we have limited resources and we need to prioritize those where it’s most important. In the case of a pregnant woman it’s important because not only do you want to enable the woman to get accurate…the best testing she can get, the best treatment she can get but also to be able to identify when that infant is born to make sure that infant gets tested appropriately.

So, the timing is really critical for infants they need to be tested ideally within the first two days of life in order to meet a case definition for Zika and in order to have the maximal probability of being able to detect the antibody to Zika, the IgM antibody. So, it’s important to identify pregnant women and it’s important to know when they’re supposed to deliver and it’s important for public health to be notified at the time of delivery, but we are not always notified, so that we can appropriately test that infant and know for infants who are affected, who are microcephalic or even for those who are not obviously affected at the time of birth, whether they truly were infected, whether they truly have congenital Zika infection. So, we need to prioritize investigations and know who is pregnant.

I mentioned about the follow-up of the infants but the other reason it’s important is to get the appropriate guidance to the providers regarding test interpretation and case management. So these tests are very, very difficult to interpret. We have…we’ve spent now a year, over a year, dealing with this in the New York City Department of Health and even amongst ourselves we’ve been dealing with it for 15 months we often have questions about what the tests mean, we answer many questions from providers about what the test results mean, so we’d like to be able to offer guidance especially to providers who are managing pregnant women to help them understand what those tests results mean and know if any additional testing needs to be done.

So, for the pregnancy data elements we did develop these priority data elements and if you’re interested please refer to the Excel spreadsheet which was put together by one of our Task Force members who is really wonderful and we’ve tried to specify the mappings in many documents that are used to transmit data as well.
Pardon me if I speak technically incorrectly because I’m just a public health person so that would be why, but I’ll do my best. We vetted these recommendations concurrently through the health IT developer community, through public health and through healthcare providers and we recommended that these data elements be included in the ISA.

So, this is a list of the data elements that were identified and on which a remarkable degree of consensus was gained. The ones in green are the ones that we considered to be the most important I think with pregnancy status, the date of the pregnancy status because pregnancy changes through time and the estimated delivery date, which is important for the reason I mentioned, we need to know when that infant is likely to be born. Many infants don’t come to attention soon enough and then the opportunity to diagnose them is unfortunately not there so we may never know whether those affected infants ever really truly have Zika or something else.

Also gestational age and date of the gestational age which is really an alternative to the estimated date of delivery and then the outcome and the reason the outcome is important is again to know whether a patient who has been being followed actually did deliver, again, the reason being primarily to make sure the infant whether it be Zika, hepatitis B or something else receive appropriate treatment, which often is to actually prevent infection or the consequences of infection in that infant.

And then there is another element which we wanted to include which is the multiplicity of fetuses, so whether it was a twin, triplet, etcetera, gestation just to know if we expect to have multiple outcomes.

So, one of the comments from the Committee last time was to explore how to focus more on the individual as opposed to the provider or public health and so we did explore an application which is called myHealthFinder, I’m sure there are others like it, but this one looked really interesting it was created by the Department of Health and Human Services and it offers a sort of tailored guidance, an interactive tool, for people to put in what questions they have, who they are, it might be “I’m pregnant where can I travel” and this tool provides that type of recommendation back to them in an interactive way. It uses an API and it can be rebranded. It does not retain any of the data that is sent into it by the patient, the person who is not a patient yet, and it doesn’t deliver the information to any provider as well.

But because of the API it can be integrated into any other website, a health department website, a provider website and it actually can be customized too, so CVS took it and put it up on their website. It can be reprogrammed to provide whatever customized information is needed for that particular site or that the person might want to know.

So, we also, as mentioned before, would like to explore ways for the individual to communicate their information to their provider electronically so that it could be captured that way as well and perhaps even followed along that way.

Okay, just as a reminder, the public health authority for receiving this type of information, the health and sanitary codes at the state and local levels are the ones that authorize public health to receive and investigate reportable diseases. We receive that information via electronic laboratory reporting, via case reporting which can be by phone, by fax, by paper, by web-based data entry screens and ideally, in the future, through electronic case reporting.

We do case and contact investigation and management of many of these diseases and then we use these data to detect outbreaks and unusual manifestations of disease and in all of these we have the authority to detect to be reported to us with identifiable information as well as to investigate.
HIPAA allows for the disclosure of this data to public health and pregnancy status may be required to be submitted with a case report when it’s relevant and this is what we do in New York City, we require that, it is actually in our health code that it be reported.

There is a new fact sheet from ONC, not quite as new now, but it’s really great and it documents the permitted uses and disclosures of exchange of information for public health. So, I encourage you all to take a look at that.

So, for sharing data on pregnancy, from hearing from the laboratories, from public health departments we really landed on Ask at Order Entry as being the best short-term option for capturing this information and sending it to public health via ELR.

Ask on Order Entry does take some work for labs to implement. It takes resources they have to modify their interfaces. So, it’s not in place yet among all laboratories and it’s not transmitting this information in a consistent or complete way so it will take time even for Ask on Order Entry to be fully implemented and to really increase the number of times pregnancy status is transmitted but it is preferred in some ways because it could transmit not only the fact of pregnancy but it could also transmit some of the other relevant data such as the date of delivery, etcetera.

In the meantime, because there is going to be time that will be taken to implement it, we would strongly recommend also the use of a prenatal test type for a Zika test that would indicate that the woman is pregnant and that can be mapped into the ELR message and we would like to recommend that it would be mapped in the same way across laboratories so that public health can receive it, know how it’s going to arrive and process it into their surveillance systems automatically that would be the best way for it to be done and we have some suggestions about that which we haven’t finalized yet but in terms of where it should be mapped to in the HL7 message.

And then long-term electronic case reporting is really the best way to go and will deliver the most amount of needed information to public health once it is set up.

**Larry Wolf, MS – Principal – Strategic Health Network**

So, the intention here is not that we work ourselves through the logic here but just a reminder that there is complex logic for the guidance and that in fact this logic has been developed as part of the ongoing work to support managing Zika and we also have a cascade of activities here that takes us through initially defining what the guidance is to creating it in a semi-structured way, to structuring it, to making it fully electronic.

And we recognize this is an evolution and an ongoing activity with a lot of work. We identified some bright spots where this is currently happening mostly built around vendors who have CDS capability and then healthcare providers would then implement that locally.

We’re also seeing examples of suppliers of clinical guidance, the sort of reference sources that might be embedded in an EHR for direct lookup from inside the EHR and that those systems are taking on the complex work of bringing the algorithms into their offerings so it’s not just a literature search but to actually “here’s guidance” here’s guidance in the form that supports decision support and can walk an individual through those screens and clearly embedding that in the workflow for the right person is really important as well. You don’t want to ask someone a question that they have no way of getting the answer for or completely interrupts the work that they’re doing.
And we’re also seeing pilot projects underway that look to make this much more machinable work that’s been done in other areas to support public health and so there’s a lot to build on here that could be used to much more fully automate this.

So, this is a reminder of how this happens. So, in this case public health is acting as the supplier of the guidelines. Those then go to developers who can embed them in the technology and developers here is being used in a really broad way, broadly, so the developers might be vendors of technology, they might be healthcare providers who are creating logic inside their own application, they might be third-parties that are creating executable environments and then putting content into them and then they go to healthcare provider that then integrate into the workflow.

I’m realizing, looking at this provider’s slide, I should have emphasized way back on the original diagram that we’re using providers here as the generic term. So, this could be, you know, a single physician practice somewhere, it could be a large multi-setting, multi-site healthcare system or almost any flavor in between. So, really looking broadly at where healthcare is provided and that workflow integration is really important for the clinical decision support to work.

So, some of the additional background here around looking to identify individuals at risk to ensure that the appropriate tests are ordered, that the triggers point to the specific actions that are needed and we uncovered lots of examples of inappropriate tests being ordered or really very low rates of reporting pregnancy. So, it’s a combination here of having good triggers in the EHR and then collecting that information and using the CDS to move that forward.

And some examples that we’ve seen of best practices that in some way are very low tech but are very helpful. So public health has started using consistent URLs for their guidance on a specific disease. So if you need to get the current version of that you just go to the same website and the website will be updated, they don’t change the URL like, you know, with the date of the update which then would require that you have a new link every time you want to use it. And also many of those websites support RSS so you could get automated feeds of when the information changes. So, they’re in some ways very primitive tools but also very usable.

And a reminder about... for clinical decision support you want to reach someone through the right channel with the right information about the right things that they need to do in a format they can act on, it goes to the right person and it goes to them at the time they are going to be able to take an action. So, really focus on making this usable and not just create alert fatigue or information overload.

We spent some time delving into what’s happening with CDS Hooks, which is an open source project, and it really has two critical aspects here, one is to embed the triggers in the EHR using the native clinical decision support capabilities of the electronic health record tools to trigger starting the hook, so that’s sort of like the hook side is the beginning side, and then it calls web services to provide the actual clinical decision support, so a call out from the EHR to web services that could be hosted locally or could be hosted out there in the world of the web.

And then protocols for how you would then access the data back in the EHR. So, it’s working within the SMART framework that was developed in the past and then using FHIR as a way to get data into that application. So, it’s a model that’s being pursued.
The Argonaut Project has chosen clinical decision support as an area that they’re going to be working on this year moving forward with the use of FHIR so we expect to see new work coming in how all of this comes together.

And looking to make recommendations to continue exploring use of open APIs and also to look at clinical decision support that support consumers. So, Anne mentioned that the myHealthFinder is not just a website but also can be accessed through APIs and so that’s an example of where you might use APIs to access guidance without it being very complex embedding of a logic engine but just a way to get to the guidance.

So, this is a reiteration of our recommendations around building on the demonstration projects, exploring sharing of CDS implementation across provider locations, so really taking advantage of a local bright spot whether it’s geographically local or vendor local. There are also other demonstration projects coming out of AHRQ for example, the CDS Connect Project that’s building a web repository that could be another vehicle for sharing this information.

In short-term to encourage use of clinical decision support for access to human guidance, mechanisms to support consumers to assess their own risks, you know, you could avoid a problem by looking at where you travel to, what you do to avoid mosquito bites and things like that. So, there could be some very specific actionable things and continue to explore use of APIs.

And finally, on electronic case reporting, so this is an area where really robust communication between healthcare providers and public health could be a really important step forward but it’s an area that’s relatively recently getting renewed attention to directly build this into the systems and to improve use of healthcare as a source of information for population management, for detecting outbreaks and for working with the local needs.

We talked about the difference between eICR and eCR. So eCR is broadly electronic case reporting to generate the information and support the exchange and eICR refers to some specific data sets and specific document types and so we’ve tried to keep those clean in most of what we talked about I noticed going through the slides there might be one or two places we still need to edit that.

Our intention really here is to focus on the process of electronic case reporting and make that better and to make sure that the eICR, the document, includes the standards that we’ve put forward for reporting pregnancy.

I’ve covered a lot of this before so building on the standards to use those as part of any work on case reporting in the eICR documents, that we build on the work of DigitalBridge, that we look at RCKMS and other projects that are looking to formalize the knowledge and making it accessible, and that we look at bidirectional data exchange as really a key piece, we didn’t show that in our initial slides, we really focused on this initial reporting to public health but clearly there’s a lot of follow-up activity and anything that can be done to streamline that and build on the information that’s already been sent would be really helpful.

Okay, we’ll give you a very quick recap on these and then we’ll open up for discussion.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
This is really just a summary slide with the actual recommendations that we’ve already reviewed. So, I don’t think I will dwell on it. The only thing I will add, which as I was sitting here I remembered, is that we did hear at the last virtual meeting that we had, about the concern about linking the pediatric community in with all of what’s going on with Zika and other conditions that can affect the infant. I don’t know where that went forward, I’m going to go back.

So, we did hear about some best practices where data reflecting the mother’s pregnancy status and tests that were done during pregnancy for Zika and for other conditions are presented in the newborn’s record and I do want to highlight that as a best practice.

I think that one of the things we’ve observed in public health in managing a lot of these pregnant woman/infant pairs is that the infant when delivered there is no information necessarily available to the caregiver’s for the infant about the mother’s status and so presenting that front and center at the time when the infant is born is really critical and some systems do that, gather the information and put it right in front of the pediatrician’s space, that is an important thing to do and I would like to highlight that. I do think that that’s something that we should also be calling out as a best practice.

Okay, so this is really just a rehash and this, again, sending and sharing pregnancy status with public health, this will fall on laboratories in the short-term and we’re hoping that these recommendations will be implemented by laboratories and by systems who are using the interface with the laboratory because it’s really critical, especially even for this upcoming season that this be implemented as widely as possible.

Currently in New York City we’re getting a really small proportion of cases of Zika where in pregnant women, we’ve looked at our data where pregnancy status is actually indicated. So, again, I won’t dwell on these because we’ve already gone over them.

**Larry Wolf, MS – Principal – Strategic Health Network**
So, since I just talked about clinical decision support and electronic case reporting I’ll use the time for our discussion.

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**
All set? Wonderful thanks again, thanks again to the Task Force. You can see there’s a lot of detail that is required in order to make seemingly a simple fact about an individual known to the people and machines that needs to know it in order to improve our care and avoid things falling through the cracks.

One of my favorite recommendations they had was the ability to have self-reporting. It reminds me of the attending case rounds in the inpatient setting where the house staff in terms of residents present to the attending and normally the interns and residents are debating about whether this person has a risk for this or what it has based on all the lab and imaging and then the attending would say “have you asked the patient” and that would sort of bring a pause to the discussion.

So, it’s wonderful that people are allowed to...that you’re recommending that we have a way to incorporate when a person wants to self-report that they’re pregnant. So, thank you.

And the first card I saw was Arien.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**
Ah, Jon, you want to go?
P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
No, no, go ahead.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
This is more by way of editorial. So, first of all, thank the Task Force for incredibly detailed and thoughtful recommendations.

When David McCallie and I were Co-Chairing the API Task Force one of the points that we made about driving to a common ubiquitous set of APIs and content standards is that it enables more general capabilities and there’s a tendency in public health to, in some sense, fight last...the last war and in another sense is to invent new and bespoke standards for particular purposes. To the extent that we can double down on the progress we’ve made in SMART on FHIR in enabling API access in areas like electronic case reporting or in clinical decision support hooks, we’re able to get more leverage out of HIT vendor system development and not force them to adopt and develop more specific standards for this thing and that thing and the other thing. So, Clinical Decision Support Hooks is a good example of this.

The ability of...through SMART on FHIR and the work that we’re doing in the Argonaut Project to treat the EHR more like the iPhone and launch Apps I think is a good template for electronic case reporting.

So, more a plea to, in the public health community, double down on the trajectory that we’re already making with HIT vendor systems and make sure that we can do the more general work there.

None of that obviously mitigates against the need in specific outbreaks to get to the level of specificity that the two you noted and that Paul just noted that you need to get down to more granular and more specific levels but to the extent that you can do that on a more generalized platform you’re going to have a lot more tools and flexibility in public health. Thank you.

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

Larry Wolf, MS – Principal – Strategic Health Network
Yeah, Arien, thank you for the comments. We really tried to balance what’s actionable today so the focus on ELR, which is what’s in place today, a large volume of information is going through there if we could improve the percent of tests results with pregnancy status that would be a big step forward in the short-term.

We had a lot of discussion about had we done enough due diligence, if you will, at all of the various options for implementing things to make a stronger recommendation on new technologies than we are making here, but I feel like there really is a huge opportunity here to leap into the emerging technologies and really give us a more powerful base to build on. So, more a personal editorial statement as it were.

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

Larry Wolf, MS – Principal – Strategic Health Network
I’d like to see that get a lot of traction.
Thank you. Jon?

I’ve got a raft of thank yous so I’ll say, Anne and Larry, thank you. This is incredibly important stuff and, you know, all...you know Zika is the match, right, but the, you know, it’s a big pile of kindling that it lights up. So, I appreciate you all grappling with this and pulling your colleagues together to do it.

I would love to also acknowledge the good Dr. Richards here with us today and his team of course you know how much we love Sanjeev Tandon but we love everybody there too, so thank you for working with us and the Task Force, you know, and kind of trying to think through these recommendations, so thank you.

And of course, my beloved team at ONC, Jim, Lee, everybody else, thank you I appreciate the effort that you all put into this and kind of getting these recommendations in front of us.

There’s just one thing in particular I wanted to ask about, you know, when you hit that first set of recommendations and said, you know, we don’t really have standards for capturing pregnancy status I thought to myself, oh, dear lord, you’re getting...I can, you know, talk about, you know, the encounter with...repeat in ICD-10 but I can’t...I don’t have a...surely we’ve got standards but did you mean to say instead they were not using them or could you drill down on a little bit?

Yeah, so maybe I’ll jump in first on the tech side and Anne could fill in some more color commentary. So, there is a spreadsheet that was circulated to the Committee that actually identifies the specific standards Jon.

Yeah.

And what we found is depending on context there was a lot of variability. So, if you’re describing a lab result that indicates pregnancy you would code that one way. If you’re using an ICD-9 or 10 coding for a diagnosis you might say someone’s pregnant, right, it doesn’t sort of get us to the level of granularity that we were looking for.

Or consistency.

Rather than granularity it’s consistency.
Larry Wolf, MS – Principal – Strategic Health Network
Right.

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

Larry Wolf, MS – Principal – Strategic Health Network
Right. So, what we did was to say, this is what’s out there today, what actually is in use, and can we make some recommendations on moving forward with narrowing those and our suggestion was to bring that into the ISA process so the Interoperability Standards Advisory process and specifically address the way in which pregnancy is coded and where we can get... so move ahead the consensus, if you will, to get better convergence.

A lot of people are going, yes, we need to converge but as soon as you get into the “let’s converge” the conversation diverges. So, it needs more...

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
The full power of standards, right?

Larry Wolf, MS – Principal – Strategic Health Network
Right, it needs more help and more effort to get that convergence forward and I think the ISA actually has been a really good vehicle for surfacing the options and beginning to narrow them and give people the decision logic around why you would choose one approach over another and so I think there is some positive motion to do that but, yes, there’s continuing work to be done.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
All right, Mr. Posnack you owe the good doctor a drink.

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

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Thank you. Gayle? Oh, go ahead Anne.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
Yeah, I guess I would just like to add that we specifically did not want to stipulate or add any work to the providers need to document in a particular way.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yes.
Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Or to dictate how the data should be collected but we wanted to improve the ability of EHRs to capture the data so that it could be shared for women of childbearing age including not pregnant, pregnant, not pregnant to the extent possible. Obviously for every woman, for every encounter you’re not going to be able to necessarily document that, so unknown is an option for somebody who comes in with a sprained ankle, you know, a 15-year-old, that does not necessarily need to have an explicit pregnancy documented, but for it to be able to be captured in a more standardized fashion so that it’s expected to be there and be able to be at least calculated and transmitted.

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

Thank you. Gayle?

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

Thank you, very much and first I want to thank the Task Force for their recommendations and their report, and their hard work on this.

Having run an OB/GYN very large practice for many years I can tell you having some standards really in determining pregnancy and reporting it, making sure that the records are consistent, if you’ve ever changed vendors and you have had one standard versus another standard and you’re trying to determine age of gestation, estimated delivery date, those kinds of things it’s very, very difficult. So, that...for the practicing physician that would be tremendous.

Also, coming from Florida, I can tell you Zika is...we are probably the epicenter of what is going on with Zika, at least in this country, and with Miami having had several outbreaks and the need to really address Zika; we’re putting 80 million dollars currently in our state budget just to address the Zika situation.

But I do want to bring up something and I hope that the Task Force will have a little conversation from the political side of this and the political perspective of it and the privacy concerns that are there when you come to pregnancy and the potential termination of pregnancy.

We have various state laws and states vary state by state as to what is the level of consent necessary to have any reporting of termination of pregnancy or when you’re talking about the age, the gestational age of the fetus and all of a sudden there is none, that’s a termination of pregnancy. So, you have a lot of people who will be very concerned that there may be privacy concerns about abortion here.

So, as you go forward with your discussion please, please have that discussion and also the understanding that many states have very specific state privacy laws that must be considered when you are going to be transmitting information without specific consent whether that is coming from the laboratory or whether that is coming from the providers, the physician’s office. So, those are things that must also be considered as you move forward with these recommendations. Thank you.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

So, thank you for that. I actually think that’s a very important point and I do think it’s one we should grapple with. I very much agree with that and thank you for bringing it up.
For reportable disease reporting I believe that the...at least in the New York City Health Code, which is what I can speak to, but we should explore the...how those laws that you’re mentioning, the privacy laws, impact the transmission of reportable disease data relative to pregnancy or termination of pregnancy.

I believe in...under the New York City Health Code that transmission of any data relevant to that condition can be transmitted and obviously needs to be protected in the same way any confidential medical information would be protected but I do think it’s a really valid point that we need to explore as to how those privacy laws might interact with that other law, which is a local law and other state laws, which enable the transmission of confidential patient information to public health.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Follow-up on that please? Follow-up, yes, I would just like to say that there are specific consents necessary in order to transmit.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
So...

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
And it varies state to state as it does with HIV reporting. So, although that is a reportable condition you require consent at various levels. So, that needs to be considered as you move forward.

Larry Wolf, MS – Principal – Strategic Health Network
So, Gayle, thank you, just a reminder that there also is an ONC fact sheet that’s linked to from the material, I guess if you have the actual slides you can get to it, we could get the URL added as well...

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
And...

Larry Wolf, MS – Principal – Strategic Health Network
To try to frame this issue because we did recognize that there are privacy concerns as well as public health law that allows for the sharing of this information and it clearly requires protection of it on the receiving side.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
I’m not aware of consent being required for reporting of reportable conditions but I will certainly look into it further and for the associated data I’m not aware of that. I think the consent for the HIV test is obtained at the time of the testing but not for the transmission of the data.

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

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I do not believe that pregnancy is a reportable condition.
Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I think it’s an important issue that Gayle brought up...

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
Yeah.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
And I think it’s worth going through your recommendations to see how to incorporate that in light of her issue that she’s raised and see if there’s a way...I’m sort of sensitive to the fact that we have to...we’d like to approve this but I think we want to make sure that these considerations are at least incorporated...either incorporated or at least described so that the reader would be aware of these kinds of considerations.

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

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

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

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
Thank you, so first of all great work, I think this is incredibly important spending over a decade in the Dallas Fort Worth area as a CIO I saw firsthand, you know, ground zero when Ebola broke out and the left-hand/right-hand syndrome that occurred because we had not collected the appropriate data upfront upon admission and, you know, credit to the government, CDC and others stepping in and giving recommendations after the fact but then it was, you know, too late, we were literally spending nights putting up tarps in the units in the children’s wards worried that we were going to have an outbreak in the city.

So, I wanted to stress that I feel that this is incredibly important to get ahead of a potential issue. It’s very important to standardize this information in general and look at it.

I do also want to touch upon what Gayle said I think that’s important such as in a pediatric sense that consent is considered especially when it comes to pregnancy status that was something we grasped and dealt with even at a state level from an HIE perspective how do we share data, how do we do this with consent especially with minors and then what is that...what does that look like, I don’t know the details of specificity to be answer your question Gayle, but I do think there are some other aspects of that which should be considered.

However, the importance of collecting this data in a standardized way I cannot stress enough after seeing it firsthand we must do something and start aggregating this in a very meaningful way.
Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health

Thank you. Andy?

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

Thank you. First of all, so my thanks, I was on the Task Force, my thanks to the chair persons because it was, as usual, a fairly large herd of cats and they did a great job. And as the pediatric infectious disease doctor on the Task Force I was very gratified by the outcome of the work.

I would say that we did talk about privacy concerns in general and the fact is that...and we also talked about, to Arien’s point, trying to make the recommendation something that were not sort of Zika contingent but rather generalizable so that the next Zika that comes along would be a useful set of recommendations. So, we did grapple with that.

Just for everybody, again for the clarification of this particular last discussion, Zika is a reportable condition just like varicella is a reportable condition. Pregnancy is a patient’s status that’s relevant to the care of the patient and the care, in the case of a pregnant person, the infant after it’s born. So, I think the context for understanding the privacy concerns has to be taken in that order.

We’re worried about Zika if you’re pregnant and you’re going to have a baby that has an impact on the baby and it’s got an impact on what’s done for the mother and what’s done for the infant beyond that.

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

Thank you. Anne or I’m sorry I didn’t see Leslie’s popped up, thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, Leslie Kelly Hall. I just really admire the work that you’re doing and getting ahead of it as the earlier folks have indicated.

One of the ideas through around the standardized assessment tool that could be formed as you go forward is to make sure that assessment tool is also for self-assessment so that patients can participate and be educated along the way, self-assess and communicate both with their providers and public health.

In times of crisis we often look to government to help us and the CDC does an amazing job let’s provide a way for patients to help in this process to understand their conditions, to seek treatment as appropriate and help for their babies after the fact. Thank you.

Larry Wolf, MS – Principal – Strategic Health Network

Well...

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Yeah, go ahead? Thank you so much for that point and I think that’s a really critical and important point. I wanted to mention something that came up during our deliberations that wasn’t included in the slides, which is we are...in New York City we’re actually using a paper...we’re printing a paper card that’s sort of like an immunization card for the mother to be able to carry around with her so that she might...would be able to present it to whatever provider she goes to with her Zika...the information about her Zika status, the tests, because the tests...if she goes to somebody else they may not know what her test
results are and then also to present to the pediatrician once she has the baby so that the pediatrician will be able to look at that information and so...and add information about the infant and the infant’s testing.

This is a paper solution to a problem where information is not flowing well from obstetricians and hospitals to pediatric providers. So, but to make that in an electronic form would also be a great idea and to make that available to the patient so that the person herself could have access to that information as well as to provide additional information to the providers I think is a great idea.

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

Good, thanks. Anne?

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

So, I reviewed this with our internal experts and I just wanted to pass along their commendation and applause for your Task Force’s work it is really a nice piece of work.

I would like to add on just to support a little bit of Gayle’s comments anything our software developers can do to help us appropriately capture this information in a uniform way I would highly recommend and if they can help us get from the point of capture whether it’s a provider capturing it or the patient capturing it and bring that into orders so they could review, edit and then pass along, they have to capture so much of this information it’s becoming quite a burden. So, I would like to see them encouraged to help us use software to solve that problem but thank you all.

**Larry Wolf, MS** – Principal – Strategic Health Network

Yes, it was certainly our intent with the focus on standards that would allow for reuse. So, once you know it the process of moving that data forward could be streamlined.

**Anne Fine, MD** – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Right.

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

Thanks, Anne. Lorraine?

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

Thank you. Thank you for a phenomenal presentation and welcome Dr. Fleming. At CMS we not only have long titles but we also work a lot of tables and so I have a couple of different comments to share with you, one is the presentation was really meaningful to me because I have a person friend who was in Florida who had been bitten by a mosquito and so she had the risk of being...of having Zika and her physician burst into tears when the test was being taken so it has resonated with me a lot. So, thank you for the presentation.

One of the things that I wondered if you had looked at, and I know ONC has looked at, something that HL7 is working on which is the personal health record system functional model which has as part of it public health reporting which would have...is connected to the electronic health record and the public health reporting would go both to the electronic health record as well as to public health agencies and
that would be one of the ways that Zika could be reported both from the individual to the physicians and to public health agencies.

The ballot has just gone up and the deadline is tomorrow for commenting on it and then it will be available for review in May. So, if you would take a look at that I think it would be...it might meet some of your needs because that very issue is being addressed there. So, I wanted to bring that to everybody’s attention and ONC I know knows about the PHR model and how it’s connected.

And then the other item and this is part of the Alternative Payment Models that the Center for Medicare and Medicaid Innovation has in talking about the whole data issue of pregnancy. There’s a maternity action collaborative that’s been...that they are working on and one of the questions they have too is, what’s the indicator that they capture and so that might be something and I don’t know if anybody in the room has been working on it and looking at any of the maternity action collaborative models that are around the country but one of the questions is how do you capture pregnancy and looking at who is in those models and what patients are they capturing and whether they’re even looking at Zika patients or the potential for that. So, that might be something to look at too.

**Larry Wolf, MS – Principal – Strategic Health Network**

Yeah, thank you, Lorraine, we’ve had lots of conversations across many of the pieces of HHS and with HL7 and those two specifics did not come up in our discussions. So, thank you very much for bringing those forward.

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

Thank you. Floyd?

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

So, first of all, as a member of the Task Force, I want to thank the chairs for their comprehensiveness and for keeping us on task, which was not always easy, and especially for the attention and care about clinician workflow because that was part of the discussion all the way along and thinking about things like pregnancy specific tests so if you just order the right test it actually indicates the patient is already pregnant and Ask on Order Entry, which we didn’t go into here or specifically on the Task Force, that an inference engine within the software could help to prefill and the doctor could accept or not accept that answer.

So, there are mechanisms that can help that and that’s...that was clear attention to workflow and also to the consumer workflow, the consumer finding the information and sending it to the doctor because they know, they’re aware.

I think it’s important to...Larry in answering a comment mentioned the spreadsheet. There is an accompanying spreadsheet so some of the comments...I think Paul when you first said there’s a lot of detail here, a lot of the detail that explains the comment, the specific elements within the slides is in that spreadsheet so the group did look at the details.

One of the details that may need a little more definition is if you’re going to include this for any chronic reportable disease then identifying what they are to make it easier for vendors to be able to connect the two.

And the last comment I would make is about CDS. There actually are current prototype pilots, not necessarily in production yet, going on in HL7 with CDS Hooks to try to use it specifically for Zika virus...
and also other emerging hazards, and so there’s really good work going on this year and you’ll see more of that in HL7 standards for the September ballot cycle.

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

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**
Thanks, Floyd. And someone on the phone?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**
We did have Troy Seagondollar but he took his hand down.

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

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**
But Paul Egerman also has a comment.

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

**Paul Egerman – Businessman/Software Entrepreneur**
Yes, this is Paul Egerman and I want to add to everybody else’s comments, this is excellent work so I want to thank the presenters.

My question is about privacy, basically pregnancy status is not a legally required reportable item right now I think in most states, in fact I’m not aware of any state where the pregnancy status is required to be reported to public health agencies and I can think of a lot of areas or situations where the patient wants to keep that information private, for example, if the patient is a teenager there may be special privacy considerations and so how do privacy considerations impact your work and is there a need for special privacy rules around this information?

**Larry Wolf, MS – Principal – Strategic Health Network**
So, Paul, we did look to bring privacy considerations into the work really focusing on the reportable pieces and then really looking to make sure there were mechanisms that we could report pregnancy. We know it’s a very charged area for privacy, you know, there’s been some discussion here already about recognizing that and I’m also hearing a suggestion that we probably should explicitly include that in our materials as we get our letter of transmission together. So, thank you for bringing that back up.

**Paul Egerman – Businessman/Software Entrepreneur**
Thank you.

**Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health**
Thanks, Paul. Jitin?

**Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance**
Thank you. I wanted to share a couple of comments, one was from a provider’s perspective or maybe I should say provider workflow perspective, I just want to first of all double down on what Arien said at
the very beginning which is, to the extent that we’re utilizing what’s already being built out there in order to capture the new data that makes it...that will be a big deal in terms of the adoption and usage. So, I just want to double down on that comment. I know that that’s direction this Workgroup went down so I just want to applaud you for that and commend you for thinking about it in those terms knowing that that’s really what’s going to help drive adoption beyond just great sort of software that comes out of these Committees in general. So, I really appreciate that kind of outlook.

I’d like to make two other comments really around the consumer. One of them is we’ve...in the course of this discussion a lot of it is focused on clinicians being able to capture that information for...related to the pregnancy that’s important in the case of public health, in the case of, you know, care of that patient, and one of the things we realize of course is that the data the patient provides may or may not be accurate, may not be complete.

Me and my wife we just had a baby a couple of months ago and we almost learned that the hard way that even though somebody who is actually a medical professional may forget to share information that is extremely relevant to the pregnancy at that moment because pregnancy itself is such an ordeal that it can actually subtract from your faculties to be able to share that information to you provider. So, we actually we saved our kid by sort of the teeth of our...the skin of our teeth because I happened to remember something that my, again, medical doctor, wife completely forgot because she was so exhausted.

So, that just underscores that interoperability has to be a big part of the data capture, you have to be able to get data from places where the patient themselves may not remember they have had data and that leads me to my real point which is, unfortunately sort of a half-baked off the wall comment, but it’s probably important here particularly to our federal partners if not as much so to your exact report which is when you think about...with the example you used today, and I know there’s a broader case of examples that don’t require travel as a key component, Zika is obviously a very travel related sort of issue, but for those class of infectious diseases for which travel is actually a big component or other types of issues for which travel is a component, nobody really travels outside the US...I mean outside of people who work for the CDC, travel outside the US thinking about the next infectious disease that they may contract.

On the other hand, when they do travel they do want to know that they’re going to have a safe and successful, and fun journey or whatever that case is and they have to start making calls to various organizations to ensure, you know, that their credit cards will work when they get there, that the US Embassy knows that they’re going to be available for them if they get there and they get robbed or mugged, or whatever the case.

So, there’s this list of things that, at least when you’re traveling abroad you think about to which “notify my doctor that I’m traveling” sometimes occurs, sometimes does not “let me know what the CDC guidelines are for that place I’m traveling to” sometimes occurs, sometimes does not.

And I think maybe it’s time for...again, as...this maybe more addressed maybe to federal partners than to this specific Workgroup, but it may be time for us to start thinking about, well is there a way that we can put into the consumers sort of jobs to be done workflow not the EHR workflow, not the medical workflow or the healthcare workflow, but I’m a traveler or I’m about to be a traveler I want to be able to share data with organizations to help me and have a safe and successful journey who I might or might not remember to share with. There’s no technology reason why we cannot do that today.
I think it’s a matter of figuring out where the dots are and connecting them but that’s something to I think seriously think about as we come out this Workgroup among others that suggest that we should be thinking about the consumer and the total type of thing that they want to do including but not limited to healthcare and I think we have an opportunity to interoperate at a level that transcends, you know, a specific case or specific sort of public health type of use case. So, I’ll leave it at that.

Larry Wolf, MS – Principal – Strategic Health Network
So, a couple of comments back, so we actually did talk about travel as an obvious risk factor for Zika and in fact talked about that when people are traveling that they often from lots of sources get reminders about immunizations that they might want to get and vaccinations they should get before they travel but it doesn’t always extend to emerging diseases and risks like this and so there may in fact be hooks within the existing information flow around travel Apps people use to track their travel, websites people use to track their travel.

The CDC website does have an option for “I’m traveling, where are there hot spots in the world I should be aware of” but you need to think to go there so to start to push that out into the normal consumer workflow would be a really good thing.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
The My Health software that we saw did hook into the CDC website. There is a place where I think you can indicate travel and it will take you to, you know, through a number of clicks to the CDC website that gives more information about that and that’s something that I think could be built out.

There is also an “I’m Pregnant” piece of that software so obviously you’d like to get the recommendation not to travel, unfortunately for women in Florida they can’t not travel to Florida for people who live in Florida, but for those who are planning travel to areas where whatever infectious pathogen is circulating having access, easy access, to that information and the most current information would be very, very helpful and it would be great if more people used it but I thinking bundling it together with other kinds of health concerns for the public is probably the best way to do it.

Larry Wolf, MS – Principal – Strategic Health Network
And I also think it’s probably a good place where we had some discussion about while in some cases the geography is pretty broad the actual outbreaks in Florida and in Texas are all very geographically limited.

So, you want to actually know did you travel in this neighborhood, did you travel in this, you know, pretty tightly constrained area and so knowing that is often tough and requires the right level of specificity to not spin up a lot of anxiety that’s not appropriate but also to be able to direct it where there is specific risk.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Well, speaking of public health and the CDC, Chesley did you have a comment, question?

Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention
Yeah, thank you. I had a couple of comments. One, I wanted to say for CDC that we’re deeply appreciative to the Task Force particularly the leadership of the co-chairs, the support we got from ONC particularly, Jim Daniel, and the members of the Task Force. This was an urgent issue that needed to be addressed and you did it in a timely way. All that is, as we’ve talked about, exceedingly complex and there are issues that still have to be addressed.
The second thing I would say is that I think there’s recognition that while CDC plays a very important role at a national level, global level in public health the rubber meets the road at the local and state level that’s where the work is really being done on a daily basis.

One of the things that we’re trying to do at CDC is to find ways that we can support local and state health departments to work more as one public health as opposed to working in individual silos. So, the work of DigitalBridge around electronic case reporting has been critical in trying to move forward as a united sort of public health and work with vendors and health systems, and I’m glad that was also highlighted in the recommendations.

Around clinical decision support I think one of the things that CDC can do, and as Dr. Fine said, our guidelines often have to be modified or different parts emphasized at a local level but one of the things that CDC can do in the guideline production we have is try to do more to make those guidelines more easily adjustable in the decision support.

So, we’ve got groups within the agency now working and we’ve met with HL7 and with others to think about how do we get our part of it done in a way so it’s easier as a handoff. And again, I appreciate that in your recommendations you highlight some of the work in the clinical decision part.

And the final thing I’ll say is, in terms of the recommendations here, these are really important for us. They help us think about what policy we need to do in collaboration with ONC but also how we support both with financial support and other guidance to state and local health departments. These recommendations really help us in thinking about how to do that better. So, thank you very much.

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

Thank you. Floyd?

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

All right, thank you, I just wanted to follow-up on the travel question. So, as the chairs noted in the Task Force we did talk about that and I think they were referring to the CDC website that folks with gray hair will remember as the Yellow Book that they used to publish every year...

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

Yeah.

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

But it’s on line and is available for consumers. As Larry mentioned, it is a challenge when dealing with many times, you know, a country is at risk but it might be a part of a country so even in looking at Zika virus you can’t really use a zip code when you want a four block radius in Miami Beach, it becomes complicated and so those are some of the issues.

I think your cell phone knows if you were in the four block radius but how that can actually get shared is something that needs to be explored, but it is something that was considered and I think you’re right that consumers could have this information and if they find risk could decide to share it and we talked about that.

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

Is there someone still on the phone? Okay.
Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Troy Seagondollar.

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

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente
Thank you, very much. Commendable work, I mean, this is something that we absolutely need to be able to track and keep a close eye on as well as anything else that comes up.

My comment has to do with really looking at the support for the community health centers, federally funded community health centers, as well as, the Title X and the planning clinics, you know, with the volatility that we see with healthcare reform and the American Healthcare Act, the discussions about defunding a lot of those entities, my concern is this, I mean, while the majority of them, actually most of them, are on electronic health records and they are capturing data electronically if the funding dissolves, I mean, we lose a lot of the population that goes to those centers most, you know, are low income and a lot are Medicaid patients, we will lose that.

Were there any discussion about provisions in trying to, I would say, advocate that because of these disease outbreaks, different things that are population health managed, managed in community health centers, as well as family planning centers, as to what we would do in those situations?

I mean, what provisions do we have besides them being able to log onto a website and say “yes, I’m pregnant” and “yes, I was in an area” and “yeah, I did get a mosquito bite” what are the provisions that were discussed in the Task Force or are we leaving it up to further discussions on down the line?

Larry Wolf, MS – Principal – Strategic Health Network
So, yeah, so, I’ll provide some context and it sounds like Anne has some things to say as well. So, the first piece is we did talk broadly about providers and the whole host of providers that actually make it possible for people to stay healthy, manage their illnesses including community health services of various kinds.

But we also tried to really hold to our charge which said, it wasn’t to us to advance either the broader health policy or the clinical guideline process but really to provide the tools to enable that to happen.

So, we were trying to, if you will, sort of finesse and focus on these are the things that we’ve really been asked to accomplish but recognize the context of it really takes a very broad net to provide good public health.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
Yes, I will add that I don’t think we really addressed issues such as funding of health care institutions or medical care for people who need it and some of this happened while the Committee was actually doing its work, so we didn’t explicitly discuss that, however, I will note that your point is a very good one and that much of the care for many of these women who are exposed to Zika is occurring in, at least in New York City, publically funded hospitals and in federally funded health centers and we did find that in New York City at least that there were some pretty significant disparities at the beginning in terms of who
was receiving appropriate testing and we did a major outreach campaign based on those disparities that were observed in order to ensure that the appropriate women with the actual risk of Zika were being tested and tested...detected and tested appropriately.

And I think some of these tools we're talking about could really help with that type of identification to prompt the questions to be asked and could actually reduce the burden on the medical providers in those settings for ensuring that they’re ordering tests appropriately, etcetera.

So, it’s a major problem that I’m hoping that some of the work that we’re doing could reduce the time it takes to care for and do the appropriate testing to identify these types of conditions and make sure that we do identify them in all the populations that are at risk.

**Larry Wolf, MS – Principal – Strategic Health Network**

I’d also like to put in a strong acknowledgment of the highly interactive, engaged and maybe even coordinated efforts of both public and private areas to try to address this. So, we had a lot of collaborative work with everybody from the government agencies, from CDC, from many of the other parts of HHS, from the vendor community, from the provider community all looking to really come together and make this happen, obviously standards is a key piece on the technology side to make this happen and so the funding in all of this is complex and interwoven.

There was a lot of adoption that was funded through HITECH but public health was not one of the recipients of the HITECH funding and so, you know, there’s a question of getting the appropriate technology into public health to be able to act on the information that’s becoming available.

So, there’s a continuing need I think broadly to be looking at funding and lots of funding mechanisms here, but, again, we didn’t bring that into the work of the Committee.

**Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)**

Just one other editorial comment I’ll add is that these are really public safety risks. For example, we have, rule out MERS cases show up in New York City, they can show up anywhere. They can show up in an emergency room in a public hospital, they can show up in a family health center or they can show up in a very well-funded, private hospital. We don’t know where they’re going to show up and really in order to detect the first case of MERS in New York City we need to make sure that every patient who has a risk factor, who might have traveled to the places where that is, are screened appropriately and detected, and reported to public health so the appropriate infection control measures can be taken.

So, this is...these examples will keep on coming and I do think it’s a really critical piece that if we can improve our ability to do this overall as these risks emerge we will protect the entire public’s health.

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

Thank you and Gayle, final comment.

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

Yes, I just wanted to jump into that subject matter on the public health issue and I can...I want to thank CDC for the work they did especially on the Zika thing in Florida and what we have faced down there but I also want to say that from the public health perspective HITECH did not include dollars for public health and it should have done so, I really felt it should have done so, and there are many states who do not have the technology or the wherewithall to purchase the necessary technology to do what needs to
be done and especially as we have emergent diseases that are so travel related and that can be dispersed across the country very, very easily Ebola, you know, Zika, a variety of things.

So, I think that is something from the federal perspective that perhaps needs to be addressed is funding for state public health agencies to really have that coordinated approach across the country that would assist states, especially those who don’t have the wherewith all to do it and the technology there to do it. So, I think that’s an important issue this Committee doesn’t have purview over but in the larger context of conversation on the issue I think needs to be heard.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Thank you for that comment.

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

Thanks, Gayle and I’ll point out that even though the HITECH didn’t include funding for public health, Meaningful Use made the EHRs capable of sharing information to the public health department so that was one way that we helped to address that.

I want to thank both the Task Force and the Co-Chairs of the Task Force for tremendous work and point out this is a good exemplar, you know, coming to the end of our...the end of our tenure in terms of the formal HIT Policy and Standards Committee of an important issue that is...that involves the detail...that shows the details required in order to do good and to prevent tragedy, a condition that can affect half of the population of the planet and all the families around them and the offspring, so clearly something that’s an exemplar of the unification of public and individual health.

It’s also a good opportunity, and it was very heartwarming to see that the Task Force worked on the consideration of the workflow, as Dr. Fleming open up, certainly none of us physicians want to go back to the paper because that was untenable and not good medical practice, but we also live in a world where we don’t quite yet have the tools necessary either to share information with public health departments or to manage information in an appropriate way so we certainly have that as our challenge ahead both the sharing and the interoperability as well as the appropriate management of information in ways that are useful, usable and actionable as you point out.

So, thanks again and so we’re going...we’re ready to have a vote on the recommendations. I think I’ll give Gayle a chance to just phrase the consideration she would like to have as an update as we vote on it because I would imagine that we want to have an amendment to the words that are already put there in order to incorporate her concerns that were echoed by other members of the Committee. Do you want to...

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

Yes, I would just really recommend that we include some provision to have the discussion on privacy and how we address the specific dealings with termination of pregnancy, and how that might be included in a condition that would be reported or...especially if you’re having lab data reported directly, you know, to public health that could indicate there was a termination of pregnancy. I don’t know how you might word that and I think perhaps if you could come back with some kind of a recommendation and put that within your specific recommendations that those privacy concerns be very carefully considered and also want to offer the difference...the specific regulations state-by-state on consent dealing with that issue.
Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health

So, let me try to incorporate that as an amendment to the approval motion and see if others agree with that. So, is there a motion to approve the recommendations as amended by Gayle?

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

So, Paul...

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

We need a motion in a second then we could have discussion again. Was there a motion?

M

So moved.

W

Second.

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

Okay and now we’re open for discussion. Kathy?

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

So, I think it would be helpful for us to have specific language that addresses the two points brought forward by Gayle and Gayle I don’t know if you have crafted specific wording that you would like to propose to the group?

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

No I have not and what I would suggest perhaps is if staff could come up with some specific language and we circulate...we do need to approve these recommendations, and we approve the recommendations and circulate the amendment for further approval and that can be done via e-mail.

So, rather than hold things up we may not have another even electronic meeting that this can be done and that those recommendations, that last recommendation, could be somewhat wordsmithed as necessarily through e-mail, but the content being essentially addressing the two points of privacy and state consent and privacy laws.

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

Spoken as a true legislator. So, you are recommending that we approve the recommendations and circulate an approval, a draft for approval as an amendment?

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

Correct.

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

Okay.
Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

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

Let’s have a re-motion for that then.

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

I so move.

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

Okay and a second?

W

So moved.

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

Okay, any further discussion about approving the recommendations and you know that there’s an impending amendment to be circulated. Floyd?

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

To perhaps avoid the need for that, perhaps just some wording that we recommend further analysis of privacy and national privacy and state consent issues, laws, regarding pregnancy and just that way we can just approve it today, just a suggestion.

W

It’s basically termination.

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

Kathy?

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

Or could I suggest some substitute language for that because I’m of the same mind I think that especially knowing that our tenure is short and I think just adding the Task Force and the Committees acknowledge the need to address the state laws which may impact implementation of Task Force recommendations and the further need to address the complex privacy issues related to pregnancy.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)

Are we...just a question, are we talking about specifically termination of pregnancy or are we talking about pregnancy as a whole?
Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I think it would involve both.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
Okay.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
All right.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
When the initial lab report comes in that there’s a pregnancy you don’t know whether there’s going to be a termination but then if you have further reporting at that point there would be an indication.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
I would suggest contra to that, that we focus more broadly on data that may be secondary to reportable conditions that may have some sensitivity attached to them and address this as a more general rather than a specific point.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Other discussion about two alternatives, one is to have the amendment accompany the motion today. Another is an alternative amendment today or in the future.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Can I clarify maybe?

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

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
This is Jon...nope, now it’s Jon. Just to be clear. Does anybody think that the general gist of what Gayle is getting at is a bad idea? Okay.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
What is...

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
So, however you phrase your recommendation we’ll follow it, okay, so just as you think about parliamentary procedure...thank you.
Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
This is Michelle, can I suggest since I’ve heard a few different options that it might be better to do over e-mail so everyone can see it and we can work on revising it, but overall it sounds like we’ve decided that, you know, I’ll let everyone vote, but that will be the next step.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, I mean, that’s consistent with what Jon said which is the wide agreement about the need to be sensitive in this area and let’s get the words correct, you know, pretty precise so that this recommendation and sentiment can be clearly communicated back to ONC and Dr. Fleming. Okay, Anne did you...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So, I have new motion that I think will help with this. I move that we approve the current recommendations of the...that we have before us contingent on e-mail approval of language to be submitted regarding pregnancy and privacy concerns or some such thing, okay?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
That’s good as well.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Is that a reasonable motion?

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

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
To have approval contingent?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Yeah, so we are approving this and...I mean, I don’t know what word you want to put in there, but we approve this and we except also to approve language related to concerns regarding privacy and termination of pregnancy.

Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
And so, just to jump in, I think what we’ve done on occasion in the past is something similar where the recommendations are approved on their face now, we can add in a little bit of a sentence or two, or whatever is needed to address this point noting, I think, Arien’s point about the sensitivity in general of certain types of data in this space and we can share it by e-mail and get final thoughts on that before we submit it, but I think where we land, based on what I’m hearing, is that we’d have the recommendation approved today, we can fine tune that bit of language, add it in before the transmittal letter goes forward.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Yeah, I think that’s what we have done in the past and that’s cleaner, in my view, way of doing this.
Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
And I think we need to withdraw the existing motion on the table and restate the motion. I withdraw my motion.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay. I think the original motion was that we would approve the recommendations with the further instructions to the Task Force to develop precise language that incorporates the concerns raised by you.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
I so move.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Okay, thank you, and a second?

W
Second.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Any further discussion? And I think both the ears and the minutes will reflect what we’ve said and I think we can work this out and follow-up. So, all in favor, please say aye.

Multiple
Aye.

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

M
Aye.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, was the aye...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Can I ask for the folks on the phone if you’re in the webinar if you can use the…there’s the green and the red, if you could use those so we can tell how people are voting; it will be easier, thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
So, people on the phone, please vote and then I’ll ask for any abstentions or nays. Okay, the motion passes and thank you very much to the Task Force members and to the Co-Chairs, thanks, very much.

Anne Fine, MD – Medical Director, Reportable Disease Data Analysis and Informatics Unit, Bureaucracy of Communicable Disease (BCD) – New York City Department of Health and Mental Hygiene (DOHMH)
Thank you.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
At this point I think we’re going to break for lunch Michelle?
Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We have...

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

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

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

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, if there is 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 will turn it over to Jim to open up the lines to see if there’s anybody on the phone with a public comment.

Jim Wetherill – Technical Specialist – Altarum Institute
Okay, if you would like to make a public comment and you are listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you are 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’ll wait one more minute for folks on the phone but while we do that we’re going to break a little bit early for lunch.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Actually can I just make a comment?

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

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yeah, also while we’re waiting comment, it’s Jon White again, I had somebody ask me a question while this has been going on, just to be a little bit more clear about Dr. Fleming, so Dr. Fleming is here as the Deputy Assistant Secretary for Health Technology Reform. Dr. Fleming will be reporting to the National Coordinator, obviously we don’t have a National Coordinator Appointee yet, which is why I’m sitting here being the acting, but at such time as that happens that will be the working relationship.
I think those of you who have worked with ONC over a long period of time know that, you know, we’re a team, so that...you know John is part of the team but just in terms of the actual structure of ONC that’s the structure, so appreciate the request for clarification.

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

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**
Thank you, Jon. So, it looks like we have no comment in the room and no comment on the phone. So, we’ll break a little early for lunch and we’ll come back at 12:35.

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

**M**
I’m going to call back in.

**Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation**
Many times much of what is in our chart comes from the patient both in the terms of some of the subjective experience and increasingly in the form of objective data and as we’ve been making those observations clearly the consumer ecosystem has exploded in the health...the digital health space. So, against that background the Consumer Task Force reviewed a Draft White Paper on the use of Patient Generated Health Data, so called PGHD, because we have to have an acronym for everything, and the Task Force is going to review their comments. So, Leslie and Emily are here to provide the overview from the Consumer Task Force. Thank you.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
Thanks, Arien and first I’d like to say thank you to the group and I’m going to tell you a little story. So, about five years ago, I think, we heard some testimony on patient generated health data. At the time it was quite a difficult concept to grasp we weren’t quite ready for that. And I think Paul you were there, we we’re in a hotel, and a Geisinger physician presented testimony and she started with her arms crossed and said “I really didn’t want to do this, I hate the idea of patient generated health data, I was afraid of noise, I didn’t want to know but I’m a better doctor now.”

She went onto to describe how the medication errors in her charts were significant sometimes as much as 30% and that when patients participated in recording the drugs that they were actually taking that the records were much more accurate, more dependable and as a result things like her time to review a chart became lessened because she was more confident in the data that was in front of her and so we had a convert and I remember at that meeting shoulders dropped, people felt more at ease and wondered “well, how could patients help with patient generated health data, how could they help increase efficiencies in our organizations, provide better accuracy, better outcomes and improve our relationships” and it was a real turning point for us.

So, after much of that work we, under ONC’s leadership, then began to look at patient generated health data in earnest and as a result had this wonderful White Paper to review.

So, today I’m going to take the place of Patty. Patty Sengstack is our leader and done a great job and she was not able to attend today so I’m here in her stead so thank you and bear with me.
So, today we’re going to review the charge and have some presentations by Elise, by Emily Mitchell here working on behalf of Accenture and providing great work on the White Paper, and then we’ll go over our review from the Consumer Task Force. So, next slide.

Our group...and can we get this screen here to...ah, thank you. Our group was really diverse, representing providers, patient advocates, technical liaisons, wonderful staff, Margeaux from ONC, and we were able with this group to see a very broad spectrum of how patient generated health data might be interpreted, used and embraced. So it was a great, great group.

The Task Force was convened on a needed basis. So, the Consumer Task Force, as you’ve seen, we’ve brought different information to you on an as needed basis under the direction of ONC and so in this particular case we were asked to take a look at the Patient Generated Health Data White Paper and we provided feedback and today you’ll hear that feedback. Elise?

Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So, I thought we would kind of start by talking a little bit about kind of ONC’s interest and how we got here and I think Leslie’s story is a perfect segue to that because PGHD is not something that, you know, we just started looking at it’s something that ONC has been very interested in for some time just thinking about how the health IT environment can benefit the patient, how the provider, the doctors can also benefit from having the information that patients can provide.

So, just to start on...yes, this slide. So, patient generated health data I guess the first part is to think about how ONC thinks about that and part of it is first thinking about who holds or who collects the data and that starts obviously with the patient.

We’ve done a lot of work to make sure that we are noting not only the patient but obviously the authorized representative. We recognize that the care team for a patient can also be diverse so we want to think about that in terms of the collection of the information.

In terms of the type of information it could be diverse, it could be the health history, it could be biometric data, it could be data that’s collected from a device, obviously in these days and times it’s very common for information to come in through different types of trackers and so forth and that this information could also be provided to the doctor, to the provider.

So, there are different types of it and our goal has been not to be limiting in terms of the type of data that can come in but recognize that it can come in from different sources and serve the needs of different types of patients whether it’s a passing patient or someone who has a chronic illness and can also benefit a diverse set of specialties. So, next slide.

So, in that regard we talked a little bit about this already, but one of the things I wanted to note on this slide is the types of care and I think you see that in how ONC has approached our work here and our interest at the person being at the center, which is another piece of this equation, is that the benefits are also to the patient in terms of them being able to have a voice and being able to share with their care team what exactly is happening and provide more ready information possibly on a daily basis or automatic information that is transferred over to the provider or the patient.

The opportunities to reduce costs, to reduce readmissions, to provide a more complete record of what is happening in terms of the care to the patient we think is there and we want to make sure that we understand the full landscape.
Obviously, there are a number of sides of PGHD or patient generated health data that inform our thinking and that’s a lot of why we are working to have the draft White Paper and we’ve been working with Accenture and now with the Committees is to have an understanding of the landscape.

So, as we think about policies going forward, as we think about next steps in terms of whether it’s interoperability more generally or consumer engagement in their care we want to understand what the landscape is so we really do appreciate the work of not only Accenture but also of the Committees in thinking through these issues and helping to inform our work as we go forward. So, next slide.

One of the things I did want to mention is, you know, this is an ongoing process in terms of us thinking about PGHD. In our 2015 Edition Rule, as you see on this slide, we included patient health information capture criterion and this criterion is really to get at PGHD and different information that can come into a health IT system and possibly be integrated in or be provided for the doctor to have at their ready in terms of the care.

The patient health information capture criterion is also broad and that was very purposeful because what we heard from commenters through the proposed rule and what we heard even before that is that the type of information that comes in through PGHD is different and it depends on the specialty, it depends on the need. So, we wanted a criterion that set in place the functionality that we would be looking for in order to certify to it but allow the flexibility for vendors, for the providers and the patients that they serve.

So, there are two key components to the criterion, one is the ability to identify, record and access information directly and electronically shared by the patient, and again, or their authorized representative.

The second part is a reference or a link to patient health information documents and that allows flexibility whether it’s a birth plan, it’s some type of care plan, something else that actually can be linked into the record through this criterion and the functionality that it provides.

When we put this out in the final...when we put it out in the proposed rule and we got comments back we really did get broad support for this criterion and I think that recognizes where health IT has advanced over the years and the interest in thinking about this happening in a way that benefits all in the care team and across the care spectrum.

I talked about some of the different ways that...some of the different types of patient generated health data that would fit into this functionality criterion, the care plan for example, but also you can think device information, information that comes in through a device, could also be integrated into the health IT system for purposes of meeting the certification requirements. So, again, it’s very diverse and that’s purposeful.

So, as we go forward and as we talk about now the White Paper itself we wanted to put this out here as something that we’ve already started on the path to think about PGHD. And not speak for CMS but CMS also has done that. If you look at MACRA and you look at the Quality Payment Program in the Advancing Care Information Category, information category, I’m not going to use acronyms today, I’m trying very hard not to use acronyms, but in the ACI category, Advancing Care Information Category, there is a PGHD component so that a provider who is participating in ACI can get additional credit if they in fact...additional credit in their performance score if they do engage in a PGHD activity and that points back to ONC. So, again, the harmonization and working between ONC and CMS on addressing issues like this and bringing PGHD opportunities to the care continuum.
So, those are two activities that are ongoing but we look forward to continuing this conversation and I think the White Paper is an important component of that and of course we look forward to hearing the feedback from the Committees that have been working on this. Thank you.

**Emily Mitchell, PMP – Senior Manager – Accenture Federal Services**

Great, so I’m Emily Mitchell from Accenture Federal Service and I’m the Program Manager for the Patient Generated Health Data Project.

As Elise and Leslie introduced, back in January, ONC posted the White Paper my team drafted entitled “Conceptualizing a Data Infrastructure for the Capture, Use and Sharing of Patient Generated Health Data in Care Delivery and Research through 2024.”

Since our contract began with ONC in September of 2015 my team has been investigating best practices, opportunities and gaps in the use of PGHD in care delivery and research. We have conducted industry outreach to individuals and organizations familiar with PGHD and we’ve created environmental scans and literature reviews to develop our understanding of PGHD building up to this Draft White Paper which is now available online for public comment.

And I do want to emphasize that this is the draft version and the intent of our project is to update it based on findings from our two pilot demonstrations that I’ll talk about a little bit later as well as feedback received from the Consumer Task Force and public comments as well.

So, through the course of our project to date the scope of our research on PGHD has been structured around seven key topics requested by ONC, which you see listed on the slide. The first is the collection and validation of data and tools which identifies tools used to capture PGHD. It also considers the types of PGHD that clinicians and researchers collect and how they validate the data and the tools.

Second, we have the ability to combine PGHD with medical record data which examines the opportunities for combining PGHD with data captured in the clinical setting.

And third we have data interoperability which examines the benefits and barriers to increased interoperability between the health IT systems and devices used to capture PGHD and that includes cultural as well as workflow barriers.

The fourth topic assesses the technical and cultural challenges related to using PGHD in big data analysis.

Fifth we have data donation which explores patient expectations for data sharing and methods to encourage and sustain data donation.

The regulatory overview discusses the current federal statutory and regulatory paradigms relevant to PGHD.

And seventh we have patient recruitment for research studies and trials which focuses on ways PGHD can be used to identify patients for studies and to connect the patients directly with the researchers.

So, some initial observations and trends we learned from our research indicated that the use of PGHD can have a very positive impact on patient satisfaction. In fact, through our pilot demonstrations we’ve heard directly from patients who have told us that they’ve changed providers because they wanted to get access to a healthcare program that would help connect their data to their care team and since
they’ve made that switch they feel they’re getting better care and are better able to manage their conditions.

Patient satisfaction is of course dependent on a number of variables such as how comfortable the patients are with technology they’re using and what sort of feedback loops they have with their clinicians.

And from the organizations that we spoke to through our outreach those that are seeing benefits from their implementation of PGHD tend to be focused on a specific disease or population segment. They’re also using some form of data analytics and simplified user interfaces such as dashboards or data visualization that can draw attention to key data points such as biometric values that exceed certain thresholds.

We’ve also heard that successful use of PGHD requires workflow changes. It’s really important for clinicians and researchers to assess what changes are needed to existing workflows and to implement relevant changes such as determining who is going to review the data and what steps they’ll take with that data.

In some cases we’re seeing organizations that are assigning specific members of the care team to triage the data and taking steps to minimize the burden on physicians.

Our initial research also indicated several opportunities for the benefits from PGHD. For example, PGHD can help patients engage in healthier behaviors. It can increase treatment adherence and potentially improve health outcomes.

PGHD also provides clinicians with a broader range of data helping clinicians make timelier and better informed decisions. And the use of PGHD can also help improve collaboration between clinicians and patients to develop a personalized care plan and to engage in joint decision-making.

There are also significant opportunities for researchers, PGHD can provide vast amounts of data and give researchers a more complete view of patients health. So, compared to traditional research approaches the use of PGHD provides opportunities for researchers to access more data, spanning broader timeframes from more patients from a broader geography.

So, based on the findings from our research and outreach, which took place between the Fall of 2015 and Fall of 2016, we synthesized our key findings into the Draft PGHD White Paper and this White Paper discusses emerging trends that enable PGHD and provides a vision for the future that enables the capture, use and sharing of PGHD.

The White Paper is organized around stakeholder groups and describes the opportunities, challenges and enabling actions for each of those groups. To align with the scope of our project the White Paper focused primarily on patients, clinicians and researchers as the key stakeholders but we also discussed other stakeholders that will play significant roles in supporting PGHD and those include policy makers, technology stakeholders and payers and employers. So we see all of these players as being critical components that need to collaborate with each other in order to realize the future vision of PGHD capture, use and sharing.

The White Paper discusses the opportunities relevant to each stakeholder building on the opportunities I mentioned a few slides ago. A few of the opportunities we highlighted in the White Paper include
improved patient experience and reduced time and effort on the part of the patient when PGHD use can reduce in-person visits.

Clinicians can have increased visibility into their patient’s adherence to treatment plans and depending on how they use the PGHD clinicians may be able to detect issues in their patient’s data and make timely interventions before it escalates to a costly care episode.

For the researchers PGHD offers the potential of a much larger pool of participants of data and the ability to monitor adherence to study protocols.

And in our paper we’ve identified many challenges that will need to be overcome in order for PGHD use to be effective. A central challenge to that is the business case. Traditional payment models haven’t reimbursed or incentivized clinicians to utilize PGHD and in order for healthcare systems to justify the cost and overhead required to implement PGHD program there needs to be a really strong business case.

Some of the other challenges include concerns about the accuracy of the data coming from consumer grade devices, concerns about privacy and security policies, the health literacy of patients and their comfort level with the technologies they would need to use to collect and share PGHD is also a prominent concern.

Additionally, there is user authentication, interoperability and data provenance concerns and cultural challenges such as the liability implications for providers and trust of the accuracy and the relevancy of the PGHD.

And, as I mentioned a few slides ago, the use of PGHD introduces the need for revised clinical and research workflows to ensure that the PGHD can be used in beneficial ways without overburdening the involved stakeholders.

So, in our White Paper, after discussing the opportunities and challenges for each of the stakeholders we also list several enabling actions that we suggest each stakeholder can take action on to contribute to the improved use of PGHD.

So, on this slide you see just a few examples of the enabling actions we called out in the White Paper. So, we encourage patients and caregivers to collaborate with their clinicians and researchers to determine how and what types of PGHD can be valuable for managing their individual health.

We also feel it’s important for clinicians to share their own observations regarding the benefits, challenges and best practices for PGHD and to support the use of PGHD for research purposes.

Our team recognizes that there is a need for increased funding for research studies that continue to investigate and get further evidence of the benefits, challenges and outcomes related to PGHD use and researchers should help to investigate new methods for data donation using PGHD and explore approaches to addressing patient consent.

We recommend that policymakers collaborate...I’m sorry, we recommend that policymakers encourage collaboration with the industry to strengthen model practices, consumer education and outreach as well as a review of medical malpractice and liability laws related to PGHD.
We recommend that technology stakeholders continue efforts to improve usability and to incorporate user centered design principles into PGHD products as well as strengthening privacy and security practices.

And for our final stakeholder group payers and employers, we encourage them to motivate clinicians to use PGHD through reimbursement programs.

So, as part of our project we’re working with two pilot demonstrations with the goal of using their insights from their findings to help inform the final version of our White Paper. Those two pilots which began late last summer have been testing the policies and workflows identified in our paper and my team is now working with them to begin analyzing the results of the pilot demonstrations.

And the two pilots are Validic working with Sutter Health in Northern California and TapCloud working with AMITA Health which is a health system in the Chicago area.

The Validic and Sutter Health demonstration is testing personalized care using remotely collected PGHD from devices. The pilot is focused on diabetes care but builds on knowledge gained from their previous pilots with patients with other chronic conditions and the pilot is researching the technical infrastructure and the clinical workflows needed to implement and scale PGHD initiatives and it also includes ethnography to investigate patient’s engagement and reactions to the program.

For the TapCloud and AMITA Health demonstration they are gathering PGHD and associated clinical results across several medical areas which include orthopedic surgery, behavioral health, bariatric surgery and stroke. Through the use of the TapCloud patient App and the associated clinical platforms this pilot is connecting patients and clinicians outside of the clinical setting with the goal of identifying how the patient’s feel and identifying when someone’s symptoms are improving or getting worse to help clinicians identify when a patient needs help.

Both pilot demonstrations have received really positive feedback so far from both the clinicians and the patients involved and the pilots have insights on possible approaches to dealing with some of the challenges that we’ve outlined in our paper. So, it’s very beneficial to have their real-world examples and data points as input for the final version of our paper.

And on this final slide, we have links to the Draft PGHD White Paper. It is open for public comment through May 8th and any public comments can be sent to the e-mail address listed here which is ONC-PGHD-Policy@hhs.gov and I just wanted to say thank you to the Consumer Task Force for...I know they spent a lot of time on calls the past few months and really appreciate the thoughtful and focused comments through all of the calls.

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

Thank you, Emily. It was exciting to look at the paper, it’s really well done and the group had some great constructive and thoughtful feedback which we’ll review.

So, we...our first impressions, overall...and I’m waiting for that to switch, there we go, okay. Members really did feel that this was very well written and had some general themes that they’d like to see expanded upon.

Identifying priority use cases and build upon the evidence of the benefits that are received, the outcomes and impact we think can really help inform concepts and also standards in the future.
We also noted that some populations with special needs or health literacy issues, low income and the underserved may not be able to participate in PGHD collection initially and have some barriers that we’d like to see addressed.

We felt that the conversations about the collection and the use should be expanded from not just static data but really trending data and I would add collaborative data. So, as individuals we create data and interact with each other but when you start to then have groups of people and stakeholders interact you have a whole new network effect and we feel that there’s an opportunity with patient generated health data to be inserted into this environment that will have new stakeholders really working well together in a collaborative way.

We felt that the...we appreciated the difference and the inclusion of stakeholder but we noted that a multi-interdisciplinary collaboration across the stakeholders is critical and we’d really like to see that vision expanded upon so the collaboration is as important as any individual stakeholder communicating.

The strength of the White Paper included that it was very well written and clear, thank you, very much, guys, did a great job, and we liked the fact that all the stakeholders were included. We felt that the real-world examples were very beneficial because often time’s people aren’t envisioning what this world might look like or how to incorporate things. Things as simple as e-mail is patient generated health data and we all know that when a provider asks a question of a patient they expect an answer back and that seems like a great way to start with patient generated health data, have real-world use of information coming back into the record to inform care.

We also felt that plain language is important because there will be new stakeholders that are looking at this paper and wanting to understand it in a way that doesn’t quite have as many acronyms and as many tech descriptions as we often do in our work.

And we also wanted to make sure that this is a coordinated work effort across ONC so where there is opportunity to use other work let’s build upon that. For instance there are 13 use cases that our Task Force...the ISA Task Force recommended to be included in the Interoperability Standards Advisory that are all about how patients interact and very much about patient generated health data and we’d like to see that work continue and to be collaborative across all groups.

We felt that the definition needed to be broader and to include not only the definition of an ONC provider but also phenotypic data, medical history, social determinants of health, maybe text messaging is also included as well as e-mail. So, we also wondered if the definition varies by setting or is it the application of this varies by setting. We do think that’s absolutely true.

We felt that the term person generated data might expand with the hope that we have data beyond the clinical setting where most of our care takes place and then also we felt that re-writing a future scenario that’s more person centric and less EHR centric, I think as we evolve into a collaborate and learning health system the EHR will be one data point not the whole data point and so having a broader look at person generated health data would be important.

We felt that the...we were a little bit divided on the future vision, we wanted to see the scenario expanded a bit but others imagined more automation than some and I think that’s just the nature of anything new as we envision a future that includes all stakeholders, the patients and their family members, it’s hard to really envision and so I think describing that is always a challenge.
So, let’s see that change again...go back, there we go. So, on the...each area of the stakeholders we provided feedback. For the patients...okay, here we go, one more slide, the other way. Okay, let’s go...here we go.

So, we felt there should be a greater emphasis on the caregiver role included in this so that patient generated health data is expanded beyond the patient themselves but also those who care for them and about them.

And we also felt that the patient’s want...in return for sharing their data and what motivates the patients to collect and use and share patient generated data so not just...we want some feedback loops included in all of this.

We felt that there should be more discussion on the use of PGHD for better quality of life outcomes not just quality of care outcomes and we felt there is a great opportunity, patients can provide input on how well they’re doing not just clinically but their life outcome, their expectations and wellness.

On the clinician side we felt there should be more examples of the business case and Emily touched on this. The business case is about creating efficiencies, maybe creating convenience, developing opportunities for patient retention, for revenue enhancement and also to create new connection and empathy between all parties each of which is an important business case that can drive the use of patient generated health data.

We also felt that the section for the clinician concerns like multiple data types, liability should be expanded so that there’s real clarity around what the opportunities and what the actual constraints might be.

On the research side we felt that the researchers should be encouraged to demonstrate the value of the collection and return meaningful feedback to patients. We heard over and over again patients who might be willing to participate but they really want to know how was their data used, how does it help me, how does it help those who are also participating in that research and the providers themselves.

We felt that the patient must have an increased role in research that uses PGHD and it’s a likely outcome as people are invited to present and participate in research and interact more digitally and directly.

We felt that there needs to be better description about the responsibility of researchers regarding the collecting, using and sharing of PGHD.

And on the policy side we felt that there needed to be more content about how federal agencies are engaged in supporting PGHD and also that their section needed more funding and incentives for PGHD use.

Members also felt that we should cover the role of policymakers in the state and local levels, back to Gayle's point earlier, patient generated health data is new, are there opportunities to review and due diligence that needs to be done by states to see how that will be addressed or what can be done at the federal level.

For the technology stakeholders we believe that it really needed to broadened our opportunities beyond technology standards and that usability issues were key, not just for the technology but also around the integration and presentation and use of PGHD inside the EHR.
We felt that developers must involve patients and clinicians in the technology design process for human centered...true human centered design.

And that there was a great opportunity for payers and employers around the use of incentives to encourage patient generated health data and collection of that data to improve quality and outcomes.

We...privacy also came up around privacy and discrimination concerns that patients might have by giving their data to payers and employers so that section should be expanded.

So, we also suggested some other tools and resources and outside the scope of this White Paper we believe there are opportunities like a table that will illustrate the types of PGHD by technologies and devices that are collected.

We also felt that actionable advice and guidance on how different stakeholder groups can interact with PGHD would be helpful and create some educational materials for each stakeholder.

We felt that there are very relevant and actionable information related to PGHD as we look at new policies and rules. For instance in MACRA and MIPS, Advancing Information and 21st Century Cures where each of these have opportunities for patient generated health data to improve those initiatives so we think it’s an exciting opportunity for patients.

And I think that in closing I would like, before we have comment, to add that I think it’s quite appropriate that the last presentation of this group is all about the patient because I think each one of us came to this group with that in mind, how can we help, how can we create a better environment for patients and the physicians that serve them so that we develop an ecosystem that promotes health, promotes wellness, promotes collaboration and care. So, ending on that note here today seems quite appropriate for each of us who have put our work and our hearts in here. So, thank you.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Thank you for the presentation and for the work of the Consumer Task Force and for the Draft White Paper. I’m going to take a little bit of chair’s privilege and make a couple of comments relating to this topic.

You know I think it’s important to use Farzad’s often quoted phrase “to keep eyes on the prize and feet on the street” it’s useful to paint a very vivid picture of where this might go. We get in danger sometimes when we try to turn that picture into a specific action and drive changes in workflow, changes in physician behavior, changes in patient behavior at a pace more rapid than they’re able to make and in that vein I’d observe that we have a really interesting natural history experiment going on right now in that there are a number of systems that have deployed system wide secure messaging with attachments. I’d mentioned Kaiser, DoD as just two examples of system wide capabilities for secure messaging with attachments.

And in my past experience I’ve seen a good amount of emergent experience in doing things like attaching a picture, a digital picture, of, you know, something on the skin or uploading a spreadsheet that contains a seizure diary or a set of glucose readings and that those kinds of emerging experiences can be useful in understanding the role that PGHD can play incorporated into workflow.

And I guess the last comment here is relative to the kinds of incentives that we put in place. I think that CMS got it right with respect to the way it framed PGHD. It’s important not to be too prescriptive because ultimately what really matters is driving better care, better health and more efficient care, and
PGHD might be the right tool and it might not be and it’s important to give local decision-makers, physicians, patients the tools that they can use to better design a good patient experience.

I think we’ve got Andy and Kim, Gayle and Lisa in the queue. Oh, and there’s...we’ve got more, so we’ll start there and then we’ll go...we’ll pick it up from there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Carolyn’s in the queue.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Yeah, Carolyn as well. There’s more in the queue. Go ahead Andy.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So, thank you and thank you for the report. Arien took with his bully pulpit and said one of the things I was going to say...

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Sorry.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Which is that there also already substantial experience with rather nascent forms of patient generated health data at places like Kaiser Permanente where today, which is my former organization for those who don’t know, where today more than 50% of all patient encounters are in fact through these kinds of methods and I will editorialize by saying any history is patient generated health data the question is who is responsible for recording it accurately, who is responsible for maintaining it, who is responsible for using it in any form of decision support or clinical management, not where does it come from. It all comes from patients. So, that’s the sort of editorial message.

I would also say that I’m not worried about the business case for this at all because the country is moving to value-based care and as fast as that happens this is going to happen really fast. There was no need to make a business case inside of Kaiser Permanente for doing these kinds of activities and no need for making more business case to make more of it happen.

It will happen when physicians and healthcare organizations understand that they are best serving, creating value for patients by allowing patients to participate in their care and you won’t have to reimburse them for these activities because they aren’t going to be reimbursed for activity.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Right.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
They’re going to be reimbursed for quality and service and outcomes, and that will be served by using these kinds of techniques very well. So, I don’t think you have to spend a lot of time fretting about what’s the business case for this as long as the country continues to move in a value-based direction. Thanks.
Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I think adding to that it’s what we don’t know about a patient that hurts us in value-based care and so patients can help by participating in giving their information.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Yes, absolutely no question about it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
No question about it and I’ll give you one teeny-tiny example for the doctors in the room who weren’t part of Kaiser Permanente, this was a huge learning when we first implemented an electronic health record we decided, because the prescription ordering part was automatic and the pharmacies were ours, that the script would straight to the pharmacy, the drug would be, you know, put in the bottle and ready for the patient to pick up when they walked, literally, down the hall before they got out of the medical office. Would anybody like to hazard a guess as to how many patients failed to pick up those prescriptions, when there was no economic barrier whatsoever, half.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
We had the same experience.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Half. Half of people don’t take the medicines, they don’t even pick them up when it would require two minutes to get it and so what that means to me is that we need to understand from people what they are and are not choosing to do and you only can do that if you have an integrated record like this.

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

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Okay. Kim?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.
Thank you. This is very good, thank you Leslie and team and Leslie you’re always so eloquent with your words and, you know, one of the points I wanted to make I think feeds into what Andy was just talking about and you can always use medication adherence or primary non-adherence as something to look at with a patient is...and ways to use the patient generated health data is in shared decision-making and so that is a great way and I think it can help minimize some of the things that people are experiencing with the primary non-adherence of the medications.

And then the second thing or a way to use the patient generated health data is in the between visits. We have a lot of knowledge and intelligence around the face-to-face visits but it’s the in between time that there’s a big white space that we don’t know a lot about and I’m hoping I get to work on a paper where we can look at some of the attributes that are important in the in between visits that would go along with patient generated health data that would be valuable in that space.
So, those are two places where I see that shared decision-making and the in between visit where the patient generated health data could be really valuable.

And then the third point I would like to make is it can be a lot of data and you may not know what to do with it. So, there has to be a way to make it consumable and usable and I think that kind of goes along with what Arien was trying to say is, once we have all of this how can we make it consumable and usable so that it can be used in the right way for the patient. So, thank you it was a very good presentation.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
To build on that on the shared decision making, I mean, we know that when people participate in shared decision making they make cost-saving decisions as well as care adhering decisions and these are not mutually exclusive. So, having that back into the record, having that kind of communication go forward is very important, so thank you for bringing that up.

Emily Mitchell, PMP – Senior Manager – Accenture Federal Services
Yeah, and I’d say regarding your final point with the volume of the data I think both of our pilot demonstrations have shown, you know, good examples of how you can use different approaches of...you know using dashboards to kind of simplify the process of reviewing the data. They’re not going through individual data points of this was this person’s, you know, hemoglobin level at this point in time, but they’re kind of looking at a dashboard and then just calling out where were the discrepancies that they need to pay attention to.

And our other pilot is pulling in symptoms where they’re looking at, you know, is someone indicating that they’re feeling a lot worse than previously and so it kind of summarizes for the nurse care team that’s reviewing the dashboard, you know, these are the top five patients that you really need to pay attention to right away and then you can kind of quickly just glance through and decide whether or not you need to reach out to any other folks but I think those are good examples of how you can take the volume of data and kind of distill it down to the important points.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
We have a very long queue. So, I’m going to review who I have right now in the queue. I’ve got Gayle, Lisa, Larry, Carolyn are you still...okay, Carolyn, Lorraine, Chesley, Karen, Jamie and Paul.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Wow, okay.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
So, we’ll go to Gayle.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And Troy on the phone.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Oh, and we’ve got...and Troy on the phone, okay, we’ll get there.

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

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature
Since we do have such a long queue I’ll try and be very, very brief. First of all I want to say, you know, patients are the center of healthcare, I mean, that is why you have healthcare it’s about their health not about our healthcare system. So, putting the patient in the center and having their active participation is essential, it’s also a cost-saver.

In the long run the more buy-in you get from the patient the more the patient participates in their own healthcare the more likely they are to take the medicine and not be among the 50% of people who don’t pick up their medication and then don’t take it or don’t take it accurately.

But the one issue that I would love to see more information on and a more in-depth review of as you move forward is really looking at the liability issues. I think from the provider’s perspective when you have a large volume of information coming into the chart where does the liability sit, how often does that record have to be reviewed?

If the information that’s coming into that chart is not accurate or doesn’t present the whole picture...if you’re downloading glucose monitors for instance and you’re not doing it all the time and you’re making decisions on insulin levels are you...where are you...and you’re advising a patient to do certain things and then you’re doing it incorrectly because you’re depending on that patient’s information that’s coming into the record, where does the liability sit and how do you determine that? So, you know, where do we go on the legal system on that?

So, I think especially with your two pilots going on I think that is part of a conversation that needs to happen as we move forward into this very, very important arena.

Emily Mitchell, PMP – Senior Manager – Accenture Federal Services
Yeah, that’s a great point and liability is something we heard raised through almost all of the outreach calls we conducted during our research phase. I know from some example for instance when we’ve spoken to the VA they’re very focused on setting expectations upfront with the patients about, you know, you’re providing this data, your doctor can access it but they’re not looking at it all the time. If there’s something that concerns you or is troubling you, you need to reach out immediately if you need urgent assistance. So they’re kind of setting that expectation that the patient should not assume that the doctor is going to act on every piece of data, but, I mean, it’s a very...yes, it’s definitely a challenge and I would certainly appreciate thoughts from others in this room on what you consider to be the right path towards addressing that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
But, I think as we do the revision then we’ll expand that section.

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

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Great, we...the queue is only getting deeper, so we’ll go to Lisa.

W
...
**Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation**
I got it.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**
Thank you and I’ll keep it short as well. Lisa Gallagher, I want to thank Emily and Leslie for a very good report and Leslie I want to commend you for your long-term dedication in the issue of patients as the center of healthcare.

Just a minor point, as I was thinking about this being our last meeting and in the entire body of work that we’ve done as part of each of these two Committees and the combined Committees and Task Force work as well, I look back at some of the material that we’ve created and posted on the website and was just reminded of the Data Provenance Task Force which I Chaired, we provided a report, it’s two years ago in January, so January of 2015.

And that Task Force was asked to look at the S&I Initiative on data provenance and the use cases that they defined and at that time we gave comments on the use cases but we also tried to outline some areas for future work around data provenance and so there were some recommendations in terms of communications and information interchange requirements, system requirements for data provenance, consideration of security aspects, policy issues that remain such as levels of trust for the data that traverses and the need to define a core set of requirements around data provenance.

And so, as I look back at that work I think it’s still relevant and hope that I can make a note to all that work on patient generated health data to continue to look at that and think about the technical aspects of implementing as well. So, again, thank you very much.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**
No, that was discussed and I think that beyond patient generated data using provenance information for patient intermediated data or mediated data whereby the patient might be collecting aggregate data from multiple sources and then acting as the point of transfer some way to know that this data has not been altered in any way was brought up. So, all the provenance information is relevant to this so thank you.

**Emily Mitchell, PMP – Senior Manager – Accenture Federal Services**
Agree, thank you.

**Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)**
Thank you.

**Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation**
Great and we’re lengthening the queue faster and then we’re draining it. So, Larry is next on the list. Please keep remarks and questions brief.

**Larry Wolf, MS – Principal – Strategic Health Network**
Okay, so just let me pick up on the data provenance piece that was perfect timing, thank you for coordinating that. So, I think the important piece for me on data provenance that Leslie touched on is as we move into an era of information moving across traditional silos it becomes really a key element regardless of the source of the information. So, it’s not whether it’s generated by a person about their own health or coming from a professional, or coming from a particular piece of equipment that we’re actually track that as part of the core information that we manage.
So, I think that we’ve got some important words in the acronym here for PGHD. So, I think the health piece is really a huge piece for continuing emphasis and if we really focus on the health and take it from the individual managing their health, managing their life that there’s a lot of activities where there is data generated that becomes useful to assessing health issues.

There’s a lot of work being done on the determinants of health and most of it says that what happens inside the health system is 10 to 20% of what matters and the other 80% is outside those four walls. And so engaging the activity outside those four walls I think is really essential if we’re going to really make progress in both the quality of health we provide and the cost of the health that we provide.

In terms of value back to the individual for their data there’s a really key piece and you touched on it of closing the loop back. So, I’m offering up information about me, a really valuable thing is to get back what does that mean, right, so it might mean, sort of diagnostically for me what does it mean but also it might mean in terms of the other people like me where do I fit, give me context of the information, help me understand my life by giving me the context of the data.

There’s been sort of plus and minuses over the years of reuse of information, you know, de-identified sale of data that then generates value for somebody. That value chain has value back to the individual as well and whether it’s a dollar return or an information return I think that’s an area where particularly around health data we could do a lot more.

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

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Great. Carolyn?

Carolyn Petersen, MBJ, MS – Senior Editor – Mayo Clinic Global Business Solutions
A follow-up on all the fine comments and praise for this work I think it’s really, really a large job, it’s really all-encompassing in many respects and a great, great start to something that’s going to become only more important as we move into the value-based environment and see more work with consumers through mHealth and other opportunities.

One suggestion I did want to make is to start considering the role of patient as a researcher, you know, there is quite some discussion about how patients are more engaged in decision-making and this can, in some cases, control cost because they’re engaging in that discussion.

I think one thing to consider also is that in some cases in the clinical environment the patient doesn’t engage or doesn't follow the prescribed plan that may or may not have been reached in a shared way because the patient is looking to answer a different question or address a different problem than what the provider has decided the actual problem is and by working as co-researchers with patients, with physicians, with researchers, other investigators, allied health individuals that can help us forward the motion because the patient is involved in the question and the research design as well and better utilizing this body of data we’re accumulating. Thank you.

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

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Okay, thank you. Lorraine?
Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health and Human Services

Thank you. I have a comment and a quick question, obviously, thank you for the presentation. With respect to the medication compliance issue it also works that people pick up medications and don’t take them, I’m certainly guilty of that for picking up a medication reading the side-effects about becoming homicidal and then deciding not to take it, so there’s also that part of the reliability issue of patient generated data.

But I did wonder if your Workgroup had discussions about sort of the unknown unknowns of what patients might choose to provide in the digital environment and then the physicians relying on some of the information that they may not have that the patient has chosen not to disclose so that they have some information so we kind of rely now on this electronic record that has some information but not all of it and making decisions based on that and if your Workgroup had discussions about what they can use and what they’re liable for and if that had come up in your group?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, I hear several questions there. The question about liability did come up briefly and warrants more work is indicated but the decision of what data goes into the chart is left to the provider...

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

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So the relevance to care is in that work step.

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

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It was also felt the high degree of usage will initially be questions the providers are asking who want a response, that opportunity also could include having structured data around that questionnaire in fact there is work already been done against that in the Patient Generated Health Data Workgroup under HL7 and the Consolidated CDA that I mentioned in the ISA we have these use cases for, so we do believe that the patient response is going to be one of the first areas of opportunity.

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

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And the third part of your question I’ve lost was that...
Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health and Human Services

About what they choose to put in and not put in...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, yeah.

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

And how the physician kind of works through...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Knowing what they might not have chosen...selectively not to put in.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, so, the...if we look at just practice of any kind of information that comes into the clinical setting the provider, the front desk, the nurse indicates whether that should be included sometimes its paper that is scanned into the record if it’s relevant.

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

When it’s relevant it’s indicated how it’s relevant, where it’s relevant in care, perhaps which episode of care that relates to that workflow is the same but is just now coming in electronically.

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

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You know I would consider just as you would get any sort of observation or a result that’s coming into the record it comes into an entry point, you can see that it’s a lab generating this, it’s a patient generating that and so forth, it’s a new data point.
It’s also very hard to manage voids, it’s impossible to manage voids so that is hard to do. But I think the more that we see this kind of collaboration take place the more opportunities are for alerts to say, I’m missing something, how do I fill that we think that’s an evolving spot. Yeah, anything else to add? Okay.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Great. So, just to review the queue, we’ve got Chesley, Karen, Jamie, Paul, Kay, Aaron, Troy I believe...

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

And Troy.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Is on the phone, any...

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

And Josh.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

And Josh, okay, so Troy, Jon and then Josh. We’re not even halfway through. So, Chesley.

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

But who is counting?

**Chesley Richards, MD, MPH, FACP – Director, Office of Public Health Scientific Services – Centers for Disease Control and Prevention**

Thanks for the work it’s terrific. I didn’t see public health mentioned as a sector and so it maybe more broad than thinking about EHR certification or patients it maybe people in other forms of health information technology but I really think that’s an unexplored but potentially very important part of what we do in public health.

Right now we’re very dependent, as you heard this morning, on the data coming out of the clinical system and yet for prevention and health promotion early detection of some types of epidemics or health emergencies person centered data may actually be a real goldmine but we need guidance on how to explore that so anything you could say about that would be really helpful.

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

You know shame on us for not doing that and including that. I think we envision a time when the patient is interacting just as any other stakeholder would interact including public health so that’s worthy of more work. Thank you.

**Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation**

Great, thank you. Karen?

**Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition**

Thanks very much for your work and I work in the employer, payer, purchaser space so I appreciate that we were pulled out as a stakeholder. This is a very active area, several of the Committee members have mentioned about shared decision making and value-based care, and that’s what we do at coalition, business coalitions.
On the bullet point that says, members thought this section should provide more discussion around the alignment of incentives I would just add a point that what we’re finding is you have to make sure that the incentives are to the physician and the patient, and that they are aligned. So, we’re really finding that this encourages that shared decision making conversation that needs to happen.

Another barrier, I’m wondering if you spent any time talking about, is the very low health literacy rates that we have across the general population. I know you...there’s a note in here about some special populations that may not be able to participate in this important sharing of data but what we’re finding is that just the general population...you know we all deal with healthcare all the time so we have a higher health literacy level but generally it’s very low and the docs are really concerned about the data quality, especially when it is self-reported and what we’re finding, long story short, is that this shared decision making opportunity, that conversation that the doctor has getting that trust from the patient really, really improves the health literacy about their conditions, it improves adherence, all the things that we’ve talked about around the table.

So, I guess my question is have you talked about the health literacy aspect and when you were talking about the alignment of incentives were they for the patients and the doctors?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yes and I would also add the word “incentive” doesn’t always mean monetary.

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

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I can be relationships.

Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition
That’s correct.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
It can be things that each party feels there is value and therefore we do this together so we need to think more broadly than incentives and automatically go to finances in this case.

We did talk a little bit about that, the health literacy issue, you’re right on as you participate in shared decision making there are opportunities for education. One point was brought up, I can’t remember who talked about a provider who said if there is a...if information is incongruent, the provider is saying a different thing than the patient, that itself is valuable...

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

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Because now we have an opportunity to discuss something that we didn’t even know existed that this incongruence existed so that was another aspect.

Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition
Okay, thank you.
Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
Thank you. So, Jamie?

Jamie Ferguson – President, Health Information Technology Strategy & Policy, Fellow, Institute for Health Policy – Kaiser Permanente Institute for Health Policy
Thank you, well, I’m in a position where other people made 2/3 of my comments so I can be brief without repeating those things but I do feel like I’m also repeating a comment that I made, I think six months ago, when we talked about this, and that is PGHD is not one thing and, you know, we do have a lot of experience in Kaiser Permanente but we really see three distinct types of patient generated health data generally. The first is one-time electronic questionnaires. The second kind is data from consumer grade general wellness devices and the third is professional grade monitoring devices for remote monitoring and the only evidence of clinical efficacy refers to the professional grade monitoring of people with serious conditions such as diabetes or congestive heart failure.

And so I think it’s really important to differentiate the different kinds of patient generated health data and the different use cases. It’s not all one thing and we should stop talking about it as if we were one thing and I think that, you know, many of the benefits, however well-intentioned that we are talking about, really are speculative and so I think we need to point back to those things that have proven efficacy.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Good comments.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
Great comments.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Thank you, good comments, Jamie.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
So, Paul?

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Great, I want to thank the Committee...the Task Force members and I agree with Leslie it’s good that we’re ending on this topic you can clearly see the generated interest and I think the White Paper is really good and the comments from the Task Force are really good.

I’m going to echo some of Andy’s comments. I have still a small practice at Palo Alto Medical Foundation and we work with our vendor, who is Andy’s vendor as well, to develop their patient portal and now we have...and we’re the first to implement it and we have 86% of our people online with us. So, it’s just the way they want to interact.

Three important lessons from that, one is convenience. I had dinner with Regis McKenna, which as you know is a renowned marketer, and one of his comments is convenience is the only thing that matters and that’s true with people who have a health condition or health question.

The other important lesson is being instead of the point-of-care, which is confined into four walls; it’s really at the point of need which is where we need to be. Scheduled, as you know, are basically random events they aren’t tie to any physiology or any need, if we can reach them, as we can, now online, reach
them at the point of need we can head off things or we can head off anxiety for example and get answers to them.

Somebody else made a comment about whether PGHD is the right new term. I think I’d agree with that. So, it’s really the voice of the person, not patient generated health data...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Right.

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
I think we’ve sort of put our technology bent on something that’s very natural which is communication and we just need to be in line with their life. The in between...what we consider in between is actually their life so can we have the voice of the person just be manifested and incorporated and you mentioned social determinants of health which, as you know, is a far more potent and influential in a person’s health and well-being.

So this is our avenue to capture that important information just like we talked about pregnancy, why don’t we just ask the person, this is another one of...there’s so many hints that we have in the end its behavior that we’re trying to change, behavior influencing a person’s health and this is an instrument of being able to understand the factors and then we as healthcare professionals need to be able to react to those things many of which involve participating in the community which is where we, what, live, work and play, right.

So, at any rate, congratulations and kudos to pointing out all of these important aspects of expanding our reach from an electronic health record system to life and all the important comments of the Committee members. Thank you.

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

Emily Mitchell, PMP – Senior Manager – Accenture Federal Services
Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Excellent point. Kay?

Kay Eron, MBA – General Manager Health IT & Medical Device – Intel Corporation
Thank you, so much for the great work. I just wanted to let you know that, you know, we’ve been very passionate at Intel around the patient generated data. We’ve been working on wearable data and clinical trials, and prediction of patient progression with Huntington’s and Parkinson’s disease. So it’s a very passionate area.

I wanted to mention that two areas that I thought would be suitable where you talked about business case and how you want to...we need to find more reimbursements and ability to afford kind of patient generated data and I think one suitable area is definitely, two people already mentioned, medication adherence, so pursuing that could really visibly provide the value of patient generated data.

The second piece is clinical trials and I think that’s also...you know it’s not a per se patient/physician context but it’s definitely important context for healthcare.
And for both of those I think it’s important that standardizing data sets so that data capture, if you will, so that you can ensure that this data can be reused not only in this certain situation but potentially for future research and development as well.

And then the last thing I wanted to mention was that if you look at standardization there are countries who’ve been using standards like Norway and Sweden where they embrace standards like continua which enables for this so considerations around how you would recommend that, you know, some kind of standardization for reuse of the data and the data capture would be great.

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

Thank you. I think you do bring up one gap area that we should look at and that is taxonomy, vocabulary around patient context and how do we use that. I think it’s a gap area to look at as well. Thank you.

**Kay Eron, MBA – General Manager Health IT & Medical Device – Intel Corporation**

Thank you.

**Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation**

Great. Aaron?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer & VP Government Relations – Imprivata**

Thank you and first of all, great job. Leslie, always appreciate your hard work on this and your vocal opinions on patients is so needed and so refreshing I really appreciate that, both of you, great job.

A couple of things, real quick, number one, as we learned in the API Task Force about data and data traversing from one domain to another there comes the issue of who owns the data and security and privacy around that. So, I would be remiss in saying that maybe we need to take a look at that in finite detail because that’s very important.

Hospital systems are going to need to know that they can trust the data they’re receiving and that the users and the consumers need to be able to trust the data that they may be receiving or the interpreted results of the data that they’re sharing. That’s a very big issue for me that I think we need to address.

Second would be clinical relevancy just because you had a latte at noon does that matter but if your heart rate up maybe that matters, right, and what was the cause of that. So, how do we get to the point where the data is giving us a story versus just being that you had a latte at noon?

Last, but not least, is that who. We still have an issue with identity and where is this data coming from and from whom. Hospitals are seeking a number of different types of solutions out there from biometrics to other at some point a national strategy needs to be adopted and identified as to how can we trust what we’re receiving.

You know I personally found out I could give my iWatch to a friend of mine in a golf cart and every time we rode around it showed I had many more steps than I actually did for the day. So that’s not good for someone who is thinking Aaron is really being active. So, those are the kinds of things we need to address and look at in the finite detail but great work.

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

Thank you, that’s great advice.
Wonderful. Troy?

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

Thank you…

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation

Troy if you’re…

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

I was a 28 year employee of Kaiser Permanente I can echo Andy’s sentiments about, you know, the fact that we are on the leading edge of all of this stuff. And while we attempt to use and incorporate patient generated health data in many different forms the one thing that we keep coming up against is, what I believe others pointed out, the difference between consumer grade products and the industry grade products and the variances that we see when we receive that data.

And one of the things that really kind of impedes us from going forward is the fact that how can we trust that data without knowing that the data is correct and that the device has been through some kind of quality assurance through validation?

Now, as we all know, I mean, in the healthcare setting those devices are blood pressure cuffs, are glucometers, they are QI’d frequently so that we make absolutely sure that we have the right data.

So what I’m curious about is did the Task Force talk about some kind of an approval process or validation process, or an accreditation process for consumer grade devices that would meet the industry standards that could be distributed to the public and say these are devices that actually have been approved, they’re accredited to be accurate within plus or minus percent and can be utilized for patient generated health data that can be transmitted, you know, depending on if we have the interoperability structure to do that, that can be transmitted or transcribed into your electronic health record and utilized by your clinicians to make clinical decisions?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, we did talk about…it was all over the world in terms of calibration and continuity, and accuracy but we didn’t offer up any solutions in this paper. I think it was a bit out of scope. But identifying that and maybe expanding on that as a problem to solve is an important part of the revision.

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

I wonder if I could…while we’re not to motions just yet, but when we get to motions I’d like to add that as something that should be added as a recommendation.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation

…do official recommendations out of this report this is an informational session. Before we go to our DoD Representative I want to do a brief plug for U.S. Army Surgeon General, I think former Surgeon General, Horoho’s talk on white space. If you Google Horoho white space you’ll get to that talk and it’s actually a really nice way of framing how to think about patient engagement and access in a broad
system-wide component really focusing on those interstitial moments in between the formal office visits but over to you.

M
That’s a great intro because General Horoho’s talk that you’re alluding to has certainly influenced my thinking on the subject and I don’t want to repeat a lot of what other people have said but I think an emerging theme is that or a constant theme when this subject is discussed is that the issues are about responsibility, you know, when does it become the responsibility of the covered-entity versus the patient and going back to Dr. Dr. Tang’s question, it’s not really who generated the data it’s who is controlling the data and I think it’s probably better to talk about patient controlled data and then we need to address how do we maintain data integrity and provenance and accuracy of the patient controlled data space.

We can certainly figure out how to make connections between the EHR in the patient controlled space, but how do we write policy about that?

And then tying that back to one of your recommendations from the feedback about the federal agency work in this space, I don’t like speaking for my VA colleagues, I don’t think that Dr. Nebeker is here, maybe someone is on the phone, but obviously the VA’s Office of Connected Care has been doing great work in the patient generated data space and we, the DoD, are looking at how we will make use of that for our separating service members. So we’re absolutely doing some work that I think is of interest to the group on that area of policy. Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Maybe we can use that for use cases, thank you.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
Thank you. I’d also want to plug the ONC report on non-HIPAA covered data which I think covers a lot of the same policy grant. Josh is on the phone, one more?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School
Yeah, hi, sorry it took me a moment to get to the mute button there. Thank you very much for this report. I think it’s a really important topic. I’ll try to keep my comment under a minute which I think I can do.

I just wanted to highlight what I think is a best practice for provider organizations to think about and this is for the particular flavor of PGHD which is when a provider works with an outside organization to bring data in, summarize them and maybe do things like calculate risk scores or aggregate information in a way that provides an easy to view screen or dashboard for providers and I just want to highlight as a best practice there for providers I think provider organizations should be looking for access to those summary or dashboard uses but also for ways to bring in the underlying data that support the conclusions and that’s just something providers should be thinking about for their own record keeping.

If it’s possible to try to standardize all the different ways that the supporting data could flow in and I would put standardization of those flows at may be a lower priority but enabling the raw data to flow in I think is something that providers should be considering when they’re looking in this space.

Arien Malec – Vice President, Clinical Solutions Strategy - RelayHealth Corporation
I think you made it, Josh.
Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Thank you, Josh.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
And then we have one more comment on the phone?

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

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Okay. Wanmei?

Wanmei Ou, PhD – Director, Precision Medicine and Data Science – Merck
Yes, so it’s Wanmei here, and it appears that actually my comment is very similar to what Josh just provided. So, yeah, so today, right, given the technology we are able to measure something like every second or every minute and continuously for many days and but a lot of times those raw data are not the ones that we use to make a clinical decision.

So for example, I heard someone mention about Parkinson’s disease in that arena even for the clinical grade device, the accelerometer and the gyroscope, can measure every second or so but the real clinical information is the one that’s derived from those every minute or every seconds, raw number, into something like tremor, bradykinesia or dyskinesia.

So I’m just curious about whether the Task Force has thought about how to guide a standard and governance structures for those raw data versus the device, more clinically relevant information?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
We did talk about it briefly, I can speak to some efforts going on in HL7 under the Consolidated CDA there’s been considerable work done in defining patient generated data for patient response, several different questionnaire types, also for care plans like advance directives and standards to get links of documents.

As Elise indicated in the 2015 Edition we’ve identified the overarching themes for patient generated health data and the opportunity to have the standards begun there but the groups that have been involved within HL7 we’ve looked at emphasizing the existing standards that are already in regulation and enhancing those like the Consolidated CDA, like attachments to secure messages and so forth. So, that work was being done outside of this particular paper but informs the need for standards, reuse of standards and advancing our technology.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Excellent. It is been obviously a good discussion and it was fortunate that we started a little early because we ended up pretty much on time. So, Michelle, over to you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thanks, Arien. Well, we’re going to get ready to wrap things up. You all may have noticed that there’s cupcakes. Some of you enjoyed them after lunch and that’s great and some of you if you want to enjoy them go ahead and enjoy them now.
So, we’re just going to wrap things up with a few closing remarks. You all may have also noticed that there are boxes in front of you. Those are certificates for all of you to thank you for your service with us we couldn’t thank you enough. We’re going to go through a few folks in the room to say our thanks and then we’d like to have some pictures with you all. So, be patient with us. We will give you all some time if you want to make some comments as well but we’ll start with the chairs to make some comments and then Elise and then Jon.

W
Thank you.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Most importantly, before we do all of that we’re going to open up to public comment and see if there’s anyone in the room who would like to make a public comment and open up the lines on the phone. And there is someone in the room.

Jim Wetherill – Technical Specialist – Altarum Institute
If you would like to make a public comment and you are listening via your computer speakers please dial 1-877-705-6006 and press *1. If you are 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
Just a reminder, please state your name and public comment is limited to three minutes. Please go ahead?

Dan Rodie - Independent Educator & Consultant
Thank you, good afternoon, my name is Dan Rodie I’m an Independent Educator and Consultant but this afternoon I’m representing, EHNAC, the Electronic Health Network Accreditation Commission. As the conversation went on this afternoon one of the things that became very clear, and is certainly something we’re looking at, is the issue of trust in the data that’s exchanged as we’ve talked about it both from providers as well as consumers and as pointed out there are several different ways that this data can flow.

We think it’s very important that in the final report, and certainly the consideration, that the issue of trust be looked at and the certification of products. Unfortunately, there’s 20 Apps that come out yearly and probably 18 of those don’t make it through the year so one of the questions is being able to tell individuals and consumers that this is a product that you can feel confident in both in the exchange of information as well as the privacy and security of that information not everyone has an enclosed system like Kaiser Permanente.

Likewise, I hear from a number of physicians the ability to work with independent portals that are not part of their electronic health record system, again, becomes a question of do I trust the data, do I know that the data standards match what’s in the EHR, do I...can I be assured of the privacy and security?

So, we would urge, as others have done, to consider the issue of certification, accreditation whatever you want to call it, of these products so that both providers and consumers can feel safe and secure in using these and knowing that they’re going to do what was intended and do it safely. Thank you.
Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you and it looks like we have no...oh, we have one more person in the room though, but there is no public comment on the phone. Please go ahead?

Lindsey Hoggle, MS, RD, PMP – Director of Informatics – Academy of Nutrition & Dietetics
My name is Lindsey Hoggle I’m the Director of Informatics with Academy of Nutrition and Dietetics and I began participating in the two meetings in 2009 and I just want to congratulate you for having the most thoughtful discussion on as many healthcare topics that I’ve ever heard. It is been an education for me and I really have learned a lot and I have a lot of respect for the hard work that you all put in it. So thank you so very much.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you for those comments. We appreciate that. Okay, now we are ready to turn it over to the Chairs to make a few comments. So, I don’t know if anyone wants to go first but I will let you all choose.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation
Paul has seniority so...

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

Paul Tang, MD, MS – Vice President & Chief Health Transformation Officer – IBM Watson Health
Watch it. Well, I certainly do want to take the opportunity to thank a lot of people, the amazing leaders at the National...The Office of National Coordinator, the amazing volunteers, there’s hundreds of volunteers that have participated in the Committee meetings and the Workgroups and thousands of hours certainly and the people who have put up with us through this all.

I thought since this is our last meeting and it was created by HITECH, this FACA Committee, these FACA Committees, I’d share with you perhaps the back story of how HITECH got sort of, at least my understanding, so I heard some of this secondhand and so I’m not going to say I confirmed it, but back in 2007, so AMIA, American Medical Informatics Association, has always been interested in seeing how can we deploy these tools more broadly and I had met with the Health Staffer, David Bowen, I wanted to acknowledge him, for Senator Kennedy and so he was the Staffer for Kennedy and the Director of the Staff for the Senate Health Committee. I talked to him about an EHR incentive program and I actually laid out sort of three phases, starts with getting data in the EHR and the second phase was actually sharing it across organizations or health information exchange and the third was basically using it to report outcomes and how we’re doing it so that we can improve.

The other two dimensions, one was clinical decision support because that’s what all the academic papers were written on in terms of that’s where the benefits accrue and the third one was patient support. So, I thought...back then in 2007, this is pre iPhone so that’s how old that is, I thought that was an important part if we’re going to improve health is to give people access to their own information.

So, a bill was submitted that year, it didn’t pass and one of the reasons, again, this is secondhand, is because every bill gets assessed by the CBO, Congressional Budget Office, and at the time under PAYGO you had come up with...if you’re going to spend money you have to find a way to take money in and
they didn’t believe the savings that were coming out of the academic papers. So, it didn’t actually pass the PAYGO rule, that’s 2007.

As you know 2009 is when we had the financial crisis and the banking scandal and ARRA, the American Recovery and Reinvestment Act, i.e., the Stimulus Bill was in February. Now what’s…and there’s a guy named David Bowen, again, this is where I understand who’s the one that put HITECH into that bill but many of the things...you know bill get written they don’t see forward action, they don’t get passed, but fortunately some staffers keep it around and so the whole era was passed in six weeks because of the financial crisis and so somebody had to put that in, in a short order, and I think that someone was David Bowen a really bright, well-motivated, mission-driven person and I think that is...and as you know...oh, the second part I was talking to David about back in 2007 was as part of the incentive program in order to reward the early adopters you should have a decreasing amount of incentives, so perhaps there’s a little bit of origin there.

But, regardless of where we are now and we’ve certainly...we’ve gone from zero to sixty in five years in a sense. Before HITECH 3% of docs had what was called a comprehensive EHR, none of those, incidentally, would have passed Meaningful Use Stage 1, a lot because we didn’t have the patient access and so now we do have these repositories, as Dr. Fleming mentioned, sometimes we’re struggling with the things that we have, but we have it and we now have data to even deal with and systems to improve.

So I think a lot of what these combined Committees, basically the Policy Committee made some of the objectives and the Standards Committee helped with the certification really did move the United States from last, in terms of computer use in healthcare, to first in the world, I don’t think anybody in the world really even passes Meaningful Use Stage 1.

So, I think there’s a lot for this combined Committee to be proud of and the amount of the dedication that people from the very start put into it, there are hours of meetings and calls that people showed up for and contributed, contributed their expertise, their experience and led...and I would say everybody was in it for the country. People were wanting to do the right thing and we had different opinions and different stakeholders watching out to make sure we were not inadvertently, as Gayle was pointing out today about the privacy, doing something that would mess things up.

There’s always unintended side-effects for sure and we do have some of those and we’re trying to fix them but the dedication of the people in this room and all the people who preceded us is amazing and it’s only because of that dedication and it’s not even dedication it’s the hard work that went into this as a volunteer effort that we were able to provide some of the advice.

And the original National Coordinator who both commissioned this and received that advice was a David Blumenthal. He was a very steady hand and he had the charge to disperse two billion dollars that came out of HITECH initially and I think he did a great job and one of the...the tone he set was he was going to participate in and at least listen to and hear the advice by these FACA Committees and I think that was very influential at that time and he set that tone and that precedent.

The next person was Farzad, who people know, has boundless energy and patience for getting things done and did that in New York City and proceeded to implement some of the programs that were put in place in David Blumenthal’s era.

And then Karen DeSalvo brought with her, her passion around public health and translated that into championing the interoperability and Vindell Washington carried on that need of making sure that we achieved true interoperability and exchange of health data.
So, we’ve had some great amazing leaders that had vision and a mission, and were listening to and participating in the activities of these two FACA Committees.

I need to finish up with ONC, the amazing work of ONC. It started out...it was known as a startup within an agency and it really acted that way, you know, we tried to follow the timelines which were extremely fast. I mean, Meaningful Use Stage 1 was put up in six weeks so that was...because ONC, you know, wanted it that way and wanted to keep up with the timelines that Congress originally intended.

So we have people...I talked about the National Coordinators, Jon White, I’ve known for a long time when he was at AHRQ and then moved over here, another guy with boundless energy, deep passion around this as a tool for improving health and a man whose actions follow his words and he’s a physician and a gentleman together.

And Elise has brought her deep policy experience from CMS into ONC and has just been able to oversee...she oversees the whole FACA process and works on policy and that kind of expertise...you’ve got to translate some of our ideas that we come up with into things that can really work in policy and really needs a deep understanding to do that.

And of course, Michelle, everybody knows that nothing works without somebody like a Michelle in the sense of we may say things but how does what we say in our opinions and advice turn into something that gets written down and documented and moved forward and that is because of people like Michelle.

And I had the privilege of working with her in the early days on the Meaningful Use Committee and she was the primary staffer there and she helped us get through all of that. We had vigorous debates and idea generations like you’ve all alluded to and we consolidated into mostly consensus almost most of the time and Michelle helped us shepherd that into the words that come out and the recommendations and the things that go into the transmittal letters that become public.

So, it’s just an amazing experience I just want to share that working with...working in partnership this is a true public/private partnership. It’s sort of government at almost it’s best in a sense and this whole NPRM process, the whole ability of the public to engage and for the government to hear the advice and many times act, you know, very much in concert with the advice.

So, on behalf of, at least the Policy Committee, I want to thank ONC and thank all of the members of the Committee and the Workgroups and it’s just not Meaningful Use, it affects privacy and consumers, you heard about interoperability. We covered the whole gamut in trying to make the world a better place. So, thanks to everyone.

Applause

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

Okay, I’m going to keep this short. I want to echo some of what Paul said. I’ve been on the Committee for a while and Co-Chair of the Standards Committee for about two years and I really cannot help but think about all the people who have been on these Committees and Workgroups and Task Forces before and with us.

You know for those who aren’t here hopefully this goes in the record, every single one of you deserves a thank you for your dedication as we’ve all contributed, led, collaborated towards our common national goals. This has been an amazing experience for me personally and all of the folks that I’ve met and seen contribute to this effort I just want to say a profound thank you.
I also want to talk about ONC. I want to thank Dr. DeSalvo, Dr. Jon White, Michelle, of course, you know you are just the glue that holds all of this together. A few folks who aren’t here anymore but contributed and I worked with very closely Lucia Savage, Jodi Daniel. I want to thank Elise as well and Steve Posnack, I don’t know where he ran off to.

And I have to call out one colleague who was my partner in crime in the data security area, Dixie Baker, wherever you are Dixie today, thank you for all of your collaboration as well. Dixie and I were both on the Committee as data security folks in that slot, you know, and so I have to make my final comments around cyber challenges that the industry is facing. They remain profound, very serious and ever-changing. It’s a daily battle in a larger war at every healthcare organization.

So, my hope and my call going forward is that the new and any future Committees retain a focus on cyber and the needs of the industry. Keep these issues at the forefront and with the primary goal of providing and addressing the needs of the industry itself for helping guidance, for resources, expertise and support through best practices, standards and promulgations of tools and techniques to fight that daily cyber battle.

So, we haven’t had cyber on the agenda too much lately. We did a lot of work on that which is, you know, part of the historical record and I hope that this work continues going forward. Thank you to everyone both on the Committees, Task Forces, Workgroups, and at ONC and HHS in general. Thank you.

Applause

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation

So, I obviously want to echo the thanks, the profound thanks to the member’s current and past of the Committees as well as the staff and leadership of ONC.

I’m going to bookend Paul who started with the origin story, the origin myth of the HITECH Act, and talk a little bit about where we are and what we pass on to the HITAC. I looked at, as a sort of history project, the first formal reporting out of the HIT Policy Committee, which was the second meeting of the Policy Committee, where Paul and Farzad presented the famous swoosh for Meaningful Use and back in those days optimistic and eager as they both were Meaningful Use started in 2011, went to 2013 and finished in 2015 starting from adoption and then to exchange and then to more of a learning health system and quality improvement. Needless to say it’s taken a little longer than that plan.

I think we need to recognize that the US Healthcare System is large, complicated and slow moving. We can sometimes frame that progress as disappointing depending on how we frame where we expect to be as I’ve said a number of times if our expectation is that the US Healthcare System is like the banking sector currently, we need to recognize that it’s almost like as if the banking system went from paper ledgers to electronic interchange in the space, as Paul said, in five years and then berate it for not having, you know, personal finance Apps that allow me to do everything I can do right now. We need to recognize that the US Healthcare or sorry the banking sector started to get digitized in the 60s and 70s. So the progress we’ve made I think has been incredibly profound.

Just as a couple of notes clearly adoption utilization of EHRs, as Paul mentioned, is in a really profound difference now than where it was before the HITECH Act was passed. There were things like electronic results that were nowhere to be found or very rarely found in 2009 are now nearly ubiquitous joining electronic prescribing and financial transactions as ubiquitous electronic transactions.
We have nationwide networks for directed exchange driving through transitions of care. We have public/private partnerships like Carequality and CommonWell that enable nationwide query-based access and we have emerging API access to every EHR built into the EHRs the physicians use in most cases backed by standards with public/private consortia like the Argonaut Project.

So, by any stretch of the imagination that is pretty profound progress and it’s all backed by some hard work that we did in these Committees, work at narrowing down to a final set of content standards, narrowing down to a final set of vocabulary standards, working through the privacy security, cybersecurity, etcetera, issues that these Committees and the Workgroups spent untold hours working out.

So I think we are passing the torch onto the HITAC Advisory Committee in a much better...we’re passing the state of Health IT on in a much better state than when we received it. There is still a lot more work to be done in the areas of usability, in adoption utilization of electronic exchange, in better tying information exchange to quality improvement, payment and, you know, consumer access, but we have made tremendous strides and I think we all should congratulate...both members current and past members of this Committee and ONC, should congratulate ourselves for the progress that we’ve made more than berate ourselves for the progress yet to be made. So, thank you.

Applause

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

If I may say something. First of all, I want to thank ONC staff for everything they do to really assist us as Committee members but I especially I want to say thank to Paul Tang. He has been Chairman of the Policy Committee since the very inception. I think Paul Egerman and I are the only two members, other than Paul Tang, who have been on the Policy Committee who has served on the Policy Committee since its inception. So, I think we have a long history. Jamie, were you on both Committees or who...he’s been back and forth between both Committees, but I think we are the original threesome that started out together and your consistency, your calmness and your insight and your brilliance has just been phenomenal. And although sometimes we’ve had a lively discussions and sometimes disagreements, and sometimes lots of questions along the way, I can’t tell you the amount of really deep thought that has gone into what the Policy Committee has done and now that the two Committees have been suddenly merged for the last year or so the two Committees together have worked so well and with many, many topics, various discussions on things.

As we move forward into HITAC I think we’ve built a real foundation with these two Committees and there’s lots of challenges still going forward so I think perhaps if I would challenge each of us to give our advice to ONC and to the new Committee as to what we have learned and really set out that roadmap that we originally started setting out and saying, okay, where do we go next? What have we as Policy and Standards Committees learned over the last eight years that can inform the next Committee, the next step, and certainly with payment models changing significantly moving into MACRA and HITECH is gone MACRA is next and what do we...how can we help move this thing, the whole effort that we have worked so hard for eight years to accomplish and I think interoperability is certainly one of the things that we need to continue to work on.

Privacy and security, we just had this discussion today, on continuing that conversation on privacy and security. We live in a very dangerous world and lots of people would love to get all kinds of information. So, security and privacy are both there.
I think also we need to look at availability of data and data hording. I have seen this again and again and the inability to get a essential data as we move into MACRA and payment models are changing and we’re looking for really value-based care we have to make sure that we have…and using those National Quality Strategy Standards we need to make sure that in reporting the domains that providers have the ability to get the information they need and that’s one of the major challenges that I have seen out there and I have heard, and as I’ve said many times I’m kind of the bottom of the funnel, people always come to me to complain, as an elected official you get used to it, but I can tell you that this to me is one of the major challenges that we have moving forward in the expense and interfaces, and the inability to be able to do things.

So, I would challenge the new HITAC Committee coming forward to really make sure that this data is available and there is not that constriction on data and data hording that moves forward. But the new Committee has lots of challenges to continue to improve and create that learning health system that we envisioned on this Committee and we are passing the torch as we do that I think we can be very proud of what we’ve done. Thank you.

Applause

**Elise Sweeney Anthony, Esq. – Director, Office of Policy – Office of the National Coordinator for Health Information Technology**

So, I would like to talk little bit about kind of next steps, but before I do that last night and this morning I was looking at our archives, which are wonderfully kept by Michelle, another plug for Michelle, and looking at all of the issues that we’ve examined over the years and I think the first Workgroup I worked on might have been Stage 2 when I first got here and that was a very quick learning curve to jump in at the Stage 2 time but even going back before that one of the things that I’ve noticed and over the years of working with the Committees is the excitement and the vigor with which you work on things whether it’s the newest thing out, whether it’s QPP or Stage 2, the big pieces, but also the pieces that we need as ONC to move things on from a very technical, deep understanding level like transport standards. Things that without those pieces we wouldn’t be able to do what we do. We wouldn’t be able to have effective rules. We wouldn’t be able to create the new additions. We wouldn’t be able to take into consideration how things actually happen on the ground.

So when I was looking back from everything from the Privacy and Security Tiger Team to the data provenance issues, to the S&I Initiative Framework, to the Certification Program initially and thinking about the construct that would work, all of those items have really gotten us to the place that we are today and I think, we as ONC, are extremely thankful.

So, in the same way...I’ve heard so many people thanking ONC, I think it’s so important that you understand our appreciation for the work that you have done because while we’re all policy wonks or tech wonks, or you know, government wonks, we can’t do what we do without having the input of stakeholders and not just passing input but really digging deep into what’s happening on the ground and what needs to happen next and I think the two Committees have been amazing at that.

One other group I wanted to thank are all the Workgroup members because I think the Committee members obviously the work that you do is phenomenal, getting us feedback and recommendations so that we can move forward and incorporate those into what we’re doing but there are so many more folks as well, all of the Workgroup members who don’t sit on the Committees but toil over kind of the initial set of recommendations, initial understanding of the White Papers and frameworks that you’re looking at and really providing feedback and really their substantive level expertise and all of that work
is critical as well. So, we really appreciate I think not only the Committee members but also the Workgroup members.

And then the last group I wanted to thank are all of the folks who participate in the public comment process over the years. And I think it’s really important because anytime someone comes and talks with us and says, hey, we’re interested in this and I say, participate in public comment, did you hear this...it’s really an important opportunity, the Committee members listen and I think that that’s important as well because every meeting is recorded. We do go back as a staff and review the transcripts. We listen. We try to figure out what was the impetus, how things got recommended, what where some of the considerations and hearing from all of those three groups has been critical.

So, I mean, on behalf of all ONC, not just my team, not just Michelle and the wonderful work that she does, but also all of the staff leads because it takes a very strong army to support the work of the Workgroups and making sure that we’re taking everything that you guys are putting together and putting it together in something that’s cohesive that can be shared with the larger Committee and that represents your views.

So, it really takes a lot of work on the backside and I think the best evidence of the work that we do is that hopefully you don’t see how much effort it takes to get it done. We really want it to be seamless and to feel as if everything is running as smoothly as possible because we know that this is your second or sometimes your third job but not your first and everyone here takes their time out to volunteer to participate in the Committee so we really value that and we hope that we’ve done a service to your time over the years as well. So, we appreciate you.

Applause

And with that I want to talk a little bit about the transition so this is a bittersweet meeting in terms of we are excited about the opportunities that Congress has set forth in Cures but obviously bittersweet in terms of closing out these two Committees.

So, as folks know in Cures there is a new Federal Advisory Committee that’s set up. ONC will be leading it’s the Health Information Technology Advisory Committee. The structure is a little bit different and the focus is it lays out a more structured focus in some ways in terms of some of the things that we will be working on. But all of it you can see the thread of interoperability; you can see the thread of privacy and security, of patient access weaved throughout the section on HITAC.

And I shouldn’t say HITAC, because it sounds a lot like HITECH doesn’t it, right, so for the new Advisory Committee. A couple of things to note there, the appointment process has already begun with GAO. GAO has 14 appointees that they will be be putting into place and I believe they have their announcement out now in the Federal Register. I think their deadline is April 14th if I have that right. April 14th is their deadline. ONC obviously, we’re still closing out the Committee process here. We still to complete the transmittal letter for the Public Health Task Force and the work that was discussed today.

Once all of that happens we will also be putting out our announcement for membership and appointment to the Committee. We have three appointees. The other group is Congress and that’s divided between the House and the Senate and they also have combined eight appointee positions as well.

So, I think more...you’ll hear more in the coming months and weeks in terms...weeks and months in terms of the role out of the next Advisory Committee. In terms of again talking about all of the things
that happen in the background that you guys don’t see there is a lot of work for us to wind down this Committee, these Committees, and to wind up the new Committees and we’ll be working with that working on that pretty much as soon as we finish up this meeting to make sure that we’re keeping the trains rolling and everything is moving in the right direction. So, more to hear from us in the coming future, we’ll be sure to keep you guy’s up-to-speed. Thank you.

M
Leslie, did you want to...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So, we have heard a lot about Michelle today and I think all of us really value your work, your skill, your kindness, your ability to herd all of us to answer the same question 50 times with a smile and patience and we just have a little note for you to take with you and our appreciation. Thank you, Michelle.

Applause

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Better than being a good job, amazing job. All right, I have some prepared remarks and then I have some unprepared remarks. I’ll start with prepared remarks.

I said at the start of the day that, you know, everybody here is valued and extraordinary and that’s true. I’m going to take some of our limited time and just talk to you a little bit about the leadership that you’ve had in your Co-Chairs. They have been...they are extraordinary individuals and they have done extraordinary things for us so I just want to talk a little bit about what they’ve done while they’ve been here.

Paul Tang, Founding member of the Health IT Policy Committee has been on the Policy Committee since its inception. He has provided us continuity through ONC’s changes including various National Coordinators. He has been the Vice Chair or Co-Chair of the Committee since the start. From the Policy Committee perspective he is essentially “The Father” of the framework (and the father is in quotes) that helped lead to health IT adoption.

He led the Meaningful Use Workgroup informing all three stages of Meaningful Use. He has also led the Advance Health Models Workgroup making recommendations to facilitate the effective use of Health IT to scale advanced health models in support of delivery system reform goals, recommendations on policy issues that facilitated the effective use of Health IT to support outcomes focused advanced models for healthcare delivery and value-based payment and that’s a lot of words because there is a lot of meaning packed in there. That is something Paul felt extraordinarily, and still feels extraordinarily, passionate about.

Paul said that he and I worked with each other for a long time and that is true. It is been well over a decade at this point and you have always been, you know, a gentleman of the highest quality so I thank you very much for your service.

Kathy Blake who is sadly not here with us is giving another talk at the moment but has served on the Policy Committee since 2015 and she has been are go to person on quality measurement discussions which is a significant piece of what we do.
Most notably she has served as the Chair of Quality Measurement Task Force providing comments to CMS’s 2016 Physician Fee Schedule Notice of Proposed Rulemaking. As a representative of our physician community and our provider community she has always provided good humor and a level head and I will immensely miss working with Kathy, although as you all have heard me say before, this is the Health IT tribe we don’t go away we just kind of, you know, circulate. So that’s good.

Arien Malec. Arien has been on the Standards Committee since 2011. He has served on or been the Chair of 11, eleven, Workgroups or Task Forces, that is a lot of Chairing to do. Notably, he Co-Chaired the Health IT Standards Architecture Services and Application Programming Interface Workgroup with David McCallie, particularly meaningful for me as the project officer for that original JASON Report that kind of started us about...on a lot of discussion about APIs, so there was a lot of good and vigorous discussion and I am incredibly grateful for the grace, skill and intelligence with which it was handled and that had to be you, it couldn’t have been David.

The Workgroup sought to create a framework for evaluating technology policy, providing key architectural principles and patterns as useful guidance for important policy statements such as the interoperability roadmap standards and implementation guidance and certification criteria.

You know I will also add that, you know, I’m going to say something about you that I think I’ve only said about one or two other persons...the other person I said this about and that’s fierce intelligence. You know any time you engage with Arien on almost any subject there is this, you know, just kind of sparkling brilliance that underlies it but also this intensity and application and effort, and that’s a really special quality and I’m grateful for the chance, you know, both for your time at ONC, as well as on the Committee and on into the future for the chance to work with you so thank you.

Arien Malec – Vice President, Clinical Solutions Strategy- RelayHealth Corporation

Thank you.

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

Yeah. Lisa Gallagher. From the Standards Committee she has been on the Standards Committee since 2013, she has served as our Advisory Committee’s Security Expert as you had heard. She has served on or been the Chair of five Workgroups or Task Forces. Notably Chaired the Data Provenance Task Force, which you heard about earlier, which made recommendations regarding data provenance standardization that would be most broadly applicable and immediately useful to the industry and that’s absolutely critical, you know, knowing from where your data has come and what it means...that underlies the whole value of data. So to be able to address that in a robust way is as meaningful, if not more, than a lot of the work that we do, most of the work that we do so thank you for that.

She Co-Chaired the Standards Transport and Security Standards Workgroup with the Dixie Baker. The Workgroup made recommendations related to user authentication too for one adoption of multifactor certification...authentication certification criteria and two certification criteria for encrypting authentication credentials, for example passwords at REST.

You know on a personal level you’re passion for security issues of course comes through on a regular basis. You know when people ask me what keeps me up at night it is our security of our information systems. It is the foundation upon which all of this stuff rests; you can’t do all the cool stuff without the security. So both for your expertise as well as your commitment to it I thank you for it and I thank you for your leadership in this.
Lisa Gallagher, BSEE, CISM, CPHIMS – Managing Director – Pricewaterhouse Coopers (PwC)
Thank you.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Absolutely. So, we have all been blessed to work with amazing leaders so I think give them a round of applause if you don’t mind.

Applause

All right and these are the unprepared remarks. So, all things end, okay, that is a fact of life. I’ve come to appreciate that in my personal life, appreciate that in my professional life as a physician and, you know, as long as you accept that as a fact of life then, you know, really what becomes important is what you do with the time that you are given.

And as I look around at all of you and as I think back on what you have done you have made the most of your time working on these issues. These are substantive, these are meaningful, these affect people’s lives in some of the most, you know, foundational ways that I can possibly imagine.

You know I used to have a job where, you know, I worked, I would go in with the shock paddles and sharp things and, you know, stick them into people to try to save their lives, I delivered their babies, I, you know, held them when they were born and I held them as they died and that was a terribly meaningful job, this is just as meaningful as that if not more so because of this is how we make our health system work and we need that information in order to get to where it needs to in order to do it.

So, you know, at times it may seem wonky, at times it may seems dry, this is absolutely critical to everything, it’s the key to everything and that’s why I’m here on a regular basis. I can tell you that’s why everybody at ONC is there doing what we do.

So, thank you for what you do and what you have done. There is a future, we’ll move on ahead but I think taking a moment now to just reflect on what you’ve done and how well you’ve done it is a gift, so let us do that.

You have in front of you glasses, alas, I am told this is cider, but it is a bubbly beverage as is the tradition on these occasions. So, I considered many things to raise the glass to and I thought about Health IT, you know, I thought about, you know, ICD-10, I thought about the bride and the groom but ultimately I decided to the health of the nation.

Multiple
Here, here.

Toast

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Thank you so much.
Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Well, don’t leave yet we want to do pictures but before we do that I just want to say my own personal thank you. This Committee is made up of amazing people. I’ve learned a tremendous amount from each and every one of you, not just because of your crazy expertise in something that oftentimes I don’t know what you are talking about, Arien, but you all are brilliant people but more importantly than that I am so grateful for all of the relationships that I have created and just how wonderful all of you have been and I’m really going to miss all of you so thank you so much for this opportunity.

Picture time.

Are we done? I guess that means we’re done.

Public Comments received during the meeting

1. Jonathan Nebeker: There is a standard for getting huma-readable guidance called InfoButtons. VA is now using this. Many vendors support it.

2. Jonathan Nebeker: Regarding the inconsistency of standards, this is exactly the work that Health Services Platform Consortium is doing by integrating work from CIMI and SOLOR. There is current work in collaboration with the American College of Obstetrics and Gynecology for maternal-fetal health and registry reporting that directly addresses some of the issues relevant to Zika.
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