



**HIT Standards Committee
Transport and Security Standards Workgroup
Transcript
December 17, 2014**

Presentation

Operator

Thank you, all lines are now bridged.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Good afternoon everyone this is Kimberly Wilson with the Office of the National Coordinator. This is a meeting of the Health IT Standards Transport and Security Standards Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Please also keep your line muted if you are not speaking. I will now take roll. Dixie Baker?

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

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Dixie. Lisa Gallagher?

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

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Aaron Miri?

Aaron Miri, MBA, PMP, CHCIO – Chief Technology Officer – Children's Medical Center, Dallas

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Aaron. Brian Freedman?

Brian Freedman, MS, CISSP, PMP, CHCO – Senior Information Assurance Analyst – Security Risk Solutions, Inc.

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Jason Taule?

Jason B. Taule, MS, CMC, CPCM, HCISPP, CCISO, CISM, CGEIT, CRISC, CHSIII, CDPS, NSA-IAM – Chief Security & Privacy Officer – FEi Systems

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Jeff Brandt?

Jeffrey Brandt – mHealth & Security Consultant – Brandt Professional Services, LLC; Manager, Technical Architecture – Accenture

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

John Hummel?

John Hummel – Director, IT and Systems and Innovation – Tahoe Forest Hospital District

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

LeRoy Jones? Paul Clip?

Paul Clip, MBA, MSIN – Vice President, Platform Services – RelayHealth/McKesson

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Peter Kaufman? Scott Rea?

Scott Rea, MS – Senior PKI Architect & Vice President of Government/Education Relations – DigiCert

Yes, I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Sharon Terry? Steven Lane?

Steven Lane, MD, MPH, FAAFP – EHR Ambulatory Physician Director – Sutter Health

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

And do we have anyone on from the Architecture and Services and API Workgroup?

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

Hey, it's Arien here.

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

And David McCallie.

Janet Campbell – Software Developer – EPIC Systems

This is Janet Campbell.

Gajen Sunthara, MS – Presidential Innovation Fellow – Department of Health & Human Services

Gajen Sunthara is here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

And the Privacy and Security Workgroup?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Hi, it's Deven McGraw.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Deven.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

And this is Stephania Griffin from VA.

Wes Rishel – Independent Consultant

Wes Rishel.

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office of Civil Rights

Linda Sanches from the OCR.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Was that Wes Rishel?

Wes Rishel – Independent Consultant

Yes.

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office of Civil Rights

And Linda Sanches.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

And do we have anyone from the Consumer Workgroup?

Philip Marshall, MD, MPH – Founder & Chief Product Officer – Conversa Health

Philip Marshall.

Clarke Ross, DPA – Public Policy Director – American Association on Health & Disability

Hi, Clarke Ross.

Cynthia Baur, PhD – Senior Advisor, Health Literacy, Office of Communications – Centers for Disease Control & Prevention

And Cynthia Baur from CDC.

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

Kim Schofield, the Lupus Foundation.

Luis Belen – Chief Executive Officer - National Health IT Collaborative for the Underserved

Luis Belen from the National Health IT Collaborative.

Will Rice, MBI – Director Health Informatics – Walgreens/Take Care Health Systems

Will Rice.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

And the Interoperability Workgroup?

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Larry Garber.

Shelly Spiro, RPh, FASCP – Executive Director – Pharmacy Health Information Technology Collaborative

Shelly Spiro from the Pharmacy HIT Collaborative.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies

John Blair.

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

Nancy Orvis from DoD.

Wes Rishel – Independent Consultant

This is Wes Rishel I think I reported in under the wrong Workgroup, this is my proper Workgroup.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Wes, we forgive you.

Wes Rishel – Independent Consultant

Merry Christmas.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Any other members that may have come on?

Brian Ahier – Director of Standards & Government Affairs – Medicity

Brian Ahier.

Deb Bass, RN – Chief Executive Officer – Nebraska Health Information Initiative (NeHII)

And Deb Bass with NeHII.

Carl D. Dvorak – President – Epic Systems

And Carl Dvorak but I'm falling back to listen mode.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Thank you.

Peter N. Kaufman, MD – Chief Medical Officer & Vice President Physician IT Services – DrFirst

I didn't know if somebody...this is Peter Kaufman I don't know if somebody replied for me or not since I was gone, I'm back.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Thank you. And from ONC do we have Lucia Savage?

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

Yes, I'm present.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

And Julie Chua?

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yes, I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Kathryn Marchesini?

Kathryn Marchesini, JD – Acting Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Marchesini, yeah, I'm here, thanks.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Excuse me, sorry. Anyone else from ONC on the line?

Debbie Bucci – Office of Standards & Interoperability – Office of the National Coordinator for Health Information Technology

Debbie Bucci.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Debbie.

Gajen Sunthara, MS – Presidential Innovation Fellow – Department of Health & Human Services

Gajen Sunthara.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

And with that I'll turn it over to you Dixie and Lisa, thank you.

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

All right, thank you and thank you all for joining in on this meeting of the Transport and Security Working Group. Today we are going...our whole meeting is devoted to hearing and discussing the results of the ONC study on the electronic consent management technology capabilities and I'm really pleased that our two...our ONC primary support, Julie Chua and our primary MITRE support Kris Miller, who participates in all of our meetings were very instrumental in this study so we thank them for all the work they've done on the study and we're looking forward to hearing the results and I'm glad so many other Workgroups were able to join. Lisa, would you like to add anything?

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

No, thank you, Dixie.

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

All right, with that let me turn it over to...I believe the primary speaker will be Lucia Savage or Julie will it be you?

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yeah, thanks, Dixie, Lucia will tee it off and start the conversation and then I will take over with the actual landscape findings.

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

Sounds, great, thank you.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Thank you, Dixie.

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

Good afternoon everyone this is Lucia Savage and for those of you who are wondering, yes it's Lucia like fuchsia and now you have the mnemonic and you'll be able to remember it. I think I'm starting my 8th week here at ONC and I thought if you would just bear with me for a moment since I know some of you from my past work but most of you I don't. I'll give you a little bit of background about myself so you know what I bring to the position of Chief Privacy Officer.

My opening line, I'm going to have to get a new one pretty soon, is that I started practicing law before Al Gore invented the Internet. But, yes we used to have floppy diskettes and computer meant labs in the law school nobody had one in their dorm. And I actually was fortunate enough to be working in house at an academic, Markey Academic University at Stanford when HIPAA was first enacted and was sort of in the first wave of regulatory analyzers and reviewers and commentators there and it really peaked my interest in the versioning area of healthcare.

So, when I left Stanford I spent a little bit more than 5 years as the General Counsel Pacific Business Group on Health where my portfolio was sort of split between helping with the legal work of PBGH as a convener of big data analytic projects before that term had really been invented, they were called quality improvement projects back then. And actually General Counsel for the old California Insurance Exchange which preceded Massachusetts in time.

I left United at the end of 2007 and joined the Law Department at...I left PBGH 2007 joined the Law Department of United Health Care where my portfolio consisted exclusively of legal support on issues of health information exchange, data sharing and large data projects with the clinical PHI that derives from administrative claims data including negotiating agreements with HIEs and that's how some of you know me on the phone as well as working on all payer claims databases and many other items.

So, I bring all that with me and I'm thrilled to be here and I'm going to just sort of jump right into our comments today. And if we can...

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

I just want to say we're thrilled to have you Lucia. We really appreciate your taking the time to join us.

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

I'm happy to join, now if you can kind of orient us for slides we could just sort of start on slide two, sort of what we're going to go over today and Julie and I will be going back and forth, and we'll be handing the slides back on and off to each other. So, I'm going to have Julie walk you through the actual outline for today.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

All right, so thank you, everyone for joining and if you look at the slide we will be going over the history of electronic patient consent basically what ONC has been doing in this space. We're going to go over the individual permissions environment for electronic management of those permissions, reorienting everyone in terms of the permitted uses and disclosures within HIPAA and Lucia will end her portion of the presentation with a framing or a little bit of a snapshot of the interoperability roadmap and how we are putting this into perspective.

And I will take over when we go through the consent terminology that was used in the assessment. I will go over computational privacy and why is it important and the actual assessment and findings and we'll open it up to Q&A and open discussion after that.

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

And this is Lucia, while I normally love in a small group to take questions as I'm going, this is a big group and it's a big phone group so I think we're just going to charge right through the presentation and if you'd just hold your questions until the end that would be really helpful for us. So, that being said, could we have slide three? Perfect.

So, this is just kind of a history of where we are and I bring an outsider's perspective because I was outside of ONC for almost all of this work having arrived here on October 20th but you will all remember one of the first things we tried to tackle after the enactment of HITECH was the Tiger Team's work on consent and we've given you the link there, we have invited the Privacy and Security Workgroup the new iteration of that same body today.

And then we...two years later or a year and a half later we took some of those recommendations and we turned them into a program information notice for our HITECH Co-Op funds so that the state designated entities and the people who are managing those funds for the states would have a sense of what were the minimum privacy and security requirements as they tried to build statewide health information exchange systems in their states.

And then in October of 2013 having come at this issue in a variety of different ways the HIT Policy Committee recommended that we actually start working the issue from the standards side and so they recommended that the HIT Standards Committee and Workgroups under it, which includes this Workgroup, start figuring out what was necessary to take our privacy and security framework and advance it technologically and that led us to the contract we asked MITRE to undertake which was kind of a landscape assessment of the state of technological capabilities for managing the permissions that apply to a patient's data and I want to pause there for just a moment. Could we have slide four?

So, the reason I'm saying permissions instead of consent is for a really important reason, you know, the current rules environment actually has that structure, it has activities that are permitted even if an individual does nothing and that's pretty much how the normal fee-for-service system has run for years, a person gets treated, the physician marks those treatments, that gets coded in clinical information that's included in a bill, that bill is sent to an insurance company, the insurance company adjudicate it, payments flow, similarly information might flow to another treater, etcetera, and all that happens without necessarily getting a writing from the individual. We have some exceptions to that and I will be talking about that in depth, so don't think I've forgotten about all the exceptions, but we have this baseline of permission.

And then we have in addition to the baseline and permission we have these categories where actual writings and specified patient choices are required to move the information around. And I think that it's really important to remember that and that's why I drafted this slide specifically to talk about permissions because we have to recognize that when a person makes a documented choice we need to respect it, but we need to have a system that functions in some way, even if an individual doesn't actually make a documented choice, and I've said this publically prior even to coming to ONC, but we can learn a lot about this because we saw how people behave when they have choices with regards to their 401K plans and many other choices they have to make in their lives and we have to think about that as we plan both what's going to work technologically and the policy in which that technology is going to be effective moving forward into our learning health system.

Which takes me to slide four, so, this slide actually gives you a sense of the complex environment we find ourselves in and the bottom line is one of the things that MITRE's work uncovered for us is that...and those of you who do this for a living will recognize this, in some ways the rules environment is so complicated and so diverse that it's very difficult to build a computer system that compliantly adjudicates which rule applies and ensures that this adjudication persists as data travels through the system. So, let me go over the layers with you for just a moment.

So, starting from the bottom and working our way to the top, you know, in the bottom row we have the normalized relationship between a patient and their physician or their nurse whoever is providing care to them and we know from historical work that was undertaken by ONC before HITECH that in many respects patients actually expect the totality of their caregivers to have appropriate information about their patients to provide comprehensive care.

On top of that we add whatever documentation we ask patients to sign and they may or may not sign that documentation. And then on top of that we have the way the physicians record keeping system now and electronic health record is capturing that and whether it's capturing, you know, a machine readable document or a scanned document and on top of that we have the architecture in which the information exchange partners are trading information, and we have our, you know, centralized system, our distributed systems and our federated systems and they all move information around differently and that impacts how we can convey information about whatever permissions apply to the data.

Obviously, we have organizations and states that have made policy choices about, you know, the so called opt in and opt out choices and those are diverse, my favorite two examples are Nevada and Rhode Island, Rhode Island having opt in and Nevada having opt out, but you guys all are familiar with your own rules environments.

And then on top of that we have special sets of rules that apply as a policy matter, the rules are longstanding related to particular clinical conditions or particular states of being for the patient, so we have age-based rules where, you know, teenagers can access their health information but the age at which that rule kicks in might vary from state to state.

We have rules that, you know, protect certain clinical categories but those rules are state statutes and they may or may not have the exact same wording in them. Part 2 falls into that as well, but, and again remember Part 2 applies to substance abuse information from federally funded activities so it's a type of rule in this category and there are many, many, many versions of these types of rules.

And then on top of that we have, you know, what is that that's required by law to effectuate a patient's choice documentation, they have to understand it, they have to sign it, some states require a witness signature. We know we have this incredibly complicated rules environment in which we're trying to build a system to capture what rule applies. Next slide, please.

So, the thing to remember about that really complicated environment is we do have a foundational constant and that is HIPAA. Going back to what I said when I first started HIPAA has permitted uses and it was designed specifically to account for the healthcare system in its totality needing to move information around in order for people to get paid for treating patients and in order for care management to occur, and in order for appropriate performance measurement to be made, and in order for quality improvement and many other features that there are all these conditions that the information can move without the patient having to give a permission first and those are generally the treatment, payment and health care operations bucket. I won't belabor the point, I think most of the people on this call are familiar with the concept of TPO conceptually and many of you are familiar with it in the details. Here's the cool thing about HIPAA...

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

That's the punchline to a joke that never arrived.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I was going to say, what a time for the phone to cut out.

Wes Rishel – Independent Consultant

Nothing's cool about HIPAA.

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

So, it supplies a background rule and we have a lot of other situations in our society as a whole where we have agreed on what the background rules are, the one that probably strikes home where people can really get their hands around is, you know, we have a whole universe of background rules about what happens to your property if you die without a will. It's not that nothing happens, there are actually a bunch of rules and the will is a way in which you do something that might be contrary to those specific background rules or in which you elaborate on how you want the background rule to apply. But we have background rules and if we all died tomorrow...there are rules that would kick into regulate it.

And I think in some ways we need to think about privacy in that context where we, again as I said before, we need to have a system for interoperability where we can accomplish the health goals we need to accomplish as a nation with background rules and with respect for documented choices that patients make which takes me to my last slide. Can I have the next slide, please?

So, you know, when we started down this path our research project from MITRE was called electronic consent management which kind of implies that you're always going to have a consent. And I think if we're thinking about this at a nationwide policy level we have to imagine a universe in which we may not have a consent and it actually may not be an emergency or break-the-glass situation.

And so, I really tried to reframe this for my staff as computable privacy, we know what the privacy rules are and a machine can understand them, convey them, persist them, document them, all the things we want our health information systems to do and so that's where I'm headed is down the path of computable privacy.

Here's the last thing I wanted to say about that which is the rules environment we have here have a wide variety of policy choices that state legislatures and congress have made over the years. And what we want to do is get to a computable privacy environment in which the reason we have those policy choices and the way that those policy choices protect individual rights remain respective and constant.

So, we're not talking about undoing anything or watering anything down, or taking anything away we're talking about making an environment in which we can achieve computational technology while we still have this layer of background rules with individual rights respected when they're documented and that being said, again, please hold your questions, I know you have a ton of them, we've planned for them, but I want to turn it over to Julie to talk about the actual process and the findings.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

All right, thank you very much Lucia and I just wanted to check is Kris Miller from MITRE on the line?

Kris Miller, LL.M, JD, MPA, CIPP/G, CIPP/E – Principal Privacy Strategist, Enterprise Strategy & Transformation Division – MITRE Corporation

Hi Julie, I am.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Great. So, everyone I just wanted to let you all know that Kris Miller and I worked together on the landscape assessment so when it comes to questions later on regarding the actual conducting of that Kris may be the best person to answer. So, just letting you know that he is on hand as well. So, if we go to the next slide, which is slide seven.

I wanted to go through some terminology and definitions that we used within the assessment to set some...to level set what we mean by these terms and the first one is patient consent.

So, within the assessment we defined that as the patient's decision to permit his or her information to be accessed or shared for treatment purposes. Specifically we focused on one, the permission to participate in electronic health information exchange what we are calling the choice.

And number two is to share sensitive health information which is what we are calling granular choice. Alternate terminology, which you will hear throughout the discussion is, patient consent, preferences, authorization, meaningful choice, release of information those are all treated the same within the context of the assessment.

The next definition we are using is privacy consent directives and within the assessment, again, we used it as an expression of that patient decision regarding how personal health information is to be accessed and shared. And also identify that this can either be expressed in paper form or electronically as a technically implementable specification. Next slide.

And the two definitions here are on consent management and electronic consent management. So, for CM it is a system process or set of policies that enable patients to choose what health information they're willing to permit their health providers to access and share. And it enables the patient to participate in eHealth Initiatives and establish privacy preferences. CM involves the dynamic creation, management and enforcement of these directives that are patient, organizational or jurisdictional defined. And electronic consent management the big difference there is it is a fully electronic consent management environment that's the big difference. Next slide, please.

So, eluding to what Lucia had mentioned earlier, reframing consent management to computational privacy and why that is important I wanted to just emphasize again that the assessment was commissioned under the name electronic consent management but now we know that this is a little too narrow of a view so just moving forward as I'm going through the assessment findings I just wanted to point out that that's a major difference with what the assessment came out with and ONC is moving forward or towards.

So, we all know that, you know, we're increasingly capturing electronic permission so that is why computational privacy is important, the ability of Health IT systems to identify and persist those decisions are going to play an important role as well.

And lastly, technology with respect to communicating those decisions is going to be essential especially when handling sensitive health information. So, next slide. Great.

So, moving forward the next couple of slides or few slides are going to go into the actual landscape assessment findings. So, I'm going to not veer off from the slides because this is actually what was reported out of the assessment. Next slide.

So, the scope of the assessment was patient consent to participate in HIE and to share sensitive health information for treatment purposes only. The objectives were to conduct a landscape assessment of current consent management practices, how sensitive data is defined and maintained. We wanted to see what the gaps in the current technology and other challenges that maybe hindering electronic consent management and a description of any technologies that can identify right now or capture, track, manage that consent decision. Another thing is we wanted to be able to use this report and the findings to inform ONC's future work and the work of all the Workgroups specifically on this call. Next slide.

For methodology we basically, and this is mostly MITRE conducted these unstructured conversations with 25 diverse contributors and as you can see on this slide it's a mixture of HIOs, developers and vendors, providers and SMEs. Next slide.

So, the landscape assessment is pretty much kind of unveiled phases of consent management maturity that we have and if you look at this slide we go through it as Phase I, Phase II and Phase III. Phase I being the current state we are in right now. Phase II is the current growth and Phase III is the ideal future state which is the electronic consent management state. So, let me go through quickly each phase to give you a little bit of an idea of how these differ.

So, for current state right now the assessment revealed that most of consent or decisions are captured in paper form. No structured data right now and a human must actually review that decision to adjudicate that and make that persistent and use that decision moving forward. There is no granularity.

For current growth, which is Phase II, it's partially electronic so we have a mixture of paper and electronic consent forms. There are some structured data meaning there are digital flags on documents but again, there is no granularity so you either have a share all or share none environment. And if you look below we've indicated that today we have seen, from the assessment, that we are in the middle of current state and current growth.

And the last state which is our ideal future state, of course, is fully electronic structured data, Health IT is the one interpreting these consent directives along with the laws, regulations and policies and the ability to have granular choice is present at that time. Next slide.

Okay, so some current state key issues that were discovered through the assessment, one is the paper consent forms that we have in PDFs they do not facilitate the ideal state of fully electronic consent management. So, the need for structured data is still existing and right now there are no existing best practice or models for electronically collecting or sharing that consent information.

As Lucia mentioned earlier there is no consensus on the definition of sensitive information so that is a challenge as well. And again, HIPAA provides the legal floor but states can and do enact more restrictive rules and the last one is that both states and HIOs have different consent models and Lucia already alluded to that earlier with the complexity of this environment. Next slide.

Okay, so current findings, this is a pretty busy slide, but if I were to point out a few key things is that for technology the assessment uncovered that there really is no gap meaning there are no new technologies or standards that are needed it's just that no industry-wide best practice or accepted framework for collecting and sharing these consent decisions are missing, and the interoperability challenge of course is still there so we have put that within the technology bucket as well as vocabularies being normalized is still a need and that's why we still see that there is a technology challenge within consent.

And as you see we have the compliance complexity in terms of varying rules within federal, state and organizational policies as well as the conflicting consent models which is opt in or opt out and more granular options.

We have the identity and access management piece as well that was uncovered in the assessments, cost, workflow and education was also revealed within the assessment as challenges, as well as the policy challenges of again state laws and sensitive information within the assessment part 2 was also...revealed as something of a challenge from the contributors. Next slide.

Okay, so for this slide we were thinking or from the assessment had a potential approach for moving from current state to ideal future state which is that electronic consent management state that we were alluding to earlier. So, one of the things is the ability of electronic consent directives both patient directed and the background rules that we mentioned earlier are able to be applied to existing Health IT and we are acknowledging that we need to make sure that we use or we normalize and harmonize the existing standards for transport, messaging and vocabulary, and the assessment has revealed that this is existing and in use, however, there is no standard framework or best practice across industry.

Another thing that we want to leverage is lessons learned from pilots that have actually demonstrated that existing technology standards can support electronic consent management and we also were proposing that tracking or identifying some of the software solutions that are already offering eCM capability be identified and looked into. Next slide.

So, within the assessment the technology standards that are presented on this slide, these are the standards that were identified during the assessment. So, we are not saying that these are the only standards out there but these were the standards that were revealed and discovered within the discussions of the assessment. Next slide.

So, for this last slide, it's called contributor suggestions. So, these were pretty much candidly shared by the contributors that were interviewed for the assessment and these itemized listings are based on conversations that were captured. So, this is in no way saying that these are things that ONC or MITRE proposes but these are captured directly from the conversations that were performed through the assessment.

So, one of the suggestions was to come up with a federal consent management framework or model and this is alluding to the standardized way of collecting and what the requirements are for capturing the consent of a patient.

Another suggestion was a standard sensitive information form which alludes to, you know, pretty much defining or standardizing what do we mean by sensitive information. Another suggestion was centralized services to store and manage consent, education was put forth as well and the standard for identity and access management solutions, that suggestion was actually focused on the concern with patient portals and patient identity proofing and authentication. More financial incentives were also put forth as well as Part 2 specific suggestions to enable more consent management capabilities.

And the last slide that I am going to go through is a summary of everything that I talked about within the last few slides, which is electronic consent management is an important capability as patient's health information becomes increasingly digitized and we are acknowledging from the assessment that there are challenges doing this but there are pilots that have demonstrated that the existing technology standards out there can support eCM.

And finally, one key take away is that a federally defined policy and technical model framework for collecting and sharing patient consent for sensitive information in healthcare maybe helpful.

So, with that I know that's a lot of information and I wanted to get to the Q&A part of the discussion. And Dixie I want to tee it over to you again to open up the discussion.

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

All right, thank you very, very much, this is certainly an interesting study and I'm sure we have many, many questions. Are we already...do we already have people with their...oh, I would remind you that on your screen in the upper left-hand corner you will see an icon of a little guy with his or her hand up in the air, we would request that you use that, click on that to raise your hand if you have a question and the people who are managing our user interface here will call on you as we go through. All right, do we have questions?

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

I've got one.

Wes Rishel – Independent Consultant

So...

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

Julie, do we have somebody who is monitoring the hands up?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes, we are monitoring and we have a question from Shelly Spiro.

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

Thank you.

Shelly Spiro, RPh, FASCP – Executive Director – Pharmacy Health Information Technology Collaborative

Hi, this is Shelly Spiro with the Pharmacy HIT Collaborative and thank you for the presentation. One of the gaps that we're finding on the pharmacy side is unless...especially because pharmacy might not be in the contractual or provider networks of some of the providers that were part of these studies, are not able to...are not considered to receive or exchange consent on exchanging clinical information.

As an example Community Care of North Carolina there community pharmacies are providing transition of care and care coordination with patients who have been discharged from the hospital but don't have the consent to receive the discharge summary from the hospitals that the patients are actually being discharged from.

And so, this is not just unique to North Carolina, we're finding this in other areas, things with prescription drug monitoring programs. So, it boils down not necessarily to the regulations about the consent but moreover the contractual agreements that have been in place prior to bringing in a pharmacy into a network. Has that been addressed in the study?

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

So, I don't think, this is Lucia, I don't think that specifically was addressed in the study I think that ONC in general is aware of the complexities between what a law permits and what two business trading partners agree to and one of the things we have to think about and I think as we...when the interoperability roadmap becomes public, you know, guys know we're working, burning the midnight oil on it, you'll see some ideas about that because they're really different things. One is about what do people need to do to comply with rules and the other is business choices they're making that facilitate or undermine, or don't facilitate, or are neutral to interoperability as a general concept.

So, you know, without getting into a dissertation on HIPAA permitted use of this, two covered entities trading about a common individual that they share information on that's pretty standard, it happens all the time. So, we have to think about, what does that permitted use do to help us facilitate interoperability and then what are other barriers that may not be related to the privacy rules landscape. Does that make sense?

Shelly Spiro, RPh, FASCP – Executive Director – Pharmacy Health Information Technology Collaborative

Yes, thank you.

Lonnie Moore – Meetings Coordinator – Altarum Institute

Okay, next we have Arien Malec.

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

Hello, yeah, thank you so much for this presentation and, you know, this is obviously an emerging area that a lot of thought has been going into. I want to go back to basics because I keep getting confused, I think I understand HIPAA, I think I understand frameworks for patient choice and then this slide deck seems to put some of that into question.

So, I just wanted to frame up maybe some discussion point here. I thought I understood...I think I understand from...the way that I think about privacy is I think about permitted uses and I think about the permitted uses that do require in context additional authorization and the uses that are permitted only when there is a specific authorization.

And I thought I had a firm handle on that. And then I saw the slide deck that appears to say that this framework is intended not for uses that require additional authorization but that this framework is intended for permitting use that's already permitted.

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

No, I...

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

And I'm just...I'm just trying to understand the framework for which electronic consent management or authorization management is intended or permission management might be a better way of terming it.

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

Yeah or computable privacy.

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

Yeah.

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

So, there actually are sort of several moving parts and they move together. At the end of the day when you're at the...you know, if you hit the 10-year vision mark from our summer release they move together. So, there are rules, background rules that operate if nobody ever...if an individual doesn't take steps to document and computer systems can adjudicate and persist those. There are technical standards, vocabulary, I'm not the technical person...

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

Hold on, could I just clarify the first point? Because, I'm not sure I understand, and obviously we've got you, we've got so many folks who understand this in more depth but I'm not sure that I understand HIPAA to say that permitted use for treatment, payment and operation is a background rule unless the patient explicitly says otherwise.

What I understand HIPAA to say is that permitted uses for treatment, payment and operation...that data use...there are permitted uses for treatment, payment and operations that apply, and there are other uses that require additional authorization. There is some language in HIPAA that says that nothing should imply that consents can't be given, but I don't understand anything to say that...anyway that's just one source of confusion.

The other source of confusion that I have in this framework is in one of the framing slides you talked about his or her data with respect to the patient and I'm not sure that I understand what that means either. I don't think of data as having an ownership framework. I think of data as having a use rights framework and I'm not sure what his or her data means in a use rights framework, particularly when the provider is in the mix, when the pharmacy is in the mix.

So, I'm just really having a hard time understanding the intent of the computable privacy framework model in the context that it was framed up on one of the first couple of slides.

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

So...

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

I'm sorry, I interrupted you and I'll let you get going if you've got answers for all of that that would be great.

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

Let me see if I can answer briefly and I want to make sure that we have time for everyone else's questions too, so, first of all, you know, we...Linda Sanches are you still on the line from OCR? I know she had to drop off I don't see...

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office of Civil Rights

Yes, I am on.

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

Yeah, so the terminology we've chosen background rules was chosen on purpose to make it easy to understand what we were talking about and obviously if you're confused then we need to go back and recalibrate because other people might be confused too, but the basic concept is actually today information accessed, used and disclosed for treatment, payment and healthcare operations without writing by individuals and that's what we are thinking of as background rules.

So, if you want more information on that there are loads on the OCR website as well as many additional loads on our website and those are all great places to go for that information. But on top of that we know from a variety of sources that are documented in historical section that people do want the ability to make choices and we need to have a computational system that captures and persists those choices. And HIPAA allows...nobody is saying choices can't be made...

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

Yeah.

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

We're saying when choices are made how to we make them computably is really the question of the day.

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

I think that's a much...so just as frank feedback I think that's a much more helpful framework for this than starting with and I thought you started off really well with the notion of permission. Choice is a great framework to use here. Preferences is a great framework to use here and then it started talking about consent for treatment purposes of his or her data...

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

Yes.

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

And I started, frankly, getting lost in the intent versus maybe some of the outcome goals.

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

Yeah, I mean, I think the key thing to remember is our presentation of two clear parts, one is a very high-level summary with a strategic direction implied and the other is the granular explanation of how the actual landscape assessment was conducted that was the difference between me and then Julie speaking and I think if you think about it that way and if you look at the slides that way it will become a lot clearer.

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

Yeah.

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

But...

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

I guess what I'm saying and I'm happy to drop it at this point, I guess what I'm saying is that when the strategic framework is presented in the way that it is, I lose it on the details because I'm not sure what the details are intending to address.

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

Okay.

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

So, I guess that's feedback for the presentation. I do think that the choice framework and permissions framework is a much better framework to be using when talking about this.

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

Okay and that's why we're not going to be calling it electronic consent management because it gets people...it moves them...we want to frame it right.

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

Yeah.

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

So, Dixie, what would be our next question?

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

We have a question from Peter Kaufman.

Peter N. Kaufman, MD – Chief Medical Officer & Vice President Physician IT Services – DrFirst

Hi, I have a couple of questions and one comment, but one of the questions has to do with patient acceptance and I value the thought about this kind of a granular consent and electronic ability to do it, but the previous attempts at it, and my own experience with patients, has been that while a very, very tiny but vocal minority expresses concerns about the way that things are. The vast majority is much more likely to just ignore it and say “oh, whatever” or just, you know, “everything, I don’t care” and if they are given an opt in as opposed to opt out for something like this not ever go on line and opt in because they just don’t have the time.

I’m in Bethesda, Maryland, I have an extremely technical group of patients and I can’t get them to sign up for the portal even though it’s a secure way of getting stuff directly into the EMR rather than using e-mail as I’ve been doing for 15 years with them. So, have you done any look into patient acceptance of this or are you just trying to build the groundwork in case patients will accept it? And I do have another question after this.

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

Our findings in the past are similar with your experience which is the vast majority of people actually don’t even know that they should be making choices or choose not to make choices but we need to have choices and computable documentation of those choices available for those who want to make a choice and that keeps being reiterated in many research articles that I’m not going to get into today, but that finding has been consistent across the work ONC has done since 2006 in the HISPC days.

Peter N. Kaufman, MD – Chief Medical Officer & Vice President Physician IT Services – DrFirst

Okay, I’m not sure I necessarily agree that we have to always meet the needs of the few with something that’s so complicated, but I do think that there will be value in the future and I think more and more patients will come on board with time if it’s offered.

The next question had to do with the contributors that you interviewed. Looking at your slide it looks like you interviewed a number of organizations and the really biggest companies producing electronic health care solutions, did you consider talking with any smaller companies that deal with smaller practices and, you know, things shy of the enterprise side?

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Right, so, hi, Peter, this is Julie Chua, so we had criteria for selecting the contributors and one of the criteria was maturity and market share, so we did make sure that we had a good, what do you call this, spread of developers and vendors and Kris Miller you can interject with more specifics, but we made sure that we had a good distribution of contributors for this assessment.

Kris Miller, LL.M, JD, MPA, CIPP/G, CIPP/E – Principal Privacy Strategist, Enterprise Strategy & Transformation Division – MITRE Corporation

Right.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

So, I hope answers your question.

Kris Miller, LL.M, JD, MPA, CIPP/G, CIPP/E – Principal Privacy Strategist, Enterprise Strategy & Transformation Division – MITRE Corporation

Hi, Julie, thanks, this is Kris at MITRE, yeah just to back that up, we did approach a few of the smaller vendors, if you go back to that slide, I believe it's slide number 12, Sandlot Solutions and Foothold Technology being some that are operating in a space that is a smaller market particularly focusing on mental health and other data specifically because that community has sort of not been participating and they've been excluded basically, that data coming from Part 2 facilities being excluded from some of the more traditional HIO networks.

So, those particular vendors we did reach out to and discuss, and in fact they did have some solutions particularly dealing with more granular consent capabilities. So, that's why we wanted to reach out to them.

Peter N. Kaufman, MD – Chief Medical Officer & Vice President Physician IT Services – DrFirst

Thank you, that answered my question. My last thing is a comment. I'm hoping that whatever standards you end up choosing that they're extremely strict and not a framework of standards but an individual standard that anybody could write and anybody could read similar to the CCR, CCD, C-CDA and different from some of the older standards that were more of a language than a standard and required people to talk to one another.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Right, yeah, thank you Peter for that comment and actually Dixie, if I may just let everyone know that this is something on the work plan for the TSS Workgroup and it is something that we would hope the Workgroup will deliberate on regarding standards and what standards should be adopted or leveraged as part of the roadmap.

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

And that...this is Lucia, that's why all we included today was a slide of the universe we identified of available standards, we didn't actually pick any and nor did we receive a recommendation as to one.

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

Julie, this is Dixie, I had my hand up with respect to exactly that topic, so if I may, I'd like to interject that the slide that addresses standards, slide 16, really I don't think is accurate. I've done considerable work around standards in this area and the existing standards do address structure and they address metadata, and sensitivity, and LOINC that you have listed there addresses consent for medical procedures, but I have not been able to find any standards that exist that provide vocabulary for expressing individual permissions with respect to the use of one's data.

HL7, you know, has CDA structure and it has confidentiality codes but it doesn't have vocabulary for permissions and similarly XACML has metadata and structure but it too lacks the standard vocabulary for expressing permissions. So, I think that this is an area that there is need for more work.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Great, Dixie, thank you.

Peter N. Kaufman, MD – Chief Medical Officer & Vice President Physician IT Services – DrFirst

If I may, since I was the one who brought it up, it may be a need for something more like the original CCR, a very strict standard but not a document, it's a dynamic standard that allows change and has a single current state as opposed to something that would be a document you have to make sure you had the newest one, just a point.

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

I'm really talking about the...I think there are standards there for format and packaging, but vocabulary specific codes that one can use to express permissions I have certainly not been able to find it, you know, within the US or international standards either one.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Great, so, Dixie, thank you so much bringing that up and that's exactly why we are putting forth these standards that were identified within the assessment so that the Workgroup can weigh in on that and say if it is inaccurate or what else we need to look at. So, Kris, if you can just make a note of that, please?

Kris Miller, LL.M, JD, MPA, CIPP/G, CIPP/E – Principal Privacy Strategist, Enterprise Strategy & Transformation Division – MITRE Corporation

Done.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Okay, thanks.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Janet Campbell is next.

Janet Campbell – Software Developer – EPIC Systems

Hi, everybody, this is Janet Campbell, I'm from the API Workgroup. Thank you first of all so much for your work and the opportunity to see it. I too had a question about granular consent and Julie you were describing a future state, Phase III, where granular consent is the norm. I've found talking to clinicians that it kind of depends on how granular consent is defined, but that it's sometimes, well not sometimes, quite often I hear a fear either of a healthcare delivery organization worrying that they're not going to produce accurate and complete data as a response to queries and from individual clinicians who feel like they can't trust the data coming in if they feel like it's been excised and I think or redacted, and I think part of that is especially around core clinical elements like medications, allergies, problems that kind of thing.

And I'm wondering if you heard of that as part of your study. And then also too, as I was looking at the stakeholders that you interviewed you talked to AMA but I don't think I saw any healthcare delivery organizations on there or non-governmental healthcare delivery organizations. I'm wondering if maybe that's a space that you're looking at for a follow-up either to address this particular issue or the wider picture.

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

So, this is Lucia, I'm going to take a stab at answering and then I may turn it over to Julie. So, the first thing I would say is you have to remember the work MITRE did was to evaluate the information, to answer the question, are there technical barriers to computably adjudicating privacy, which is different from, are there policy issues about how we adjudicate privacy and what does privacy mean. So, we really have to sort of separate those two things out.

Part of what I was trying to get at in my introductory comments was this is a dialogue between how we make privacy balances and whether we can build those privacy balances appropriately into technical systems, it's neither a just technical question nor a just privacy question it's both and that's why it was my request that all the Workgroups that are invited today got to attend is because we all have a little bit of a piece of that knowledge to contribute to the next phase in the dialogue, so that's why you wouldn't have seen large provider organizations interviewed because we think that would be about how do we solve for this...the complex environment that we showed you slide two, can we simplify it while still maintaining the balance that individual citizens have come to expect.

And that kind of leads me to your first question, which I'm going to answer second, which is we hear all the time in many different venues people's concern about whether the privacy balance at a policy level has been struck in the right way and our job is to listen and coordinate as best we can in that context but we also have to collectively understand the stakeholders, that many of those balances have been struck and have been in place historically for a very long time. Part 2 is a great example. Those Part 2 rules that are, you know, everyone weighed in on the RFI are under reconsideration for the first time in several decades.

And so, we have to think about the fact that those policy choices have been made and they may be uncomfortable for an individual or a patient in one context and might find it objectionable and in a different context a provider might find it unworkable or complicated, or objectionable but it's a balance and our job is to sort of look at that balance in the rules environment that we have and figure out how to make it inoperable. So, that's what's coming down the pike in the roadmap. Julie, do you want to add anything to that?

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

No, I think to Lucia's point, this assessment was focused on the technology piece, so we tried our best to maintain that scope and maintain that focus, yeah, and that's why we didn't really tackle the policy too much.

Janet Campbell – Software Developer – EPIC Systems

Then maybe, I think the only thing that threw me then was just seeing full on granular consent without any notice of that balance as the chosen, I guess or anointed idea for Phase III that was the thing that worried me most of all but your explanation makes sense, thanks.

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

So, the thing to remember about this slide, slide 13, the current state, the current growth and the future state, that this actually lines up really well with the 10-year vision, right? We're not going to get to the future state in June of 2015. There is so much complicated work that we need your help doing.

So, it's...there is a path and we have to go along the path, but the thing about granular choice that you have to remember is not only are there already privacy decisions at a policy level that have been made about sensitive conditions, but we know from feedback from patients that in fact there is some demand for granular choice it's not an abstraction and we have to figure out what that means as we build interoperable systems so that the granular choice for a person who lives in Maryland and moves to Idaho is the same and that's how we get to the fair information practices, is the person understands what their choices are and whether they want to exercise them or not. Does that make sense? So, just think this is where we're playing a very long game of baseball here. Next question?

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

I have some comments, I don't know if the hand mechanism...

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

We have a question from Larry Garber.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

I'm sorry, who was the next one?

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Larry Garber.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Okay, that would be me. Thank you. I'm an Internist up here in Massachusetts and I'm going to first piggyback on what Janet Campbell was just saying is that there is a technological barrier with this granular choice and that when in my free text note I have specifically protected sensitive information that the current state of natural language processing does not allow that to be granularly picked out and excluded. So, aside from the policy issues there are also technological issues with that. But that was really wasn't...that was just a statement that wasn't what I really wanted to talk about.

Which is that...so, you know, I agree with the end goal that we do want to try to have, you know, a computer interpretable consent directives and that's great, you know, they may say that in emergency situations this can be done or from requests that come from within the state that share the same laws this can be done, but if you haven't set up a framework outside of the, you know, the consent directive, a framework that conveys that this query is an emergency situation, that this query is from a physical location within the state then you may not be able to actually follow those consent directives.

So, I think there is a context that's missing that needs to be considered as you're building this so that queries can convey a context that allows the directive to be computed.

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

So, I think we actually agree. So, one of the things we've been trying to point out is that because we have a diversity of rules and the rules don't mean the same thing at every place, we cannot...our computers, which are, you know, kind of judgment neutral, right, it's all about our judgment that makes them not neutral, can't tell us very easily, you know, we don't have...to borrow the technical...we don't have the vocabulary for when is an emergency an emergency, when is behavioral health behavioral health, right?

And so, that...we're not saying there are no technical tasks to be accomplished what we're saying is that we have the tools to accomplish those tasks and we have to accomplish them to get to what the 10-year vision is. Does that make sense?

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Yeah, I think so, what you're saying is there is a lot of enumeration that needs to be done.

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

Yeah, a lot of harmonization that's what we would call it here, we need to harmonize things so that, you know, whether you're a small developer or building something within your provider network or you're a large national company, when you're capturing a patient's preference about behavioral data it means the same thing everywhere it's captured. That's what we have to do to get to interoperability and that's what you'll be seeing in the spring as we release the roadmap, some ideas about that. We look forward to your input.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Thank you.

Lauren Wu – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology – US Department of Health & Human Services

Next question is from Brian Ahier.

Brian Ahier – Director of Standards & Government Affairs – Medicity

Hi, thank you, simple question really just about as you were developing the framework and looking at HIPAA were you also considering the fair information practice principles that the ONC adopted in 2008, in particular around individual choice and consent?

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

So, the first thing I want to be really clear about is we're reporting on findings from MITRE and what those findings lead us to think we need to do next. We actually don't have a framework yet that all has to be worked out. There are policy issues that have to be grappled with. There are these, you know, we know what the technical issues are but they are not solved for yet, to the point Dixie was making about standards and what those standards are capturing.

So, it's sort of like we've gotten to this pausing point in our analysis. In a different universe MITRE's findings would have been "oh, you know, software doesn't know how to do this yet, you have to build a technical framework" that's not the case, we know what the components of the computational system are but they're not all harmonized and adopted yet.

Yeah, so I don't know if that helps clarify sort of what we were doing today, this is really just a preview of a lot of work and conversations we're going to be having with you all for many months to come. Julie, do you want to add anything?

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Yes and just making sure that we all understand why we invited all the Workgroups to this call, we wanted to make sure that you all have the information regarding our findings or the consent assessment findings to inform you when you see the roadmap when it is released.

One the things that, you know, we would want to hear back from, especially the Transport Security Workgroup, which is tasked with this topic, is exactly what Dixie had already initialized which is, you know, there are no standards for specific things that we need to have for the capability of electronic consent management. So, that was great to hear because this is...these are the conversations we need to have to make sure that we are going in the right direction. So, just framing a little bit of what, I guess, expectations are within the Workgroup and there will be also time in the future and as you see the interoperability roadmap it is a huge topic that is discussed.

Brian Ahier – Director of Standards & Government Affairs – Medicity

I was just really responding to the slides on the framing consent and patient choice strategy and the previous slides around HIPAA. And would just encourage us to think very broadly about the policy environment, thanks.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Okay, thank you.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

A question from Aaron Miri.

Aaron Miri, MBA, PMP, CHCIO – Chief Technology Officer – Children’s Medical Center, Dallas

Thank you, I appreciate it and quickly I just want to say, thank you to Lucia and to Julie for their wonderful presentation there to give us the update of what your findings are. So, Children’s Health where I’m from one of the largest pediatric health systems in the country, there are a number of items that tactically...I do understand why you guys did not focus too much on the provider side yet, but I do want to give some element of the dynamics that the pediatric landscape is facing that you might find interesting and the slow adoption within HIEs, the impediment to telemedicine all around consent management, again that opt in/opt out and the education process around that.

And I’m happy to go into detail with you guys off line about this to share with you some real world experiences of how the different policies and other privacy aspects have been an impediment to care beyond what technology allows for. A lot of credit to the vendors for trying to work around it, but even so much so that the Texas State privacy laws are much more stringent than national laws and so forth and so on have another dynamic element there. So, I’m happy to give you guys all that detail off line, but I do want to give two cents credits towards let’s also hear from the provider side.

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

Yeah, so, I think, there will be lots of opportunities for that discussion as the roadmap is made available for public comment and people develop their comments and we work on those comments. I will sort of go back to something I said before which is this issue of identifying the complexities and the rules environment and the diversity and I specifically called out the issue of teenage consent because the ages vary and the teenagers probably don’t even know if they move from one state to another that the different age of consent applies is one example of that and I’m sure that you guys struggle with that.

So, I think there will be a lot...I really appreciate your offer and there will be lots of opportunities to have that conversation that is why we invited the policy...the Privacy and Security Workgroup is because expect that they will be helping guide conversations we have to have in 2015 and in the future about how do we have the policy conversations that we need to have to get to the 10-year vision of this computable privacy issue.

Aaron Miri, MBA, PMP, CHCIO – Chief Technology Officer – Children’s Medical Center, Dallas

And I appreciate that offer and especially as we move more towards the population health, population management and more of the ACO model with partnerships with adult hospital systems it is very important that we get this right. So, I do appreciate that and I look forward to sharing.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Question from Deven McGraw.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes, thank you very much, again, thanks for this presentation this is a tough issue and I'm glad to see the focus on it. I just have a couple...one question and one thought. So, my question is, in terms of the history and "findings" on this topic I'm sort of curious why the quite recent work that we did, that definitely preceded you Lucia, but was actually within the last year that we did on the Tiger Team around evaluating the data segmentation for privacy pilots and making actual recommendations that the Health IT Policy Committee adopted about potentially moving forward that technology or at least exploring it further, I just didn't see that in here. So, it feels like a piece of background that might be missing given that you're focusing on, you know, how to persist consents or indicate them in a technological context.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Right, so, hi, Deven, it's Julie.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Hi, Julie.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

So, that's a great connection and of course DS4P and data segmentation does play into consent. One of the things though is that for DS4P just to make things clear that was focused on Part 2, right? So, when we went into the consent, electronic consent management work we wanted to make sure that we broadened that scope and not focus on Part 2 but it is included, yes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay, yeah, I mean, it might be on the list but...I guess I'm suggesting that ONC has been officially provided with some recommendations about that and so I guess I'm suggesting that if you think they're not appropriate for this effort I think it's good to sort of communicate to the public that, you know, that they're either being rejected or they're being taken into consideration but they don't necessarily quite work for the broader landscape which is what it sounds like you're saying, but I think that needs to be...that kind of feedback needs to be expressly provided since there are recommendations for you on the table about that.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Right, so, Deven, thank you again, so the recommendations from the Privacy and Security Tiger Team were policy recommendations.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

Julie Anne Chua, PMP, CAP, CISSP – Information Security Specialist – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

So, when we...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, but they have implications for technology. I mean, we actually talk about EHR certification.

Kathryn Marchesini, JD – Acting Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Deven, yeah, this is Kathryn Marchesini, just to let you know this effort to look into consent originated as a result of the recommendation from the Privacy and Security Workgroup. So, this was seen as separate, you know, the group recommended the specific policy recommendations as it related to DS4P.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Kathryn Marchesini, JD – Acting Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Those are factored into this effort. ONC is not saying that we are backing away from that topic area but as Julie mentioned we wanted to make sure that we were letting, you know, the public know, industry know that ONC isn't necessarily endorsing one technology approach over another at this point without having a landscape assessment.

So, I think, you bring up a good point. We are at the stage where we have received policy recommendations and the Policy Committee, as Lucia mentioned, suggested that the Standards Workgroup look at the technology and we wanted to make sure that the group, the TSS Workgroup when they started to look at the technology, as it relates to patient choice, they had a full picture.

So, Julie Chua actually has overseen some of the DS4P work. So, when the TSS Workgroup looks at consent we had enough information about DS4P we wanted to make sure we had the other part of the industry landscape. So, I don't think it was intentionally left out. I think it was maybe assumed coming into this call. So, that's an oversight on ONC's part and presentation.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay, that's incredibly helpful Kathryn. I appreciate that and it all totally makes sense. And I think the only other point that I wanted to make is I actually really liked the concept of computable privacy but then wonder...because it seems to me that you could be passing on consent in circumstances where it's warranted but also, you know, what's the legal basis for exchanging the information which is not limited to consent.

So, I guess then it's a little bit disappointing that even though the presentation starts with computable privacy as this sort of much more, you know, this concept that has a broader vision to it that then when you sort of get down into the details on the landscape assessment it was really just looking at the issue of consent and so, you know, I'm just suggesting stay on that computable privacy concept I think it has much more utility for a broader range of exchange.

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

So, Deven, this is Lucia, I'll just say what I said before which is you have to just think about the way Julie and I staged this which is the first five slides are what we took from MITRE's finding, the remaining slides were what MITRE did to get its findings.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

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

You know there is...we will be working on getting the MITRE findings out in more detail but the point of those findings is what do we do next not the actual findings and that's what we're working on right now is taking those findings which could not have been more timely prepared frankly and working them into how we're planning for what we want to propose to you all, you know, for the public comment with regards to the roadmap. So, I'm really thrilled that you like the idea of computable privacy and I'd say go forth and say it.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well, good, I just did. Thanks, that's all for me, thank you.

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

Quickly, Deven, this is Lucia, I just wanted to get back to the Part 2 and the DS4P for one moment. So, I just want you all to recognize that this is a great lesson in the complexity of the rules environment. So, the Part 2, the 42 Part 2 rules are the same in every single state.

The behavioral health rules that might, you know, effect the same patient population but may not be the same in every single state and that's a symptom of the complex rules environment we're in and you'll be hearing a lot about that because one of the things that might be telling us is when the sensitive condition is uniformly understood we actually can segment the data and create a computable environment where the patient's choices, to the extent they want to make them, are captured and that environment can also tell us what to do when the patient doesn't specify a choice.

So, that's what I take from the whole DS4P exercise which of course was completed before I even arrived here, but as I learned about it I said, well, Part 2 is the same in all 53 states and territories. It's something to think about. Next question.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

David McCallie, please?

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

Yeah, thank you.

Wes Rishel – Independent Consultant

This is Wes Rishel, I just want to say that I've had some difficulty with the hand raising mechanism here. I'd like to be sure I get a chance in the 10 minutes that remain thanks.

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

So, this is David, I'll go fast and I may come across a little bit as a grumpy old man here, but I've sat through enough of these high-level approaches to trying to solve this problem in the 6 or 7 years that I've been working on the Meaningful Use space to know that unless we take a fresh approach we're not going to get any further than we've gotten in the past and I was encouraged with Lucia's opening remarks that we were going to take a fresh approach because she made this very careful distinction between permissions and consent.

And then we got into the slides from MITRE, whose work I normally think is terrific, and I was very disappointed because it's just a total jumble of definitional overlaps and inconsistencies even suggesting equivalence to things like patient preference, authorization, meaningful choice and release of information, which you refer to as alternate terminologies.

So, I'm really dismayed by these slides. I don't think they set a very helpful landscape for discussion if for no other reason than the definitions are completely inconsistent, inappropriate and inaccurate. So, that's my big complaint.

My suggestion, I'd like that to hopefully have a positive, is that we really shouldn't think about this as the end goal is computable consent or computable privacy. I think we should think about this as the end goal is computable solutions to common problems around privacy and data sharing because if we go after it as a technology solution we will reach the same impasse of unimplementable system design that has plagued us for the last decade and a half that people have tried to solve this problem.

But if we go after the common use cases where we're having real world problems between real doctors and real patients, and we approach each of those use cases in a prioritized way and solve those problems with computable solutions than I think we can do something to move the ball forward.

My guess is that it won't look like XACML and it certainly won't be based on XDS. So, wrong standards for a 10-year vision, wrong approach to put computable privacy as the goal in and of itself. The goal is to solve the common problems that are getting in the way of patients having their data shared where it needs to be shared.

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

Okay, David, so I just want to say you actually hit the nail on the head because what MITRE's findings tell us is that the landscape is chaotic, diverse...

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

Yeah.

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

I won't say incomprehensible but it's chaotic and it's diverse, and it's confusing. And that takes us actually back to policy, which is how do we make it unconfusing while still having the right balance for an individual's privacy and that's my slice, but...

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

Yeah and I think we do that by solving problems that people want to have solved. So, if I'm a patient and I'm sitting with my doctor and he says "gee, I have indication that your record is scattered all over the country" and I say "go get it" he should be able to do so in a heartbeat.

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

Absolutely.

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

That would solve...that would solve so many problems. So, how do we...

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

Absolutely, absolutely, we totally agree and we think that that's where we want to get. We have a way to go. We have a lot of years to go there, but that is definitely what happens at the end of the 10-year vision statement.

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

But you don't need 10 years to get to that state and you don't need XACML to get there that's a consumer-driven...

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

...

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

Authorization to pull the record and that ought to be simple.

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

And the other thing you point out, David, and that's the exact purpose of this, not only is the landscape confusing and chaotic, and diverse, but if MITRE's identifications of this...of possible standards says to you all, as our volunteer experts, that those are not the right standards that is so important for us to know so we can identify if the right one does exist and if not how do we get it to exist.

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

Yes.

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

So, actually, 100% on point, I couldn't agree more and I know we have one more question and I can stay a little bit late so if we want to take that last question before you conclude, Dixie?

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

Yeah, that's fine; I think we should have just the one, Wes's question and then conclude.

Wes Rishel – Independent Consultant

Thanks.

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

I know other people...everybody has other things on their calendar so I don't want to...

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

Dixie, I will say, this is the first time we're going to talk about this, this is not the last time. So, we'll have lots of time to have more questions later.

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

That sounds great, thank you very much. Okay, Wes?

Wes Rishel – Independent Consultant

Thanks, Dixie. I want to say that my...I've gone between elation and fear faster during this meeting than a basketball fan in the last two minutes of a playoff game. The elation comes from the notion that something might be done about rationalizing the way that consent or the...let's just say, all the steps necessary to share data are described, you know, I'm happy to hear that Part 2 is being revisited, I'm hoping to hear that ONC is influencing other federal government opportunities to influence and rationalize consents even when it applies to the states. Then I hear, oh, but this isn't about that, this is about some technical standards. We're not paying attention to that. So, then I'm in the dumps, okay.

Then, I find that MITRE says, we have the standards we need and they are standards that have been in place since roughly the NHIN days, I mean, in 2009, but in fact those standards were incredibly complex and were never implemented for any of the semantics any different than opt in or opt out except in laboratory situations and in one federal agency where when they talked about the difficulties of informing patients of how they could make their choice their comment was "well, we need to establish a new position which is a privacy counselor to help the patients understand what their choices are."

So, I'm particularly troubled because under the current rules of the Standards Committee I can't participate directly in this project. So, I think Dixie really nailed an important point but for reasons that are broader than some people may appreciate which is the issue with the standards is the vocabulary. The thing is that the vocabulary expresses the semantics of what we mean by consent and how we can compute consent and things like that. So, it's not by accident it's not there it's because that's the hard part that nobody wants to solve.

Until we have some idea that we can solve that it seems that all of these notions about creating some centralized organization to approve every transaction for consent, which is where this seems to go, is really dangerous.

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

So, this is Lucia, let me just address a couple of things. First of all I want to remind all the Workgroups attending today, the reason I asked for you all to be invited was because we looked at the Workgroup schedule and we knew that you would want this background as you tackled your comments on the interoperability roadmap and this was the best way to make sure you had it in the right amount of time and in the right order.

So, for several of our Workgroups it's like "why am I here" a little bit out of the blue, don't worry it's going to become relevant as you get to the roadmap. So, you will have opportunities if you're on a Workgroup to read...any member of the public really, to give us input on the roadmap and this is going to be part of the roadmap and there will be other parts of the roadmap as well both policy and technical that you will be interested in this is just a big complicated one that is underpinned by some findings and we wanted you to have a chance to get a preview of those findings. So, I don't want anyone to think again, this is the first attempt to discuss this not the last and we will be talking about it a lot.

The second thing I wanted to get to was, you know, the contributor suggestions, I think it's really important to go back to what Julie said, what's on slide 18, those are ideas that the interviewees supplied to MITRE, they are not anything that ONC is asking for feedback on as a recommendation and we haven't adopted anything. They're ideas that essentially healthcare stakeholders like you who were interviewed had and when you comment on the roadmap you can tell us your ideas too.

So, there is no, you know, centralized anything planned, it's about the goal is a functional goal of being able to move data consistent with the privacy permissions that apply whether the patient documented them or didn't document them. So, that's the goal.

And the last thing I wanted to say, exactly nail on the head about the standards, if in MITRE's landscape analysis they identified standards that you as experts think are not appropriate for the technical challenges in this space or for the Privacy and Security Workgroup that identified policy questions that's the wrong question or the wrong answer that's the feedback we're going to need from you as we go through the process of finalizing that interoperability roadmap and I hope that addresses your question.

But your comments really reminded me that we need to really make sure you guys understand the context of today's call, which is it's really quite a logistical thing, how do we get this information to these four Workgroups who have an interest in it because they need it before they see the roadmap.

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

Okay, thank you, very, very much that last clarification is really useful to us Lucia, well, all three of the points that you made, and we will be tackling that when we come back after the holiday. We obviously...you've captured the attention and interest of everybody who was on the call today and we had a lot of really good discussion here.

As Julie mentioned the Transport and Security Workgroup does have on our work plan looking at consent management and that topic will be undertaken when we return at the beginning of next year. And before I turn this over for public comment I just wanted to once again thank you all for dialing in today and I want to thank Lucia and the MITRE team, and the ONC team for all the work that you've done on this, and with that I think we'll turn it over to public comment.

Public Comment

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Operator can we please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

There is no public comment at this time.

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

All right, I must admit I'm a little bit surprised, but thank you all again for dialing in and I hope you all have a very good holiday, and enjoy moving into 2015, I'll see you next year. Bye-bye.

W

Bye.

Peter N. Kaufman, MD – Chief Medical Officer & Vice President Physician IT Services – DrFirst

Same to you Dixie, thanks everybody.

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

Bye-bye.

M

Thank you, bye.

Public Comment Received During the Meeting

1. Brian Ahier: Here is what is cool about HIPAA :-)
<https://www.youtube.com/watch?v=ZJ2msARQsKU>