



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
October 27, 2014**

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy & Security 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. I'll now take roll. Deven McGraw?

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

Here.

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

Hi, Deven. Stanley Crosley?

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Here.

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

Hi, Stan.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Hello.

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

Adrienne Ficchi? Bakul Patel? Cora Tung Han? David Kotz? David McCallie?

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

Hi, I'm here.

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

Hi, David.

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

Hi, Michelle.

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

Deb Bass? Donna Cryer? Gayle Harrell?

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

Here.

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

Hi, Gayle. Gil Kuperman?

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Present.

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

Hi, Gil. Gwynne Jenkins?

Gwynne L. Jenkins, PhD, MPH - Senior Policy Advisor to the Director, OCRBP - National Institutes of Health

Here.

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

Hi, Gwynne. John Wilbanks? Kitt Winter?

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

I'm here.

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

Hi, Kitt. Kristen Anderson? Linda Sanches?

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

Here.

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

Hi, Linda. Manuj Lal?

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise

Here.

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

Mark Sugrue? Micky Tripathi? Stephania Griffen?

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

Here.

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

Hi, Stephania. Taha Kass-Hout?

Taha A. Kass-Hout, MD, MS – Director, FDA Office of Informatics and Technology Innovation – Food and Drug Administration

Taha Kass-Hout is here.

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

I'm sorry I totally butchered your name. Is Kathryn Marchesini on from ONC?

Taha A. Kass-Hout, MD, MS – Director, FDA Office of Informatics and Technology Innovation – Food and Drug Administration

It's okay.

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

Here.

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

And Julia Cassidy?

Julia E. Cassidy, JD – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Here.

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

Any other members from ONC on the line? Okay, with that I'll turn it over to you Deven and Stan.

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

Great, thank you very much Michelle, appreciate it. The first item that we have on our agenda is to do a little debrief from the joint Health IT Policy Committee and Health IT Standards Committee meeting that took place last Wednesday. And I do this with a bit of trepidation because there are a couple of people on the phone call who were present during that meeting and/or had very active presenting roles during that meeting. So it's...Gayle and David, it's nice to have you on. In case I mess this up or leave out anything important, please chime in. My goal here though is to be very...to talk at a very high level about what happened at that meeting and subsequent discussions that are going to be going on with respect to the Interoperability Roadmap that may end up requiring us to do a little bit of deliberation, but it's a little unclear at this point.

So, the joint committee meeting which took place last Wednesday, and for those of you who were not present and are interested in getting more of the details, the materials are always up on the Health IT Policy Committee Website. But the presentations that took place on that call included some initial thoughts on the scope and direction for the upcoming Interoperability Roadmap from Erica Galvez at ONC and Erica is the one who is leading that portfolio of work for ONC.

And that was followed by presentations from the...and recommendations from the Governance Task Force, as well as a report from the JASON Report Task Force, and this was a task force that looked at the report that was issued by the JASONS, which is a high-level expert group that issued a report several months ago related to interoperability. And the job of that task force was to opine on it. And so that was an all-day meeting, very interesting, robust discussion.

I'm going to draw a couple of highlights from those presentations that have some nexus to our Privacy & Security Workgroup, specifically the Interoperability Roadmap has a specific building block dedicated to the issue of privacy and security. And Erica Galvez reported some feedback from the field in terms of ONC's initial research into this issue and noted a very strong desire for some consistency and clarity in policies and standards for being able to exchange data across different regions, and particularly across different states, given sometimes the multiplicity of state law. And a desire again for some clear and...more clear and consistent policy in that regard, also a desire for clear and consistent direction around authentication and authorization with respect to the exchange of data.

Also a need to sort of address some of the more foundational issues first and then, of course, get to some of the more difficult policies like granular consent maybe not right away, but have a trajectory for reaching that point. And lots of need for increased education and awareness with respect to the individual's right to access their data, the right of individuals to see who's viewed their data, individual's responsibility for the privacy of their own health information, for example when they share it with mobile Apps or other consumer facing tools and the providers' role in securing data.

And they had a couple of initial recommendations that came out of that including the need to develop methods for consistently representing, managing and communicating privacy preferences and consent, where it's applicable, across an exchange ecosystem. And also a need for a more consistent approach to implementing security best practices, including encryption for both data at rest and in motion. And all of these issues frankly are ones where the Tiger Team, our predecessor workgroup, has provided a significant number of recommendations that are relevant to some of these issues. But it's very interesting that these issues are likely to continue to surface again with respect to the development of the Interoperability Roadmap and particularly specificity around some of the milestones in three years and five years and then 10 years out.

Similarly the Governance Task Force noted privacy and security as one particular set of issues, but not the only issue, that may necessitate some additional work by ONC, in terms of governance. It was interesting, the workgroup was divided on whether ONC needed to take a more...ONC and other regulators frankly, needed to take a more proactive role or whether they should have a lighter touch around certain aspects of governance. And they also recommended the use of public-private stakeholder groups for resolving other governance issues. But there were not a lot of specifics from that workgroup on exactly what topics should be taken on by this public-private stakeholder body or necessarily what it would look like.

And then the JASON Task Force report, which David McCallie co-chaired, had a number of recommendations with respect to standards and a health information exchange architecture built on APIs. And not going to go into a lot of detail on those recommendations, only to say that the bulk of what was discussed at the Health IT Policy Committee and Standards Committee meeting is going to be drilled down on further by the Interoperability and Health Information Exchange Workgroup, which is co-chaired by Micky Tripathi and Christoph Lehmann. I sit on that working group as a liaison between our workgroup here in privacy and security and that workgroup, and David McCallie is also a liaison, I believe for the Standards Committee, is that right David?

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

I think so.

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

Yeah, well you can be a liaison for us too if you want.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Deven hi, this is Micky, I'm on, too.

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

Hi, Micky. And we have Micky on the line, too. So there's a fair amount of cross-pollination that is really intended to be a way to sort of feedback privacy...specific privacy and security questions that come up during the IHE Workgroup further deliberations that are specifically intended to feed into this draft roadmap that ONC is expected to release for public comment in January.

So the bottom line is that we as a Privacy & Security working group do not have any specific tasks or questions that have been thrown over the transom for us to resolve at this particular juncture. Having said that, it is quite possible that there will be some issues that surface in the Interoperability and Health Information Exchange working group that we may be asked to quickly take on and in the event that that occurs, we will interrupt our discussions on big data, which we're going to start today, and try to resolve those issues in a timely way given that ONC needs to release its draft roadmap to the public in January. And at that time during the official public comment phase we will, in fact, be asked to take on specific aspects of that that are relevant to our charge, to our Privacy & Security Workgroup.

So, I'm going to see if others who were at the Health IT Policy Committee and Standards Committee meeting want to comment on anything I've left out. Michelle Consolazio, if I've misrepresented our role in all of this and there's something I'm missing, please let me know. But just wanted to give you all a general gist of what occurred last Wednesday and what could be relevant for us down the pike.

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

Deven, this is David, I have a comment. I think you summarized the meeting well and conservatively but I think the comment that you made in one of the sessions, I guess it was in the governance session, really touched on a sensitive spot. I had several people comment to me afterwards about the comment you made, and you probably can restate it better than I can remember it, but you were essentially calling for a greater understanding of how consent works and what is and is not required for consent. And I think it ties into some of the discussions that we started having about more granular consent in the context of the JASON Report that we just deferred because we didn't have time to get to, but...

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

Right.

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

...sort of calling for clarity and understanding of what is and isn't required and without changing anybody's laws, there are just gaps in understanding and I thought you made that really important point.

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

Well thank you David, it was a reaction to the presentation from Erica Galvez about the ONC sort of initial findings from its research and stakeholder outreach that there was a need for policy for consistency and clarity with respect to existing policies around when you can share data about patients and with patients. And yet the recommendation that they sort of rolled that up to was, well what we need is more consistency around how we represent consent.

And my point was that while certainly that would be needed, there is data sharing that can occur without necessarily needing to go back to the patient to ask her if it's okay and that in many cases includes sharing for treatment purposes and that just focusing on consent wouldn't necessarily provide the kind of clarity that the marketplace is looking for around when consent is required and when it is not required and when sort of liability for sharing transfers from the data holder sharing party to the recipient.

And all of these topics again are ones that we have opined on fairly extensively in the past and so maybe one particular helpful thing we could do would be to just resurface those recommendations, not necessarily rediscussing them as a group but making sure that ONC they have all of them but to just present that as, we've already done a lot of work on this. But the bottom line is we need more clarity than just how do we pass consent from one end to the other when consent is required. It's not always required, in circumstances where it is required; you absolutely need to be able to do that. So thank you, David that was the point.

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

Yeah and I'll just put my two bits in for at some point maybe going back to that notion that we talked about in the...a little bit on the JASON Task Force of putting together kind of an overall, big picture summary of where your data flows and what choices and control you have over those flows and do it as an instructional piece, just to sort of say, here's the current law...

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

Right.

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

...and use that maybe to identify opportunities where there maybe needs to change some things. Because I agree with you, it's very confusing. It's best to never use the word consent because it means so many different things to so many people.

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

And this is Gayle, I want to jump in also and thank you Deven, you did an excellent job in clarifying things for members of the Policy Committee. Also just want to reiterate the conversation a little bit more on governance. There seemed to be a great deal of controversy within the Governance Workgroup which then carried over to the Policy Committee as well, so that is an area that is going to need continuing conversation and certainly privacy and security matters play very heavily in governance and what the role of it is...what the role of governance is in how you determine what policies and procedures are in place to protect privacy and security. So, it's all interwound, everything is very much interwound with privacy and security. So I think we have a big task ahead of us on this committee...all your input.

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

Yeah, agree with that. I mean the other thing to note is that in fact the discussion that we have teed up today around this topic that we like to call big data, which frequently is defined in a way that includes how do you reuse or have secondary uses of information that you might collect in the context of treating a patient, but then want to do more with it to improve quality and to learn from it. And the Interoperability Roadmap, not the roadmap I'm sorry, the vision that was articulated by ONC, the objectives from 5-10 years out do include the ability to really leverage data and learn from it in order to improve both individual and population health and to improve the evidence base for care.

So, in many respects even taking on the big data topic, much less the issues that David and Gayle just raised, it's all connected into this sort of long-term vision for how we leverage and share health data effectively to improve health. Any other thoughts on the meeting and our role in the Interoperability Roadmap? I think the big underlying message is both stay tuned on some of these other sort of more immediate shorter term, you know, issues that pop up with respect to the short term vision around interoperability, because we're going to start today to tackle the ones that are more relevant to longer term interoperability and we're short handing that and calling it big data.

All right, well we're going to go ahead then and move to the big data discussion. And so we're now actually finally on the slide deck that we distributed to you and we're on slide 2, and the purpose of this slide deck, there's a lot in here, is to try to at least get some dialogue going about this topic of big data, to explain why we've been asked to tackle this and to start having a discussion about the issues that arise. And perhaps even more importantly, to begin to have a discussion about what particular issues we think we need to take on as the Privacy & Security Workgroup to the Health IT Policy Committee versus the entire universe of health big data.

I mean certainly we can and must limit our examination of this issue to what's consistent with our charter, which is that we look at privacy and security issues and not the myriad of other issues that come into play with respect to leveraging data for good in health. But even within the privacy and security, within that topic, there are sort of multiple directions that we might potentially go with this and so we have prepared with MITRE, who staffs us, Stan and I, and also worked with ONC staff, just to throw out some background information to get the conversation started. And we tried to limit the slides, but it's a big topic pun somewhat intended and so we're going to sweep a little broad to begin with, but our hope is that during this discussion phase of the call today and in subsequent calls, to begin to sort of scope out some fruitful territory and think through how we're go...what particular slices of the privacy and security aspects of this issue that we're going to take on.

So with that, I'm going to ask for the next slide, for slide 3 and let's go to 4 with some background. So, what is it that we mean when we say big data? And there absolutely is no consistent definition much less, some would argue, a rigorous definition, but we've thrown a couple of the more commonly cited ones up here for you to take a look at.

Big data, there's no rigorous definition. It refers to things that one can do at large scale that cannot really be done at a smaller scale, to be able to extract insights or create new forms of value in ways that change markets, organizations and the relationships between citizens and their government and more. Some people think that at its core it's really about predictions and utilizing data to make some...to do predictive analytics about the future, applying math to huge quantities of data, which is...in order to infer probabilities, that's one person's definition. Next slide please.

We're on slide 5. Here are a few other quotes about the definition, there are even more than that out there. From Gartner, high volume, high velocity and high variety information assets that demand innovative forms of information processing in order to lead to enhanced insight and decision making. From some other folks, storage and analysis of large and/or complex data sets using a series of techniques that include machine learning and other technologies and then in the privacy context the term big data typically means data about one or a group of individuals or data that might be analyzed to make inferences about individuals.

So here you go from an assumption that big data really has to be very, very big to maybe for some folks, an assumption that analytic uses of data that almost always require amassing somewhat larger data sets, how large they need to be is an open question, in order to learn something in health. And whether that's a situation where you know the question ahead of time and you amass the data that you think would be relevant to answer the question or whether you allow the data to percolate the insights without necessarily having a specific question to address. Next slide.

So without diving too much in depth into the definition, I don't even know that it would be a worthwhile exercise in our group to try to land on a definition, although I do think we need to become comfortable with the parameters that we're going to place around the question. I think it's important for members of our working group to understand why this topic is coming to us at this particular time. And this is a quote from the White House report on big data that was issued in May of this year. The government should lead a consultative process to assess how the Health Insurance Portability and Accountability Act, HIPAA, and other relevant federal laws and regulations can best accommodate the advances in medical science and cost reduction in healthcare delivery enabled by big data. This was one of the conclusions and recommendations of that report.

Next slide, please. We're on slide 7. There was also a more issuance from the White House involving an open government partnership and entitled Use Big Data to Support Greater Openness and Accountability. And here there...what the White House acknowledged is that big data again introduces new opportunities to advance medicine and science and improve healthcare and support better public health.

But we need to ensure that individual privacy is protected while capitalizing on these new technologies and data and therefore the administration, led by HHS, is going to: Number 1, consult with stakeholders to assess how federal laws and regulations can best accommodate big data analyses that promise to advance medical science and reduce healthcare costs and also develop recommendations for ways to promote and facilitate research through access to data while safeguarding patient privacy and autonomy.

And so this is what we're being asked to contribute to, the development of these recommendations by HHS. We are a stakeholder body that they have relied on previously to provide them with advice and input on issues involving privacy and security and they are asking us once again to think through a set of issues that are important and that are important both to HHS and the White House and frankly, as I mentioned earlier, do have implications for the longer term vision that is articulated in ONCs 10-year vision around interoperability, the ability to really leverage the full utility of data in ways that we need to in order to improve individual and population health.

So, we tend not to just take on issues by plucking them out of the air and this one is yet another one where we have been specifically asked to play a role in helping HHS and ultimately the White House determine how do you best leverage the potential of data while also protecting privacy and security. So it will involve an assessment of sort of where we are with respect to current law and where we may need to go, in terms of modifications to current law, or maybe even some additional policies in order to facilitate this. Next slide, please.

So these are just some other observations from the White House report that...in case those...for those of you who haven't read it yet, you may want to read it, but here are a few other sort of healthcare specific pieces that we pulled out of it. They do have a def...they did land on somewhat of a definition for big data and the difference between big and small data is that big data is characterized by volume, variety and velocity.

But they had a few other key observations that may be relevant to our discussions on this issue. De-identification is insufficient to protect privacy in big data analytics, that's a pretty provocative statement, frankly, and one that I'm sure we'll have an opportunity to discuss further in the coming weeks as we consider this issue.

Metadata, which is data about data not just the content of the data itself, also can raise significant privacy issues and shouldn't necessarily be treated as less risky than the content. And maybe the key to all of this is to focus on responsible uses versus trying to necessarily control collection through vehicles like notice and consent and we need to re-examine the role of that. Again, these are pulled from the White House Big Data Report, but certainly raise issues that we may want to discuss further. Next slide.

Current policy frameworks may work well enough for small data, but do not meet the challenges of big data, especially in health. And the complexity and this is a quote, "complexity of complying with numerous laws when data is combined from various sources raises the potential need to carve out special data use authorities for the healthcare industry if it is to realize the potential health gains and cost reductions that could come from big data analytics." Next slide.

In addition to the report from the White House, there was also a report that came out on the same day on big data from the President's Council of Advisors on Science & Technology, PCAST. They had a similar set of conclusions. It was a much more technology focused report, don't necessarily want to dive into all of the details of that report, even necessarily all of the details that are on this slide, but there are definitely some...there are some policy implications to, as there frequently are with respect to technology recommendations that may be relevant here. They also recommend focusing policies around actual uses of big data versus collection, but at the same time they understand the importance of privacy and have called for greater research into privacy, the adoption of policies that stimulate the use of privacy protecting technologies and ensuring that both patient privacy and patient benefits from medical research, which is somewhat of an interesting conclusion, in my view.

So, there has been a lot that has been put out there about this issue. We're not at all writing on a blank slate, and I suspect that one of our biggest challenges is going to be figuring out how we tackle this potentially very large issue and what we, as a working group, are going to focus on. And so my role in presenting these slides was to give you a sense of why we are being asked to take on this topic at this time.

I'm going to turn over the presentation of the deck to my co-chair, Stan Crosley, who will take us through a few other sort of background slides around various aspects of health big data. Again, we're sort of inundating you right now with some foundational background information, but the hope is to sweep broad for a little bit on this call, but then subsequently start to sort of narrow our focus, starting with the end of this call and in subsequent discussions. Does anybody have any questions about why we got into this space and what we're trying to accomplish here? I mean, we haven't...we still have some time to sort of scope that out as a working group, but sort of broadly speaking, why we're taking on this question I think is...if you still have questions about the why, now would be the time to ask them.

Okay, terrific. So Stan, I'm going to hand this...let's see, what's the next slide, I thought I was through with my...yup, I am. I'm handing this over to you.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

All right, great; thanks. And we can go to the next slide. So we're going to talk about big data in healthcare specifically, obviously and for the next few slides or the next dozen or so slides, we're going to talk a little bit about big data as applied to healthcare and then talk a little bit about landscape and some of the other environmental factors that are existing right now in this area.

So to begin with, kind of the why is there...why is everyone talking about big data in healthcare? And for most of you on this call, this will be some...none of this will be earth-shattering or new, but kind of make sure we're all on the same page with the background. So the idea that with the recent changes in insurance criteria, the ACA, other activities, escalating costs are nothing new, but the shift in therapeutic and provider reimbursement trends is really starting to drive the need for data that is specific to therapeutic effectiveness.

So, with this movement from fee-for-service to clearly this risk-sharing concept on this looking at patient outcomes and in industry and also in the healthcare practitioners' perspectives, they're looking for some real world evidence type of an idea. The concept that as therapies certainly narrow, therapies initially were very broad and you could use them for very broad purposes and now for formularies, in order to get reimbursement on increasing number of products, there are statements of medical necessity that are necessary from physicians and there are all these activities that are driving ultimately this closed loop concept of there's an illness, they present with symptoms, a therapy is prescribed and an outcome is achieved with that therapy.

And if they can show that closed loop, both the provider shows efficacy of the provider and they get better ratings, they get a better reimbursement pattern and also as industry or others who develop therapy can demonstrate effectiveness in outcomes, then they're more likely to sustain either price points or maintenance on formularies. And so there's a large draw...drive to try and amass more and more data to prove that there are...there's effectiveness in treatment and that the doctors are meeting metrics on the standards of wellness and care. If you can go to the next slide, please.

And now we're on slide 13. And while this shift in reimbursement is occurring, we're also seeing an actual shift in the clinical landscape, how patients are treated, how they are treating themselves. So the clinicians began embracing evidence-based medicine more, looking for the idea that there's data that shows that this worked and this didn't. So there's data that shows that this surgery was more effective than just staying on a drug therapy.

And so evidence-based medicine is clearly arising and we're also seeing this need for translational medicine. It's clearly come und...the whole area of translational medicine has clearly come into its own in the last decade, but picking up a lot of speed in the last 3-4 years. A number of academic institutions as well as provider institutions have translational medicine specialties where they are looking at the latest research, the latest information coming out of periodicals or journals that talk about a test or a methodology that is useful in practice and they're translating that into a protocol for the doctor to utilize. And so these treatment protocols now are being evidence-based or data driven.

The patient demand for data clearly started back in the late 90's with the WebMDs of the world and have picked up rapidly with patient ecosystem concepts, the PatientsLikeMe or 23andMe or other types of sites that are almost too numerous, well, are too numerous to count now for sure. But this self-help concept that there's data out there that others have gone through this, I can get data that I can then apply to my disease or my illness that's well known.

The first thing that people do when they have some type of a symptom is they go on and they Google it, or if you're a Microsoft employee, you might Bing it. But you clearly have a drive toward patient demand for data. It's interesting that other industries have gone through this and financial services is one and your brokerage services is one that was enabled by data aggregation where the EDGAR filing system, electronic filing system that came about in the 90's where in the late 90's where Congress mandated that companies file their periodical filings electronically.

And then EDGAR was created to accept those and then a public interface was there, but companies came along outside of the financial services industry and outside of government and created interfaces to get access to data now that enabled people to do their own stock brokerage activity. And you saw this moving much more quickly outside of financial institutions than inside of them. And so it changed a lot, banking...traditional banking at the teller, to the drive up, then to ATM machines and now online banking and even virtual money.

And so in most of the...all of these trends are data driven, they were not possible until data was developed that could back up their utilization everywhere from data necessary to authenticate appropriately to allow online access to data itself that sits behind the applications that can drive decision-making ability. And we're seeing this same trend moving toward healthcare. The idea of interoperability within the healthcare setting and there are a lot of things that have to happen. Well outside of healthcare there is a lot data aggregation that is going on and we're going to see that interface between those two worlds start to become more and more critical. If you go to the next slide, please, on slide 14.

And all of this demand really is generating a lot of data and a lot of...and sources of data now are arising. So these are the common data sources that we kind of brainstormed and thought through and hit these areas of clinical data, claims and cost data, pharmaceutical R&D data, socioeconomic type data brokerage type data, government generated data, then patient/consumer generated data. And it think the next slide has more information about these. If you go to the next slide.

We kind of consider these primary data pools, if you will. So the idea of clinical data in the clinician's office, the electronic medical records that might exist, electronic health records and medical records and images that exist within a provider's network. Now owner here, don't read as legal property ownership, we don't...we do not want to get into that conversation, certainly not today, and as most of you know who have been in this area, ownership of data is incredibly complicated and probably not worth the effort at this point. But for our purposes, just saying owner is those individuals who kind of control that data.

The claims and cost data, again, different than clinical data. Claims data is held often times by payers and sometimes by providers, but the data sets there have a lot about utilization, drug utilization, therapeutic utilization and cost.

Pharmaceutical R&D data either through pharmaceutical company as sponsors of trials, academics...academia institutions having a lot of R&D data. Clinical trials, high throughput screen libraries for identifying potential target therapies or targeted molecules. And as well as, not shown here, but the idea of data sets about clinical investigators or the ideal trial patients or the types of...or data that goes...that can be utilized to validate input and...inclusion and exclusion criteria in those types of data sets that exist.

And that kind of segues into socioeconomic, demographic behavior data. And this is patients identified as those actively involved in healthcare, consumers who are kind of looking for information. And then healthcare professionals, healthcare providers, those individuals who are interacting; all of those individuals have data about them, in essence, everybody in the US certainly has a data file about them, data brokerage areas.

And some of these are protected by laws, like the Fair Credit Reporting Act, others are protected by the FTC and still other data is HIPAA protected. So, the data sets, patient behaviors and preferences, their retail purchases, their history, their website browsing activities, all types of data that can be captured within this demographic, in socioeconomic information. And this is the data that is...that has existed for a while, but is now being looked at to do data inference on heal...you know, infer health status. So this is going to be a key area.

Government data then, another huge group of data and critical to our analysis; community health data, in Indiana we've got a community health record that gets generated from our health information exchange. So, the government data is incredibly rich here.

And then the final set is that set that we've talked about as being outside of traditional healthcare, patient/consumer generated data. And this is the observational and sensor-based data. It is everything from Fitbits to potentially the electric grid to smart sensors in refrigerators and car tires in automobiles and so, consumer generated data.

Let me just pause there for a minute and as you think about some of these slides, especially in this area right now on primary data sources, if you can think of other primary data sources or pools that we haven't included here, we'll want to talk about that a little bit as well.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

I have a question.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Yes.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

This is David Kotz. Sorry I missed roll call at the beginning. Is this...does genomic data fit into your structure here somewhere?

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Yeah, that's a great point and it could be in any one of those three...

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Yeah.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

...top three pools at least and including...and in government data; I guess pretty much anything other than socioeconomic or well, anything probably other than socioeconomic data can have genomic data in it. And it's a great point, we actually had, I think, at one point we had that broken out as a separate item.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Um hmm...

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

And it may be that it's been...

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Sorry.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

No, no, please.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

I just wanted to make sure we didn't overlook it because it has, in some ways, special properties from a privacy perspective relative to this other data.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

There's no question about it, yup, no question about it. And I think that we certainly will talk about it as far as topics that we'll want to address. It is very unique and it has elements, as you've rightly described, that...in Europe, they're discussing whether or not you can actually truly de-identify, even tissue samples, right?

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Uh huh.

Stanley Crosley, JD –Director Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Because of the existence of the DNA. So let's consider that we may want to come back and create a separate type of a data pool. I think it's in each of these pools, but it's certainly a topic we'll discuss.

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

One other...this is David McCallie, I just had one other minor comment, and I assume it falls into the socioeconomic demographic category there, but, the location data is increasingly easy to collect and very important, sort of where you are, where you've been...

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Yup.

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

...patterns of your movement.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Absolutely. Nah, that's another great point and I think location data is probably socioeconomic demographic, but it's also that patient/consumer generated data. And as you guys have already discovered, these data pools kind of bleed together, there's no question. And so I think you're going to find location data maybe in even more than that, I mean, it's possible that you could see that in the claims and cost data as well. Other thoughts on data pools or this slide that I just kind of ran through quickly? Okay.

And so now we get to the...next slide please, we'll get into the topics to discuss. And we're going to kind of talk about each of these very, very high level and fairly quickly on research, personalize medicine which is, in fact, where we're going to get into a little bit of the pharmacogenetics and even broader, genetics-based medicine, telehealth, consumer-generated and stored data and then we can see if there are other topics we want to think about in this whole area. Let's go to the next slide and dive into this a little and one more, so we're on slide 18 now.

So with big data and research, it is such an enormous topic that we tried to think of it and the idea of what would a Learning Health System want with respect to big data, if it's looking at research? And many of you probably know Lee Hood and his concept of systems biology, or not his concept, but how he's kind of advanced systems biology and some of this comes from some of the work that he's done. It's clearly there's going to be granular data about all aspects of an individual's health; clearly genomics, genetic makeup, behaviors, families, environmental, epidemiological data, all of that is going to be available for research that has never been available before.

Data collected from centers as part of clinical or epidemiological research where you're putting context around a lot more of the health, the...health or clinical data that's being collected or reviewed. Lee Hood calls it the "virtual cloud of billions of data points" and the idea is not only to become increasingly more personalized, but in his words anyway, predictive, preventive, personalized and participatory. So the idea that predictive leads to preventative and personalized leads to participatory medicine.

And so the need, if this is where you're headed in big data, then the need is clearly there to understand all of the privacy and security aspects of this, to understand how we're going to allow the data coming from, as the White House report said, data coming from all of these various environments that are covered under different laws, how can you address their use in research. If you go to the next slide, please.

And the key is in access to the data, I mean, what rights do you have to aggregate the data, the clinical data across electronic health records, all of the genetic data, patient-level data without having direct patient identifiers in a lot of ways. The issues like dates, which as we know, HIPAA sees as being identifiable from a safe harbor perspective, so gaining access to the data that's necessary has a lot of different issues to address.

Then taking that data and getting access to the right analytics or the analytics that are certainly qualified. And then the kind of the holy grail of research and treatment is that closed loop cycle where research informs treatment and treatment informs research. And if you have data systems that are learning and you have a closed loop system and you get research and translational medicine into a therapeutic and then you get the treatment results and the evidence that informs that the research needed to be conducted at a different place. So, the big vision includes those types of things. And of course all of which, which was said earlier, relates to this idea of governance and how privacy and data security is going to play a part in that.

Let me see, I think that might be...is that my last slide on research? Yeah, so we can pause on the research slide. We tried to incorporate a little bit of the genetic idea and the genomics idea. Other things that you would have expected to see about research? Again, this is very high level, trying to anticipate. Okay, we can go through the rest of these then and then we'll pause right before we have our policy conversation. I'm mindful of the time, Deven, at 5 til 3; we probably want to get through this with enough time to have some conversation.

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

Yeah, no that would be great, Stan. I don't want to short...truncate you, so just...I mean, this is the first of many discussions that we're going to have on this, so...

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Yeah, I know. No worries. Let's go to the next slide and then the one after that on personalized medicine. So the idea of personalizing medicine has been around for a very long time in a lot of ways, obviously from the beginning of medicine. Medicine itself was all about becoming more...finding that therapy that works for the individual. But now we're at the point where you're getting to this tailoring of medical treatment for individual characteristics and needs and preferences of the patient. And the data input that enables that to occur is now going to be a significant part of big data.

I think that if you go to the next slide, please, we dive right in to, because of that, this idea of pharmacogenetics or more broadly, genomics, which is probably how I probably should have written this slide is more around genomics and genetics than pharmacogenetics. Pharmacogenetics, obviously the study of genetic differences with the metabolic pathways and response to drugs and therapy, genetics and genomics the much broader study of the impact of someone's genome or their genetic biomarkers with respect to treatment decisions.

And so the idea that machine learning is going to be used to guide medical treatments. I have not met a physician yet who believes that genetics-based medicine is possible without machine learning, right; I mean it's just too much data. It's too much data to assimilate, it's too much data to utilize and so we're entering into another very significant area for privacy where we are going to have what the Europeans like to call, automated decision making, right? You have this biomarker, this issue, you have this epidemiology and it's clear that they're going to...this therapy is going to be one that's recommended for investigation for your treatment.

And so these machine learning models are going to be very important to understand exactly what they're considering and who can use them? More to the point is how can these be used? What's the limitation on the use around this information and around these things? We know certain areas that are...that they're going to be bad and then we know certain areas they could be extremely good for individuals. So the next slide.

This slide is really just kind of making the distinction between precision medicine and predictive medicine. Both are going to be incredibly important, predictive is probably much more controversial than precision medicine. Precision medicine when its talked about generally typically its thought of as being more precise than it is, certainly more precise than it is now, but in the future with more big data, the ability to target individuals' disease at the molecular level will certainly exist. Predictive medicine is much more problematic and that's where, who can use predictive analysis? Insurance companies? Employers? Other things like that that could be very problematic when you're doing predictive concepts, but probability of disease is still a very controversial area. Next slide, telehealth.

So this was, to be transparent, telehealth was a concept that I'm not as familiar with, most of my career...all of my career has been outside of healthcare provider institutions and has been across almost every other area but in the provider. And so the idea of telehealth to me, if you'll go to the next slide, carries with it just that use of long distance clinical healthcare that is being made possible by high throughput speeds and bandwidths and high definition screens and potentially robotics and fine tuning ideas.

But the idea that actually this will be aided by large amounts of data that are going to be generated and then forwarded as part of the interactive session isn't really something that I had thought much about. And so I find it interesting that the activity of telehealth will be enabled with a big data analysis so that when they're in the remote clinical settings, they'll be able to assess and analyze a patient's symptomology, potentially based on data they've seen before or it's been analyzed through machine learning. So the remote patient monitoring concept of telehealth is, I think, an interesting one to consider. Part of this, and I'm not sure it's really the huge movement now toward embedded sensors or embedded devices, so you can think initially of pacemakers, embedded pacemakers, embedded cardiovascular devices, the implantable cardiac defibrillators activity, all of those now are generating enormous amounts of data.

Wireless insulin pumps and not only the pumps, but the glucometers that are all being attached or embedded or carried by patients everywhere generate enormous amounts of data. And so whether you consider that a consumer generated health data or telehealth depends a little bit on the data path. If the data flows first to the provider, then typically you think of telehealth and HIPAA covered and if it flows first to industry or another creator of the device, then it's thought of as consumer-generated data...health data that's not covered under those regulations. So we're going to get into that area here with telehealth where I think it's going to go one way or the other or obviously it's going to go both.

Next slide, please. And then the last category here, consumer-generated and stored health data. Next slide, yeah. So the first thing that comes to mind when you think about consumer-generated data, at least for me is wearables, the huge push now to capture all kinds of information around wearables. And I think that there is a lot that has been written about these things, everywhere I think from smart shirts to smart carpet to smart socks.

I think it was smart socks can determine whether or not elderly patients in the retirement homes have suffered a stroke because now their gait is different than it was. Smart shirts that can determine mood based on elevated blood pressure and heart rate and skin temperature. So all of these things are going to generate, you know, the ingestible sensor now from Proteus that is ingested and when it is, it sends a signal to the stomach saying that the pill was swallowed and so the patient is compliant with their therapy. So all of these types of consumer-generated data are going to mount, and there's been a lot of discussion about well, the wearable movement has kind of run its course and I just don't think that's the case and I think that most people believe that we're just on the cusp of where this is going to go.

W

Okay.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Yes, I'm sorry. And so mobile devices helping people to detect Alzheimer's potentially, eye tracers that look at your eyes, smart cars that have actually sensors embedded in the rearview mirror that can tell when your eyes move off the road, potentially...for a heart attack.

W

Hello?

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

Hi, can I ask people to mute if you're not speaking on the line; we're getting some feedback, someone having another conversation. Thank you.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

And so then there's this clear trend to aggregate things in platforms and mostly outside of healthcare, the platforms that Qualcomm and Apple IO Healthkit. The next slide.

And then closely aligned to generated data is the consumer stored data, the health record banks, personal health records of the world, the Microsoft HealthVault to the NoMoreClipboards of the world that have secure repositories. They are patient or consumer directed, individual copies, they can get medical records coming out. I tend to think of these right now as being cul-de-sacs because the data kind of comes into these, but it doesn't really move out of them right now. They're sort of aggregation points, but they're not really exchange points yet. But they are growing in popularity and as the consumer wearables movement and the consumer generated data works and as HIPAA realizes the potential for interoperability and the exchange of data or the access to data that is supposed to be provided to patients electronically, as those interfaces get better and better, then data flowing out to these health banks and these health records is going to increase. Okay. Next slide, please.

And so that was kind of a flash through topics that we may want to engage on as well as kind of the data concepts. Real briefly now, at a very high level, go to the next slide please; some laws that are impacting where we are in kind of big data in healthcare and this is just at the federal level, really. The first one, of course, that comes to mind is the Health Insurance Portability and Accountability Act or HIPAA. HIPAA's scope applies to covered entities only and so it doesn't apply to most industry, device companies or pharma companies or biotech companies or any of the health App companies or mobile health development companies or 23andMe or PatientsLikeMe or any of those entities are all outside the scope of HIPAA.

It does include, as you well know, both a Privacy and a Security Rule that apply differently. And that may be something we think through on how to utilize the different elements of HIPAA. And then, of course, coming along later and then extending HIPAA is the HITECH Act and the idea that how far has this extended it? Has it, in fact, extended it to pharmaceutical companies or device companies as business associates, because they're providers? The idea that these two things together, the HITECH Act and HIPAA cover a significant part of this world is accurate but nowhere near the entire application.

If you think of the Common Rule obviously as it applies to research, human...research, GINA the Genetic Information Nondiscrimination Act which is a use statute, it doesn't govern collection as much as use and what is a permissible use of genetic information. It has a very broad definition of genetic that is again something we may want to consider at some point.

And then much to I think the misunderstanding of most individuals, the Federal Trade Commission has a serious and significant area within big data and healthcare, Section 5 with deceptiveness and unfairness has a very large footprint on what applies. And there have been joint prosecutions between OCR and FTC in certain areas and I think you're going to see some of that continuing, because these footprints are aligned.

And then, we put in the Fair Credit Reporting Act there just because of the inclusion of socioeconomic and the big data that a lot of the data brokers have, because that's the federal law that in some ways limits use of enormous stores of data that they have. And then, of course, there are a myriad of state laws and regulations as well as other federal laws that may apply from time to time. So this is by no means an exhaustive list, this can be a multi-page list...okay, next slide, please.

And just to kind of give a visual, a couple of slides on a visual. If you think of that top graphic there as kind of the traditional healthcare and how data within an electronic health record interacts and you've got a pharma company or a clearinghouse and other entities around the periphery of those small blue rectangular boxes and how data gets moved maybe for research or analytics and de-identified. And on the bottom you have all the data that's getting generated by consumers in that consumer-generated network.

And then if you go to the next slide, this is kind of an attempt to show the overlay, right? So the FTC clearly is the jurisdictional authority in the bottom half of that slide and HHS and OCR under HIPAA is the authority on the top. But the data is going to be interchanged, it is now moving one way more than two way but the data is clearly going to be moving across those sources. And if we look at our data pools, where that data is coming from and where it's going to be used is clearly moving across these areas. So, there isn't a unified law, there isn't a single law, there are dozens of laws and policies that may apply. So the next slide, please.

And then Deven, I think we've kind of wrapped up the background overview of what we've been talking about at least and kind of the things that we put down on paper and we're going to talk about policy questions. I wonder if we want to pause for a minute and see if there's discussion about any of the previous slides. Does anyone have questions? Okay Deven, I think it's yours to try and make some sense out of this.

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

Thanks Stan, yeah, no, I know. It's an enormous universe of activity going on out there, and even just taking a dive into the laws themselves brings its own set of complexities, as you mentioned. So thank you very much for that overview. So here, Stan and I tried to stake out some sort of initial policy questions, but we absolutely want to start to engage in a discussion on this.

For those of you who are new to the workgroup, it's unusual for us to have many calls that are mostly the co-chairs talking as opposed to lots and lots of dialogue, but we really felt we needed to at least present some background information to maybe bring some folks who haven't been thinking about some of these issues on a regular basis, at least introduce them to some of the topics. But ultimately we're going to have to land on some questions that we want to resolve and a process for how we want to get to some resolution on it.

And so we have teed up a few questions on the next set of slides, which begins on slide 34, are there updates or additional policies that are needed in order to address ethical privacy frameworks and research standards? And when you use the word standard in here, it may be not the best terminology because we do not want to do data standards work, that's not within our purview, but certainly in terms of sort of policies and processes that have an impact on privacy and security, is definitely within our wheelhouse.

On issues of personalized medicine and pharmacogenetics, other types of genetic information both predictive and precision medicine, what are the policies and technologies out there that exist to protect the privacy of the databases that are amassed to address these types of questions? And what policies should be considered, including but not necessarily limited to those around transparency, forgive the typo there, and notice and consent for identifying disease traits, cohort matches, testing recommendations for patients based on data within their EHR? Next slide, please.

And other questions related to telehealth including what are the individuals' protections against privacy risks that arise uniquely through the use of telehealth types of tools? What policies exist around the use of health and non-health data? Again, a lot of the data that's collected may not be health data on its face, but then gets used for a healthcare purpose and raises some of the same ethical and privacy issues that we talk about in the context of healthcare data. What are the policies around access to and use of data that creates inference...use of inferred health status for certain uses? Disclosures of inferred health status, what if it's a stated condition of using the App is that something that is to be discouraged from a policy context? Is it inevitable and if it's inevitable, what kinds of transparency to patients might be necessary so the patients understand the deal they're signing up for when they sign up for the App or when they're asked to use a particular tool?

Analytics, policies around analytics and general policy questions around almost the issues that were raised in the White House report, do we have sufficient protections in the de-identification techniques that are used today? And if not, what more needs to be done? Both the White House and PCAST both said de-identification isn't enough and we over rely on it and we shouldn't be doing that. Do we agree with that and is it still a valuable tool? And if so, what more might we need to bolster it?

Similarly both reports were critical of the role of notice and consent in big data regimes where it's almost impossible to be able to go back to the patient with any degree of sort of meaningful information in terms of how their data might be used, given that part of the value of data is circumstances where you may not necessarily know the question that you want to ask, but you want to be able to allow the data to percolate up some of the relevant findings just through mashing it up and applying different techniques to it.

But this is...these are just a few questions that we teed up to really start the discussion. I think what we want to hear from you, and we don't have a lot of time left on this call, is to start sort of getting your, even if they're very blue sky or big picture issues that you want to make sure we address let's start getting them on the table and let's...and if you have some ideas for how we might be able to narrow this a little bit, Stan and I will be discussing that in the coming weeks in advance of our next call, but getting some thoughts from you on that topic as well.

And then I think ONC has suggested that this might be a topic where we might want to have some virtual hearings or listening sessions to hear from...specifically from stakeholders in these big data environments and if you agree, who do we need to hear from in this space. And for those of you who aren't familiar, this would not be necessarily something we would do in a face-to-face setting, because those are pretty expensive, but to ask people to make presentations to us on these public calls that we have and to be able to hear from a broader range of perspectives than we would normally get just from our own working group.

Everyone is just stymied by the size of this.

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

Yes, pretty much, this is Kitt, that's where my head was.

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

Deven?

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

Yes.

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

It's David McCallie; I think one angle of attack that always helps me think about these issues is to look at the potential harms that could come from abuse of the data, to try to clarify what that means, what is abuse and work backwards from there in terms of policies that might address those harms. I mean, you can go down the list of these capabilities and start rattling off things that would be...what most of us would consider to be inappropriate use of the data.

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

That's interesting.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

This is David Kotz, I think a lot of harms are often related to the use of the data and so maybe one other way to look at these is, what is the data planned to be used for and less about sort of what kind of data it is or how it's collected, what the technologies are.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Um hmm.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

And also somewhat related to that is secondary use. I think a lot of people who think about big data, at least outside of healthcare, imagine using data that's collected for one purpose such as sales data, for another purpose because it's useful and they can draw inferences that they wouldn't have originally expected and I imagine that's true in healthcare. And so we might want to think as policy question, how do you transfer whatever consent or approval, implicit or explicit, the consumers might have provided at the point of collection down the chain to later uses of the data, whether it be "identified" or "de-identified."

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

Right.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

I don't know how to do that, but it seems like to me that once data is collected and gathered in one place, it's going to flow and the question is, how to control that flow and reuse of data long term.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Um hmm, right.

Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection - Federal Trade Commission

This is Cora, this follows up on that. I think that secondary use is a huge issue and for me, sort of that and de-identification are, in the big data context, two of the ones that jump out the most. Because I do think that the data is being collected and that...those evolving technologies are just continuing to evolve and so I think a lot of it will be about kind of how to structurally provide those kinds of protections. So, for example, additional solutions for the de-identification of data, I think is a really important topic for this particular topic.

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

(Indiscernible)

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

Hmm. And for folks, so Cora, I'm not that everyone on the phone, since I think this is your first time on a call with us, do you want to just briefly introduce yourself?

Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission

Oh sure.

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

Very glad to have you.

Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission

Yeah, I am Cora Han and Kristen Anderson, who couldn't be on the call today and myself are both with the FTC. And within the FTC, we both work in the Division of Privacy and Identity Protection, so thank you very much for inviting us to be a part of this. We are delighted to participate.

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

Great. Thank you. I thought I heard someone else's voice chime in before I interrupted.

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

It was just...it was David. I was making an inappropriate comment about de-identification, but we can save it for when we have that discussion.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

We'll take your name off of it at that time.

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

A disrespectful comment about de-identification.

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

Oh, okay and you want to hold your fire until we talk about that, that sounds like there's coalescing agreement that that's definitely an area for further exploration.

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

And this is Kitt Winter, I'd like to build on the person who spoke before...I like the idea of focusing on the initial uses and the secondary uses and getting a visual of how this information is going to be used and then kind of building on what the risk of those uses are.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Um hmm.

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

Okay.

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

You've got to handle...because for me when I'm thinking about big data and where to go from there and the privacy and security issues, I need a visual of how that data is being used before it can go into the concerns.

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

Okay.

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise

Hi Deven, this is Manuj speaking, I just want to build on that one last point. In addition to understanding the primary and secondary uses, I think what would be really helpful to help frame the discussion is to see if we can't get a tangible understanding of the benefit of some of these uses. So when we talk about improved outcomes, when we talk about improved awareness, all those things that lead to better health ultimately or maybe not...the results not being as good as we had initially thought when we kind of were thinking about what the idea was generally. So, I'd love to see if we can get some experts to give us some detailed analysis on that.

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

Hmm, okay, like actual examples?

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise

Yeah, because we go through these large buckets, right, and when we start drilling down into it, I'd love to hear, whether it be a health system or something like that that took an innovative step and started using this data and it turned out to be impactful more so than we had initially expected.

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

Right. That's great, great point. Other thoughts?

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Deven, Gil Kuperman here.

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

Hi, Gil.

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Hey. Just a comment about the size of the problem, I'm used to eating an elephant, I'm not used to eating the whole herd.

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

Right.

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

But, I think the comment before about listening sessions I think is a great idea. I mean there are so many funded initiatives these days that are kind of at the sharp edge of a lot of these issues with PCORI and there were the AHRQ Prospect Projects and so many groups working with genetic data, trying to get lessons there. I think there's real world...a lot of real world experience, people batting their heads against all this and I mean it certainly seems like a lot right here and I wonder if we spoke to people on the frontlines if it might reduce a little bit and there might be a smaller number of higher priority problems that could be identified through that kind of an exercise. So, just that thought.

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

Right. Thank you Gil. So mindful of the time, and we need to leave some opportunity for public comment, we have another call in a couple of weeks and what Stan and I will do in the interim is try to start shaping some ideas for a more clear agenda for how we're going to move forward and what specific topics or issues we might take on that will be subject to discussion by the group so that it's a collective decision about how we're going to move forward with all this and beginning to sort of think through how some listening sessions might be able to help us.

But I think also taking some time to sort of scope out a specific direction for us to go in versus this sort of broader universe that we covered today. That's what we'll aim to be able to tee up for you all and if you have any thoughts about that, in addition to the ones you shared this afternoon, which have been extremely helpful, if you have any thoughts in the interim, shoot us an email, because that will be really helpful. Stan, do you have any other questions before we open for...or other thoughts before we open for public comment?

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Nope, I think all these comments are consistent with what I've heard elsewhere and I think they're all great ideas that we can certainly talk more about. This is good.

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

Yeah, you did great in your first real co-chair call, where we...

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

There we go.

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

...thank you. And thanks to everyone, this is a big one, this is a big, hard topic but I thin...we have the right group of people amassed to explore it and I'm looking forward to doing more work on this with all of you.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Um hmm, agreed.

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

Okay Michelle, we're ready for the public.

Public Comment

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

Operator, can you please open the lines?

Caitlin Collins – Junior Project Manager – Altarum Institute

If you are listening via your computer speakers you may dial 1-877-705-2976 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. We do not have any comment at this time.

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

All right, great. Everyone have a good rest of your day; look forward to the next call.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Thank you.

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

Thanks everyone.

Public Comment Received During the Meeting

1. Patient Record Confidentiality The following federal regulations specify restrictions concerning the disclosure and use of patient records pertaining to substance abuse treatment that federal programs maintain:
 - Confidentiality of Alcohol and Drug Abuse Patient Records (CFR Title 42: Part 2)
 - FAQ: Applying the Substance Abuse Confidentiality Regulations (CFR Title 42: Part 2)